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Revised January 16, 2019 – updates to reflect 2018 revisions to Common Rule; expand policy on use of external IRBs for review and oversight of NYU Langone Health research; add sIRB policy where NYU SoM IRB is acting as single IRB; add policy to require updating of NYU Langone Health employee CVs; editorial changes throughout.
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2. Mission

NYU Langone Health fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of NYU Langone Health. In the review and conduct of research, actions by NYU Langone Health will be guided by the principles set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the “Belmont Report”), and will be performed in accordance with the Department of Health and Human Services (“DHHS”) policies and regulations at 45 CFR 46 (also known as the “Common Rule”), and also the Food and Drug Administration (“FDA”) policies and regulations at 21 CFR 50 and 21 CFR 56, as applicable. All of these principles stress such factors as, inter alia, respect for persons, beneficence and justice. The actions of NYU Langone Health will also conform to all other applicable federal, state, and local laws and regulations.

In order to effectively conduct research, NYU Langone Health maintains a Human Research Protection Program (“HRPP”) which includes a total of six (6) Institutional Review Boards (“IRB”). The primary purpose of the IRB is to review research protocols involving human subjects and to assure protection for the subjects by evaluating risks against the benefits of such research.

The mission of the IRB is to:

- safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety and well-being are protected;
- determine and certify that all projects reviewed by the IRB conform to the policies and procedures set forth in this document, including all applicable regulations regarding the health, welfare, safety, rights, and privileges of human subjects;
- provide timely and high quality education, review and monitoring of human research projects; and
- facilitate excellence in human subjects research.

The NYU Langone Health IRB Operations Office (as described below) includes mechanisms to:

- establish a formal process to monitor, evaluate and continually improve the protection of human research subjects;
- dedicate resources sufficient to do so;
- exercise oversight of research protection;
- educate investigators and research staff about their ethical responsibility to protect research subjects;
- assist the investigators in complying with federal and state regulations; and
- when appropriate, intervene in research and respond directly to concerns of research subjects.

2.1. Introduction

The NYU Langone Health IRB and Human Subjects Research Protection Program Policies and Procedures details not only the policies and regulations governing research with human subjects, but also the procedures for submitting research proposals for review by the NYU Grossman School of Medicine (“NYUGSoM”) and NYU Winthrop Hospital (“NYU Winthrop”) IRBs; together, the “NYU Langone Health IRBs”. These Policies and Procedures apply to all research involving human subjects if NYU Langone Health faculty, staff, students, or facilities are involved, regardless of sponsorship and/or performance site, whether domestic or foreign.

2.2. Ethical Principles: The Belmont Report

It is the duty of the IRB to review and make decisions on all protocols for research involving human subjects. The two principal responsibilities of the IRB are (1) the protection of research subjects from undue risk and (2) the protection of research subjects from deprivation of personal rights and dignity. This protection is best assured by consideration of three principles as set forth in the Belmont Report, which are the touchstones of ethical research:
that voluntary participation by the subjects, indicated by free and informed consent, is assured;
that an appropriate balance exists between the potential benefits of the research to the subject or to society and the risks assumed by the subject; and
that there are fair procedures and outcomes in the selection of research subjects.

These principles are referred to as Respect for Persons, Beneficence, and Justice.

**Respect for Persons: Voluntary Participation and Informed Consent**

One of the most important elements in any research involving human research subjects is the assurance of voluntary informed consent. Any person who is to be a research subject, whether designed for his/her own direct benefit or for the advancement of scientific knowledge in general, must understand as completely as possible what the study entails and the potential risks and benefits of the study. The person must give his/her consent freely, without pressure or inappropriate inducement. The NYU Langone Health IRBs strive to ensure voluntary informed consent of research subjects through a careful review of the recruitment and consent process, and a further review of the details of the consent form and/or any other materials to be viewed by subjects.

The informed consent concept is further extended to those studies in which the subjects are not able to give personal consent for themselves. In this situation, the consent document is addressed to those who have been designated responsible for the research subject’s wellbeing (e.g., parent of a child). The IRB’s concern is to verify that the consent process and document are likely to assist these persons in making an informed decision as to the best interests of the research subject. The capacity for truly informed and voluntary participation in research varies widely among study populations. At one extreme, there may be ample understanding and manifest freedom from coercion; at the other, there may be degrees of understanding and freedom that affect the consent of potential subjects. The IRB must exercise special care when considering subjects whose ability to give free and informed consent may be compromised in any way.

**Beneficence: The Risk-Benefit Ratio**

The IRB is charged with deciding, for any proposed activity that falls under its jurisdiction, whether:

> “The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept (those) risks.”

*(Federal Register, May 30, 1974)*

The assessment of the risk/benefit relation is a complex task. There are risks of injury or discomfort to the individual that can be physical, psychological, financial, and/or social. Conversely, there may be potential benefits to the individual, to a group to which the individual belongs, and/or to society. During the review of applications, the IRB must carefully assess the types and degrees of both risks and benefits for a given subject population, as well as the communication of these risks and benefits to the subject in the consent process and informed consent form. While the IRB is not charged with reviewing scientific design per se, it must occasionally do so in order to assess the risk/benefit ratio. If a study design seems inadequate in attainment of the stated aim of the investigation, then no benefit can be anticipated from conducting the study. Thus, there would be no justification for placing any research subject at risk, however minimal. Therefore, the design of the study must be sound, and the nature and likelihood of all risks and benefits must be made clear in any application to the IRB.

**Justice: The Fair Selection of Research Subjects**

Both the risks and the potential benefits of research should be spread fairly among potential research subjects and research subject groups. Study design and selection of subjects should avoid bias for or against particular group based on such factors a gender, sexual orientation, socioeconomic status, immigration status, race, or social group.
Sharing Research Risks

The guiding principle in the ethical selection of research subject groups is that any risks of the research should fall upon the groups who might benefit from the research. If the results of a risky protocol might benefit the general population, it would be unethical to focus subject recruitment on vulnerable or disadvantaged groups (e.g., institutionalized people or prisoners; patients at free clinics primarily patronized by people unable to afford other medical care) simply because this population is easily accessible or can be persuaded to participate. Further, an undue share of research risks should not burden groups already burdened by other factors. Rather, attempts should be made to include a fair sampling of the populations who might benefit from the study. When research involves persons whose autonomy is compromised, it is expected that the research bear some direct relationship to the conditions or circumstances of the research subject population. In addition, groups fully able to consider the research risks and informed consent process should be considered for selection in a study prior to involvement of the more vulnerable populations. For example, investigational drugs are typically tested in adults prior to being tested in children. Certain investigational drugs and procedures may be tested in healthy volunteers prior to being tested in patients.

Sharing Research Benefits

Attention has increasingly been paid to the rights of various groups to be included in research. Through advocacy groups, many patients have come to insist on having access to experimental treatments, as these experimental treatments may potentially provide the best medical care available. In addition, researchers, ethicists and public officials have recognized that because many clinical trials focus primarily on white middle-class research subject groups, the results of certain trials were of questionable value for members of other social, racial, sexual, and ethnic groups. As a result, both the National Institutes of Health (“NIH”) and the FDA now require that a study design include as broad a range of research subjects as feasible, and further that the data be analyzed to uncover responses that differ between groups. For example, where women of child-bearing potential, pregnant and nursing women were previously routinely excluded from new drug trials, it is now required that, whenever possible, these women be asked to make their own choices after being fully informed of the risks of the research.

3. Definitions

When the NYU Langone Health IRBs review research that is subject to the 2018 revised Common Rule (date of compliance effective date January 21, 2019) to make Exempt research determinations and evaluations regarding whether a proposed activity constitutes human subjects research when the research (or activity) is conducted or supported by an agency subject to the Common Rule, the definitions identified as “2018 Common Rule” will be applied. Likewise, the revised definitions will be applied, as applicable, to the conduct of the research, investigator responsibilities, and institutional responsibilities. Some of the below definitions were not changed in the pre-2018 Common Rule, but are included here for context.

**Agent**

refers to all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.

**Certification**

refers to the official notification by an institution to the sponsoring federal department or agency component, in accordance with the requirements of this Policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

**Clinical Trial**

means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
**Common Rule**

refers to the “Federal Policy for the Protection of Human Subjects” adopted by a number of federal agencies. Although the Common Rule is codified by each agency separately, the text is identical to DHHS regulations in 45 CFR 46 Subpart A. For the purposes of this Policy, references to the Common Rule will cite the DHHS regulations.

**Human subjects research**

For the purposes of this Policy “human subjects research” is defined as any activity that either

- is “research” and involves “human subjects” as those terms are defined by DHHS regulations (45 CFR 46.102); or
- is a “clinical investigation” and involves “human subjects” as those terms are defined by FDA regulations (21 CFR 50 and 21 CFR 56).

**Research**

As defined by DHHS regulations:

Is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this regulation, the following activities are deemed NOT to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

“Generalizable knowledge” means that (1) conclusions are drawn from particular instances and (2) the information from the investigation is to be disseminated. A “systematic investigation” is defined as a methodical planned inquiry to obtain or ascertain facts.

Activities that meet this definition of “research” may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.

As defined by FDA regulations:

Any experiment that involves a Test Article and one or more human subjects and that either (1) is subject to requirements for prior submission to the FDA under Section 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act (the “Act”), or (2) is not subject to requirements for prior submission to the
Food and Drug Administration under these Sections of the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. An experiment, as defined in 21 CFR 312, includes any use of a drug other than the use of a marketed (approved) drug in the course of medical practice, and as defined in 21 CFR 812, includes any activity that evaluates the safety or effectiveness of a medical device. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act* means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]

Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act* means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)] Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]

**Human Subject**
As defined by DHHS regulations:

[pre-2018 Common Rule] A living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) data through intervention* or interaction** with the individual, or

(2) identifiable**** private information***.

*Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

**Interaction includes communication or interpersonal contact between investigator and subject.

***Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

****Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

[2018 Common Rule] A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention* or interaction** with the individual, and uses, studies, or analyze the information or biospecimens; or

- Obtains, uses, studies, analyzes, or generates Identifiable**** private information*** or *****identifiable biospecimens.

*Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

**Interaction includes communication or interpersonal contact between investigator and subject.

***Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
As defined by FDA regulations:

An individual who is or becomes a subject in research, either a recipient of the test article or as a control. A subject may be either a healthy human or a patient. In the case of medical device research, a human subject is also means a human on whose specimen an investigational device is used.

Engagement

Institutions are considered “engaged” in a research project when the involvement of their employees or agents in that project includes any of the following:

- Intervention for research purposes with any human subjects of the research by performing invasive or noninvasive procedures; or
- Intervention for research purposes with any human subject of the research by manipulating the environment; or
- Interaction for research purposes with any human subject of the research; or
- Obtaining the informed consent of human subjects for the research; or
- Obtaining for research purposes identifiable private information or identifiable biological specimens from any source for the research. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:
  - observing or recording private behavior;
  - using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and
  - using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

Institutional Official (IO)

The IO is responsible for ensuring that the NYU Langone Health IRBs have the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official for all assurances regarding the conduct of human subjects research on behalf of NYU Langone Health, and oversees all obligations of all such assurances.

IRB

means an Institutional Review Board established in accord with and for the purposes expressed in this Policy.

IRB Approval

refers to the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other applicable institutional and legal requirements.

Minimal Risk (in context of research not involving prisoners)

means risk for which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.404]

NYU Langone Health

Includes NYU Langone Health System, NYU Langone Hospitals (including all inpatient and ambulatory facilities), NYU Grossman School of Medicine, NYU Long Island School of Medicine, and all entities that are controlled by any of them, except where specifically excluded.
Research under the Aupices of the Organization

means research that is conducted at an institution, conducted by or under the direction of any employee or agent of the institution (including students) in connection with his or her institutional responsibilities, conducted by or under the direction of any employee or agent of the institution using any property or facility of the institution, or involving the use of the institution's non-public information to identify or contact human subjects.

Research Team

For human subjects research and purposes of this Policy, “Research Team” consists of the Principal Investigator and other individuals (also known as “Key Personnel”) who contribute to the scientific development or execution of a study in a substantive, measurable way, whether or not they receive salaries or compensation under the applicable protocol, subaward, or contract. The Research Team also consists of individuals who interact directly with human subjects (and/or identifiable information and biological specimens) for research activities including the consent process, analysis and reporting of research data, and research data entry. Individuals on the Research Team must be approved by the IRB and listed on the study’s delegation of authority log.

Non–Research Team or Research Service Providers for purposes of this Policy are individuals who perform ancillary services, routine care, non-investigational testing, or other support services for a research study and do not contribute to or have involvement with the scientific development, conduct, execution, analysis or reporting of a study. Individuals with such roles are generally not considered to be members of the Research Team. Non-Research Team individuals do not require IRB approval, but should be added to the delegation of authority log.

Test Article

Test articles covered under the FDA regulations include:

- Human Drugs
  [http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm]
- Medical Devices
  [https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051521.htm]
- Biological Products
  [http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm]
- Food Additives
  Any substance added to food. Legally, the term refers to “any substance the intended use of which results or may reasonably be expected to result – directly or indirectly – in its becoming a component or otherwise affecting the characteristics of any food.” This definition includes any substance used in the production, processing, treatment, packaging, transportation or storage of food.
- Color Additives
  Any dye, pigment or substance which when added or applied to a food, drug or cosmetic, or to the human body, is capable (alone or through reactions with other substances) of imparting color.
  [https://www.fda.gov/Food/IngredientsPackagingLabeling/ucm112642.htm]
- Foods
  Includes dietary supplements, that bear a nutrient content claim or a health claim.
- Infant Formulas

4. Institutional Authority

The NYU Langone Health Human Research Protection Program (“HRPP”) operates under the authority of this Policy. The operating procedures in this Policy govern the NYU Langone Health IRBs’ conduct and review of all human research conducted under the auspices of NYU Langone Health, as well as that of any other duly authorized institutional review board in accordance with this Policy. This Policy is
The NYU Langone Health IRB is responsible for ensuring compliance with institutional policies and applicable federal law in its review and oversight of human subjects research. This is done through carrying out the IRB review processes as set forth in this Policy, education and conduct of quality assurance review programs conducted by the NYU Langone Health Human Research Regulatory Affairs staff, among other things. All human subjects research under the auspices of NYU Langone Health must be conducted in accordance with this Policy, the Common Rule, 21 CFR 50 and 56 (as applicable), and applicable state and local law in the jurisdiction where the research is conducted.

The NYU Langone Health IRBs voluntarily apply the International Conference on Harmonization ("ICH") Good Clinical Practices ("GCP") Guidelines, sometimes referred to as "ICH-GCP" or "E6", only to the extent that they are compatible with FDA and DHHS regulations.

5. NYUGSoM and NYU Winthrop Institutional Review Boards

The NYU Langone Health IRBs are administrative bodies established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of NYU Langone Health. There are currently six (6) Institutional Review Boards (five at NYUGSoM and one...
5.1. **Authority of the IRB**

The NYU Langone Health IRBs review and have the authority to approve, require modifications in, or disapprove all research activities conducted under the auspices of NYU Langone Health and under their jurisdiction, e.g., Exempt research including those activities for which limited IRB review is a condition of exemption. The IRB also has the authority to suspend, place restrictions on, or terminate approvals of research activities that fall within its jurisdiction that are not being conducted in accordance with IRB requirements, or that have been associated with unexpected serious harm to subjects.

The IRB ensures that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46.111]. In fulfilling these responsibilities, the IRB reviews all research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. Examples of IRB review documentation include, *inter alia*: protocols, consent/assent document(s) and, for studies conducted under the Investigational New Drug (“IND”) regulations, the investigator's brochure(s), tests, surveys, questionnaires and similar measures, and recruiting documents.

Before any human subject becomes involved in research at NYU Langone Health, the IRB will properly consider:

- risks to the subject and others
- anticipated benefits to the subject and others
- importance of the knowledge that may reasonably be expected to result from the study
- informed consent process to be employed

The IRB has the authority to suspend, place restrictions upon, or terminate approval of research activities that fall within its jurisdiction that:

- are not being conducted in accordance with IRB requirements, or
- that have been associated with serious harm to subjects

The IRB has the authority to observe (or delegate a third party to observe) the consent process and the research if the IRB deems this necessary.

5.2. **Jurisdiction of the IRB**

The NYU Langone Health IRBs’ jurisdiction extends to all research (funded and unfunded) involving human subjects conducted at NYU Langone Health, as well as research conducted elsewhere by NYU Langone Health faculty, staff, and students, excluding research where involvement of human subjects falls within one or more exempt categories (see [Categories of Research Permissible for Exemption](#)). For clarity, each IRB may act as the reviewing IRB for human subjects research conducted by any part of NYU Langone Health, including research conducted by NYU LIsOM faculty at NYU Winthrop Hospital and research conducted by NYUGSoM faculty at NYUGSoM.

5.3. **IRB Relationship with Other HRPP Units**

The NYU Langone Health IRBs function independently of, but in coordination with, other institutional regulatory committees. The IRB, however, makes independent determinations regarding approval or disapproval of a protocol based upon whether or not human subjects are adequately protected. The IRB retains review jurisdiction over all research involving human subjects that is conducted, supported, or otherwise subject to regulation by any federal department or agency that adopted the human
Research previously reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, officials of the institution have no authority to approve research previously disapproved by the IRB.

5.4. **Relationships with Other Institutions**

NYU Langone Health may choose, on a case-by-case basis, to provide human research protection oversight for unaffiliated institutions. In providing such oversight, a formal relationship must be established between NYU Langone Health and the unaffiliated institution through a written agreement. This agreement must be executed prior to NYU Langone Health’s acceptance of any human research proposals from the unaffiliated institution. Any such institution for whom NYU Langone Health reviews human subjects research must comply with NYU Langone Health’s IRB Policies.

When the NYUGSoM IRB reviews research conducted at an unaffiliated institution, the particular characteristics of the unaffiliated institution’s local research context must be considered, either (1) through prior knowledge of the unaffiliated institution’s local research context, or (2) through subsequent review by appropriate designated institutional officials, such as the Chairperson and/or other IRB members.

When NYU Langone Health serves as the coordinating center for a multi-center protocol, the study chair or equivalent at NYU Langone Health shall submit the protocol and other study documents to the NYUGSoM IRB for review and approval, unless such protocol relies on an external IRB in accordance with a written agreement. The NYUGSoM IRB will require that study chair or equivalent ensure that each participating site receive approval from an IRB with jurisdiction over that site prior to initiation of the research at that site. At the time of initial review, the IRB will assess the procedures for dissemination of protocol information to all participating sites. Assessment of protocol information includes, *inter alia*, unanticipated programs involving risks to subjects, protocol modifications, and interim findings.

In the conduct of cooperative research projects, NYU Langone Health acknowledges that each institution is responsible for safeguarding the rights and welfare of its human subjects, and further for ensuring compliance with the applicable federal regulations. When a cooperative agreement exists, NYU Langone Health may enter into a joint review arrangement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

When an investigator plans to conduct research at sites external to the NYU Langone Health and the external site’s IRB plans to defer review to the NYUGSoM’s IRB, arrangements must be made for the NYUGSOM’s IRB to be the IRB of record for the project and arrangements must be made for communication between the IRB and the external site.

**External IRB Use by NYU Langone Health**

NYU Langone Health may choose, on a case-by-case basis, to cede or share its IRB oversight responsibilities of certain research conducted at or under the auspices of NYU Langone Health to an external IRB. This Policy describes when an external IRB may be used, and what is required.

**Decision to Use an External IRB**

The decision to cede or share oversight responsibilities will be made by the applicable NYU Langone Health IRB Director in consultation with the IO as needed. Research teams may not agree to ceding IRB review. This decision is made solely by the IRB Director or their designee.

Use of an external IRB for review of NYU Langone Health research is generally permitted if:

- The research is industry-initiated;
- The research is a federally-funded multicenter trial that requires the use of a central IRB or single
Any exceptions may be considered on a case by case basis.

When NYU Langone Health relies on an external IRB, the applicable NYU Langone Health IRB Director may review the policies and procedures of the external IRB to ensure that they meet NYU Langone Health IRB standards. If the other IRB is accredited by AAHRPP, then it will be assumed that the NYU Langone Health standards are being met, provided that all local context and institutional requirements are considered and followed, as appropriate. NYU Langone Health will not cede or share its IRB oversight responsibilities if the external IRB is not AAHRPP-accredited or cannot demonstrate through written policies and procedures that its standards are substantially equivalent to ensure the research will be reviewed appropriately.

A formal relationship between NYU Langone Health and the external IRB must be established through a written agreement. Any Principal Investigator who wishes to make use of an external IRB for review of a study must first contact the IRB Office (defined below) for approval and initiation of a written agreement. Any fees associated with the use of an external IRB must be budgeted for in the associated study budget.

NYU Langone Health Principal Investigators may submit qualifying research to external commercial IRBs such as BRANY IRB or Western IRB, and to the NCI Central IRB, as permitted by NYU Langone Health IRB guidance documents and in accordance with written agreements between NYU Langone Health and such external IRBs.

In addition to the external IRB’s approval, any additional committee, department, and other administrative approvals required by the institution must be obtained by the Principal Investigator before the research activities can begin. Such other approvals may include: review by the Clinical Research Support Unit of applicable budgets and billing compliance review; execution of research agreements; review of any financial conflicts of interest by the NYU Langone Health Conflicts of Interest Management Unit; and NYU Langone ancillary review and approval from service providers (e.g., Radiation Safety Committee, Center for Biospecimen Research and Development, Department of Pathology, NYU Langone Health Institutional Biosafety Committee).

A record for the protocol must be created and maintained in Research Navigator, as well as all other required forms and documentation relating to the research as applicable, in accordance with these Policies and Procedures, in addition to documentation that may be required by the external IRB.

If an NYU Langone Health Principal Investigator conducts research that involves subjects who are solely recruited at the Veteran’s Administration (VA) Hospital, the VA Medical Center IRB’s review is required.

**Single IRB Review (“sIRB”)**

The single IRB (sIRB) policy is an NIH policy that applies to grants and contracts submitted to the NIH on or after January 25, 2018 for multicenter non-exempt human subjects research operating under a single protocol. The NIH sIRB policy requires the use of a single IRB for IRB review and approval for all domestic study sites performing the protocol. See [https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html). The NIH sIRB policy does not apply to foreign sites, Veteran’s Administration (“VA”) sites, sites involving tribal nations, and sites for which review by the proposed sIRB is prohibited by federal, tribal, or state regulations, or other policies. The specific law, regulation, or policy should be cited in the applicable grant application or contract proposal’s single IRB plan. A study may involve sites that must comply with the NIH sIRB policy as well as other sites that are not required to comply.

The OHRP announced its determination of exceptions for two categories of research from required use of a single IRB to review cooperative research under HHS regulations for the protection of human subjects.
Effective for all new studies submitted on or after January 19, 2020: When more than one domestic study site is involved in a research study that is funded by ANY federal agency, NYU Langone Health will require single IRB review, as per federal regulations.

NYUGSoM IRB as Single IRB
The NYUGSoM IRB may serve as the single IRB for research that meets the NIH policy criteria. The research must involve human subjects (“research” and “human subjects” as both are defined by the DHHS regulations, (45 CFR 46.102) and be a multi-site study. The research should not qualify as an Exempt research study, but can be a clinical trial, an observational study, or a basic clinical research study.

The NYU Langone Health IRB Office must be made aware by NYU Langone Health Principal Investigators of any NIH grant applications that propose the NYUGSoM IRB as the sIRB for a study, and should agree to such an arrangement prior to the grant submission. Notification must be made through a form available on NYUGSoM’s intranet page (“Selecting the NYUGSoM IRB as the sIRB of Your Study”). Single IRB fees should be assessed and budgeted for in the relevant grant application.

Any institution for whom the NYUGSoM IRB acts as the single IRB must comply with the applicable provisions of NYU Langone Health’s IRB Policies. When the NYUGSoM IRB acts as a single IRB, the particular characteristics of the unaffiliated institution’s local research context will be considered. It is the participating site’s responsibility to provide the NYUGSoM IRB with such information.

5.5. Roles and Responsibilities

Institutional Official
The ultimate responsibility over the NYU Langone Health IRBs and conduct of research conducted at or under the auspices of NYU Langone Health by investigators resides with the IO. The IO is responsible for ensuring the NYU Langone Health IRBs and NYU Langone Health IRB Operations Offices have the resources and support necessary to comply with all institutional policies and with federal regulations and guidelines that govern human subjects research. The IO signs all assurances regarding human subjects research to governmental oversight agencies.

The IO also holds ultimate responsibility for oversight over the:

- Institutional Review Board (IRB);
- conduct of research conducted by all IRB investigators;

Director of the IRB
The Director of each NYU Langone Health IRB – whether NYUGSoM or NYU Winthrop - (“Director”) reports to NYU Langone’s Executive Vice President and Vice Dean for Science, Chief Scientific Officer or his/her delegate. The IRB Director is responsible for:

- developing, managing and evaluating policies and procedures that ensure compliance with all regulations governing human subjects research. This includes monitoring changes in regulations and policies that relate to human research protection and overseeing all aspects of the IRB program;
- advising the IO on matters regarding human subjects research under the jurisdiction of the NYU Langone Health IRB as applicable;
- implementing the NYU Langone Health IRB as well as institutional Policies and Procedures;
- assuring the IRB members are appropriately knowledgeable to review research in accordance with ethical standards and applicable regulations;
- assuring that all NYU Langone Health investigators are appropriately knowledgeable to conduct research in accordance with ethical standards and applicable regulations;
- the development and implementation of an educational plan for IRB members, IRB Operations Office staff, and NYU Langone Health investigators;
- submitting, implementing and maintaining an approved FWA through the IO to the U.S.
The Director is a voting member of the IRB.

**Institutional Review Board (“IRB”)**

The NYU Langone Health IRB currently has five Boards appointed by the IO. The NYU Winthrop IRB currently has one Board. These Boards prospectively review and make decisions concerning all human subjects research conducted at NYU Langone Health facilities by its employees or agents, or under its auspices.

The IRB is responsible for the protection of rights and welfare of human research subjects under the auspices of the organization and under the IRB’s jurisdiction. It discharges this duty by complying with all applicable requirements of federal law, its FWA, and institutional policies.

**Office of General Counsel**

The IRB relies on the counsel of the NYU Langone Health Office of General Counsel for the interpretation of applicable law in the jurisdiction(s) where the research is conducted. When there are any conflicts between legal requirements, the Office of General Counsel will determine the appropriate resolution.

**Chairpersons of the IRB**

NYU Langone Health’s Executive Vice President and Vice Dean for Science, Chief Scientific Officer, in coordination with the IO and the IRB Director, will appoint a Chair and Vice Chair of each IRB to serve for renewable three-year terms. Any change in appointment, including reappointment or removal, requires written notification.

The IRB Chairs should be highly respected individuals at NYU Langone Health who are fully capable of managing the IRB and the matters brought before it with fairness and impartiality. Moreover, the IRB Chairs must endeavor to be immune to pressure from the institution’s administration, the investigators whose protocols are brought before him/her, and other professional and nonprofessional sources.

The IRB Chairs are responsible for conducting convened IRB meetings.

The IRB Chairs may designate other IRB members (including but not limited to the Vice Chair or IRB Director) to perform duties, as appropriate, for review, signature authority, and other functions of the IRB Chairs.

The IRB Chairs will advise the IO and the IRB Director about IRB member performance and competence.

**Vice Chairs of the IRB**

A Vice Chair serves as the Chair of the IRB in the absence of the Chair, and maintains the same qualifications, authority, and duties as the IRB Chair.
Subcommittees of the IRB

The IRB Chairs, in coordination with the IRB Director, may establish subcommittees consisting of one or more IRB members.

Duties of an IRB subcommittee may include the following:

- Serve as designees by an IRB Chair for the expedited review of new or continuing protocols, and/or modifications of continuing protocols. The subcommittee must be experienced (in terms of seniority on the IRB), and must be matched as closely as possible with their field of expertise to the study.
- Review and approve revisions of protocols previously given provisional approval (“Conditional Approval”) by the convened IRB.
- Conduct an inquiry into allegations of non-compliance. The subcommittee may be given a charge by the IRB, which can include any or all of the following:
  - review of protocol(s) in question;
  - review of FDA audit report of the investigator, if appropriate;
  - review of any relevant documentation, including, *inter alia*, consent documents, case report forms, and a subject's investigational and/or medical files, as the documentation relates to the investigator's execution of her/his study involving human subjects;
  - interview of appropriate personnel if necessary;
  - preparation of either a written or oral report of the findings, which is presented to the full IRB at its next meeting; or
  - recommend actions if appropriate.
- Conduct on-site review of a study. Determination of the review interval and the need for additional supervision and/or participation is made by the IRB on a protocol-by-protocol basis. For example, an on-site review by an IRB subcommittee might occur in a particularly risky research study, or approval might be subject to an audit of study performance where an investigator recently had a protocol suspended by the IRB due to regulatory concerns.

The Principal Investigator

The Principal Investigator is the chief protector of the human subjects who participate in his/her research, and is ultimately responsible for all research conducted under his/her oversight. The Principal Investigator is expected to abide by the highest ethical standards and for developing a protocol that incorporates the principles of the Belmont Report. He/she is expected to conduct research in accordance with the approved research protocol and to oversee all aspects of the research by providing appropriate training and supervision of study staff, including but not limited to oversight of the informed consent process.

The Principal Investigator must establish and maintain an open line of communication with all research subjects within his/her responsibility. In addition to complying with all the policies and standards of the governing regulatory bodies, the Principal Investigator must comply with applicable institutional and administrative requirements, including but not limited to that of the IRB, for conducting research. The Principal Investigator is responsible for ensuring that all of his/her research staff completes appropriate training and must obtain all required approvals prior to initiating the research. When investigational drugs or devices are used, the Principal Investigator is responsible for providing written procedures for their storage, security, dispensing and disposal.

The Principal Investigator must be qualified, licensed and credentialed for all aspects of the research under his or her oversight, or otherwise delegate such responsibilities to a member of the study team with the requisite qualifications, licenses or credentials. The IRB shall require a licensed physician to be on the study team for any human subjects research requiring a medical intervention.

Department Chairs

At NYUGSoM and NYU Long Island School of Medicine (NYU LISoM), the chairperson(s) of the
Department administering the research is responsible for ensuring that the Principal Investigator is qualified by training and experience to conduct the proposed research. In addition, department chairs are responsible for ensuring that the Principal Investigator has sufficient resources and facilities to conduct the proposed research.

For each protocol submitted to the IRB for approval, the department chair must certify that s/he accepts responsibility for assuring adherence to the federal and state regulations and institutional policies governing the protection of human subjects of research, including applicable institutional credentialing requirements.

Department chairs are required to review all research proposals before they are submitted to the IRB for review. The signature of the department chair indicates that the study is found to be scientifically sound, can reasonably be expected to answer the proposed question, and that the department will commit resources required to conduct the research in a way that will protect the right and welfare of subjects. Such resources include but are not necessarily limited to personnel, space, equipment and time.

**Other Regulatory Units of the NYU Langone Health Human Research Protection Program (“HRPP”)**

**Sponsored Programs Administration (SPA)**

SPA staff members review and negotiate all research agreements with federal, foundation, or non-profit funding sponsors. This institutional review ensures that all terms of the award are in compliance with institutional policies. SPA staff also review grant proposals for research to ensure completion and compliance with applicable laws, guidelines and institutional policies. Only designated senior individuals within SPA have the authority to approve research proposals and to execute research agreements on behalf of the institution. As a further control, internal documents retained by SPA as part of the application process for extramural funding include Grant applications, Principal Investigator Certification as well as all ancillary documentation required to support submissions.

When a NYUGoM or NYU LISoM grant or contract agreement includes human research activities that will be conducted by investigators who are not employees or agents of NYU Langone Health, a subcontract is executed with the collaborating institution/third party. The subcontract includes the requirement for the collaborating institution/third party to assure compliance with federal regulations for the protection of human subjects in research and to provide documentation of current and ongoing IRB approval for its site upon request. The collaborating institution/third party must also ensure that its key personnel involved in human subjects research are in compliance with the NIH policy on education in the protection of human research subjects and provide documentation of education of its key personnel to the site’s IRB.

**Clinical Research Support Unit (CRSU)**

The NYU Langone Health CRSU provides administrative services related to clinical research supported by commercial entities, including but not limited to clinical trials of new pharmaceutical and medical devices. These include industry-initiated and investigator-initiated studies. The CRSU helps prepare and develop budgets for clinical research agreements contemplating industry support (funding and/or product support), and engage in business development. The CRSU is also responsible for clinical research billing compliance and provides support in the administration of the NYU Langone Health’s research billing compliance program.

**Office of Industrial Liaison (OIL)**

The NYU Office of Industrial Liaison is responsible for technology transfer activities at NYU including NYU Langone Health, including securing patent and/or other intellectual property protection for commercially promising discoveries, licensing technologies to existing companies and/or facilitating the creation of new companies so that technologies can be developed into products to benefit the public, while providing a return to NYU to support its research and education missions, negotiating
agreements with industry to support research at the NYU other than clinical research (which are handled by SPA and (for budget matters) the CRSU), and negotiating other research-related agreements including material transfer agreements, inter-institutional agreements, and confidential disclosure agreements.

**Protocol Review and Monitoring Committee (PRMC)**
The PRMC of the NYU Langone Health Perlmutter Cancer Center provides the mechanism for assessing the scientific merit of new oncology trials proposed to be conducted at NYU Langone Health and the authority to close trials that are not meeting accrual. All new clinical protocols, after being approved by Disease Management Groups and assigned priority scores, are submitted to the PRMC. The PRMC coordinates the submissions for the Bio Statistical Group as well as coordinating the peer review of protocols for approvals before submission to the IRB.

**Office of Research Compliance**
The Office of Research Compliance provides oversight of NYU Langone Health research programs, activities, and processes, in a manner that is independent of the NYU Langone Health Human Research Regulatory Affairs (“HRRA”) office, which consists of two groups, the NYU Langone Health IRB Office (IRB Operations) and Research Regulatory Services. The Office of Research Compliance is responsible for coordinating and monitoring the compliance program to ensure that NYU Langone Health is compliant with federal, state, and local laws and regulations as well as applicable institutional policies. This office also oversees the Research Conflict of Interest Management Unit which is responsible for handling all conflicts of interest for the institution related to research.

**Research Regulatory Services**
Research Regulatory Services is one of the groups within the NYU Langone Health Human Research Regulatory Affairs office. Together with IRB Operations, Research Regulatory Services ensures the safety of human subjects in clinical and nonclinical research studies as well as compliance with institutional policies and federal regulations. Research Regulatory Services supports the NYU Langone Health research community through its Quality Assurance and Quality Improvement (QA/QI) Division, and the Regulatory Support Unit. The QA/QI Division conducts routine and for-cause audits of human subjects research studies conducted at or on behalf of NYU Langone Health and its affiliates. These audits seek to ensure the rights and welfare of human research subjects and support compliance with federal regulations, state laws, and institutional policies. The Regulatory Support Unit assists researchers in complying with requirements for clinical trial registration and data reporting, and regulations applicable to investigators who hold their own INDs or IDEs for the study of drugs or devices that are not approved by the FDA.

**NYU Health and Hospitals Bellevue Research Review Committee (BRRC)**
The NYC Health and Hospitals Bellevue Research Review Committee is responsible for protecting the basic rights, health, and welfare of Bellevue patients and employees who voluntarily consent to participate in research studies. In addition, the Bellevue Research Department staff is responsible for educating potential researchers on the protocol submission and approval process and assuring that individuals involved in conducting research-related activities at Bellevue are in compliance with facility and corporate policies and procedures, as well as federal, state, and city regulations.

The BRRC is chaired by the Director of the Bellevue Research Department and is comprised of a general medical reviewer, as well as reviewers from its departments of Psychiatry, Pharmacy, Drug & Formulary, Radiology, Pathology, Finance, the Medical Board, and Executive Administration. Committee members are charged with reviewing protocols, focusing on his or her respective area of expertise, and approving them as appropriate in the NYC Health and Hospitals electronic research application system, System to Track and Approve Research (“STAR”).

The BRRC is designated as a research review Committee and not an IRB. The BRRC accepts the NYU Langone Health IRB’s (or their duly authorized IRB of record) review and determination of all NYU Langone Health research protocols involving human subjects at Bellevue. Once a research study has
been granted NYU Langone Health IRB and BRRC approval, it must obtain final approval from the Health and Hospitals Corporation Research Review Committee, which functions within the NYC Health and Hospitals Research Administration Office. It is through this multi-level approval process that the Bellevue Research Department can ensure that the basic rights, health, and well-being of its research subjects are adequately protected.

**NYU Langone Health Investigational Pharmacy**

A pharmacist from the NYU Langone Health Investigational Pharmacy serves on the IRB, allowing the NYU Langone Health Pharmacy to have complete information about all IRB-approved research that takes place at the institution and under its jurisdiction. The Pharmacist member assures that information about all studies involving drugs used in research is shared with both the Pharmacy Staff as appropriate and that the Investigational Pharmacy is made aware of IRB approved research involving drugs.

The NYU Langone Health Investigational Pharmacy typically does not engage in the ordering/providing, dispensing, or compounding of drugs used in research, unless the drug is a controlled substance, in which case the item is ordered/received by the Investigational Pharmacy and re-issued in appropriate quantities to researchers for animal studies, or, for human studies, pursuant to a study-specific and patient-specific medication order developed by the Investigational Pharmacy in collaboration with the Researcher. The manufacture/compounding of drug products that are not commercially available is coordinated by the Investigational Pharmacy with outside pharmacy vendors. However, insofar as inpatient drug studies and/or those outpatient drug studies that have subjects who become inpatients at NYU Langone Health, the Investigational Pharmacy coordinates the use of the study drug while the subject is an inpatient, and all such inpatient study drugs must be provided through the Investigational Pharmacy.

The Investigational Pharmacy is available to provide guidance to investigators in relation to the management of the study drugs.

**NYU Langone Health Institutional Biosafety Committee (IBC)**

All research that involves Recombinant or Synthetic Nucleic Acid Molecules (“rDNA”) molecules must be in compliance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (“NIH Guidelines”). The NIH Guidelines set forth principles and standards for safe and ethical conduct of research involving rDNA and apply to both basic and clinical research studies.

The NYU Langone Health Institutional Biosafety Committee (IBC) is responsible for approving risk assessment and the biosafety containment levels, assessing the safety of such experiments which occur throughout NYU Langone Health. Principal Investigators must comply with the IBC guidelines and procedures, and applicable regulations and guidelines, and all conditions approved by the ICB with respect to their proposed research. For more information, see the NYU Langone Health Institutional Biosafety Policy.

**5.6. IRB Operations**

In addition to the leadership structure described above, other IRB Operations Office staff members are listed below. The IRB Operations Office staff for NYU Langone Health will comply with all ethical standards and practices.

**IRB Operations Office (“IRB Office”) Staff**

All NYU Langone Health IRB Operations Office staff are selected by the IRB Director and/or the Associate Director, who has day-to-day oversight over IRB and IRB Office operations. The NYUGSOM Associate Director reports to the NYUGSOM IRB Director.

Additionally, the NYUGSOM IRB Office is staffed by Senior Scientific Managers, Scientific Managers, IRB Review Specialists, Analysts, Coordinators, and Education and Training Specialists. The qualification criteria, duties and responsibilities for all staff are found in their respective job descriptions. IRB Office staff performance is evaluated on an annual basis. The NYU Winthrop IRB Office is staffed by its IRB Director,
The general criteria for selection of the IRB Office staff includes: (1) background knowledge in clinical research for professional staff, (2) high-level organizational, analytical and administrative abilities, and (3) customer service-oriented skills.

5.7. **Resources for the IRB**

NYU Langone Health’s Executive Vice President and Vice Dean for Science, Chief Scientific Officer and the IO provide resources to the NYU Langone Health IRBs and the NYU Langone Health IRB Offices, including adequate meeting and office space, and staff for conducting IRB business. Office equipment and supplies, including technical support, file cabinets, computers, internet access, and copy machines (etc.) will be made available to the IRB and IRB Office staff.

On an annual basis, the IRB Director will review the activity, workload and resources of the IRB and the applicable IRB Office and will make a recommendation with regard to resources to the Executive Vice President and Vice Dean for Science, Chief Scientific Officer and the IO. The resources provided for the IRB and IRB Office will be reviewed during the NYU Langone Health annual budget review process.

5.8. **Conduct of Quality Assurance/Quality Improvement Activities for IRB Operations**

The Quality Assurance methods whereby the IRB processes are reviewed and tracked internally are described in *NYU Langone Health IRB Quality Assurance / Quality Improvement Plan* (see NYUGSoM IRB QA/AI SOP on the IRB’s website). The staff of the NYU Langone Health Research Regulatory Affairs unit may conduct internal investigations and audits of ongoing human subjects research in the following instances: (1) when the IRB directs an audit be conducted, (2) when a complaint or allegation of non-compliance is received, and/or (3) “not for cause” audits of research.

For a detailed discussion of investigations and audits, see: *Complaints, Non-Compliance, and Suspension or Termination of IRB Approval of Research*.

6. **IRB Membership**

The IRB Director, in coordination with the IRB Chair and the IO, will identify potential candidates in consideration of IRB membership. NYUGSoM and NYU LISoM Department Chairs and/or Division Chiefs may also be requested to identify potential candidates for appointment to the IRB Board.

On an ongoing basis, the IRB Director will monitor the membership and composition of the IRB and make recommendations on the appointment of members to the IO in order to meet regulatory and organizational requirements.

Appointments of IRB Board members are made by the IRB Director or designee, for a term of one year with automatic renewal.

Requirements for IRB membership and composition will be in compliance with DHHS regulations (45 CFR 46.107) and FDA regulations (21 CFR 56.107). IRB members are selected based on appropriate diversity, including consideration of race, gender, cultural backgrounds, specific community concerns in addition to representation by multiple, diverse professions, knowledge and experience with vulnerable subjects, and inclusion of both scientific and non-scientific members. The structure and composition of the IRB must be appropriate to the amount and nature of the research that is reviewed. Every effort is made to have member representation that has an understanding of the areas of specialty that encompasses most of the research performed at the IRB. The IRB has procedures (see *NYUGSoM and NYU Winthrop Institutional Review Boards*) that specifically outline the requirements of protocol review by individuals with appropriate scientific or scholarly expertise.
In addition, the IRB will include members who are knowledgeable about and experienced working with vulnerable populations that typically participate in IRB research.

The IRB must promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects; and possess the professional competence necessary to review specific research activities. A member of the IRB may fill multiple membership position requirements for the IRB.

6.1. **Composition of the IRB**

The IRB will at all times consist of at least five members with its guiding principle to promote complete review of research activities commonly conducted by the institution and any other organization under its jurisdiction.

The IRB will be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

The IRB will be able to ascertain the acceptability of proposed research in terms of institutional commitments (including applicable institutional policies and resources) and federal regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.

Since the IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration is given to the inclusion of one or more individuals on the IRB who are knowledgeable about, and experienced in, working with these categories of subjects. When protocols involve vulnerable populations, the review process will include one or more individuals who are knowledgeable about or experienced in working with these subjects, either as IRB members or as consultants ([see: Use of Consultants (Outside Reviewers)]). Prior to the meeting, the staff of the IRB Office will review the agenda to ensure that the membership present for the meeting has the appropriate expertise and experience with any vulnerable populations that are included in the protocols being reviewed.

Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both gender, so long as no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession. The IRB includes at least one member whose principal concerns are in scientific areas and at least one member whose principal concerns are in nonscientific areas.

The IRB includes at least one member who is not otherwise affiliated with the institution and represents a member of the community NYU Langone Health serves (non-affiliate member). The member cannot be a part of the immediate family of a person affiliated with the institution.

The IRB may not have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

The IRB, in its discretion, may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that which is available on the IRB. These individuals may not vote with the IRB.

One member may satisfy more than one membership category.

The IRB Director, Associate Director and Scientific Managers of the applicable NYU Langone Health IRB Office may be voting members of the IRB.

IRB members are appointed for renewable one to three year terms. On an ongoing basis, the IRB
The IRB Chairs, Vice Chairs and/or the IRB Director identify a need for a new or replacement member, or alternate member. The IRB membership may nominate candidates and forward the names of the nominees to the IO. Department Chairs and others may forward nominations to the IO, the IRB Office, or the respective IRB Chairs or Vice-Chairs.

For faculty membership appointments, the IRB Director will contact the nominee. If there are no nominees, the appropriate NYUGSoM or NYU LISoM Department Chairs or Program Directors will be contacted in writing by the IO or the IRB Director concerning the vacancies and solicit nominees from the Department Chairs or Program Director.

The final decision in selecting a new member is made by the IRB Director, who may consult with the IO and the applicable IRB Chairs.

Appointments are made for renewable one to three-year periods of service. Any change in appointment, including reappointment or removal, requires notification. Members may resign by written notification to the appropriate IRB Chair and/or the IRB Director.

On a periodic basis, the IRB Chairs and the IRB Director will review the membership and composition of the IRB to determine whether or not the IRB continues to meet regulatory and institutional requirements. Required changes in IRB membership will be reported to the OHRP.

The IRB roster will identify the principal member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the principal member is absent. The IRB minutes will document when an alternate member replaces a principal member at a convened meeting.

When necessary, the IRB Chairs or the IRB Director may solicit individuals from the NYU Langone Health or the general community who are competent in specialized areas to assist in the review of issues or protocols requiring scientific or scholarly expertise beyond, or in addition to, that available on the IRB. The need for an outside reviewer is determined in advance of the IRB meeting by the IRB Director or the IRB Chair or may be recommended by the primary reviewer. The assigned IRB Office will ensure that all relevant materials are provided to the outside reviewer prior to the convened meeting.

The consultant’s findings will be presented to the Full Board for consideration either in person, via telephone or in writing. If in attendance, these individuals will provide consultation but may not participate in or observe the vote.

Written statements of outside reviewers will be kept in IRB records and filed with the relevant protocol.
Key information provided by outside reviewers at convened meetings will be documented in the meeting minutes.

The IRB Director reviews the conflict of interest policy for IRB members with consultant(s) (see: IRB Member Conflicts of Interest). The consultant(s) must verbally confirm to the IRB Director that no conflicts of interest exist prior to review. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest with the sponsor of the research will not be invited to provide consultation.

Ad hoc or informal consultations requested by individual IRB members (rather than the Full Board) will be requested in a manner that protects the study Principal Investigator’s confidentiality and is in compliance with the IRB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular Principal Investigator and research protocol).

### 6.5. Duties of IRB Members

The agenda, submission materials, protocols, proposed informed consent forms and other appropriate documents are distributed to IRB members at least one week prior to the convened meetings at which the research is scheduled to be discussed in order to ensure full participation in the review of each proposed project. IRB members are expected to treat the research proposals, protocols, and supporting data confidentially. All copies of the protocols and supporting data are returned to the respective IRB Office staff at the conclusion of the review for professional document destruction.

### 6.6. Attendance Requirements

IRB Members must attend a minimum of ten meetings annually, and should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, that member should inform the IRB Chair, Vice Chair, or a staff member of the IRB Office. If the inability to attend will be prolonged, a request for an alternate to be assigned may be submitted to the Chair or the IRB Director. If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she must notify the IRB at least thirty (30) days in advance so that an appropriate replacement can be obtained. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the IRB. If the member has a designated alternate (see: Alternate Members), the alternate can serve during the principal member’s absence, provided that the IRB receives advance notice.

### 6.7. Training / Ongoing Education of Chair and IRB Members in Regulations, Procedures

A vital component of a comprehensive human research protection program is an education program for the IRB Chairs and the IRB members. NYU Langone Health is committed to providing training and an on-going educational process for NYUGSoM and NYU Winthrop IRB members and the staff of the NYU Langone Health IRB Office, related to ethical concerns and regulatory and institutional requirements for the protection of human subjects (see Education and Training Plan).

**Orientation**

New IRB members, including alternate members, will meet with an IRB Chair and the respective IRB Director for an informal orientation session. After the initial session, all new IRB members will meet with the respective IRB Associate Director for a formal introduction to the IRB and members’ responsibilities. At this session, the new members will be given an IRB Handbook that includes:

- The Belmont Report
- NYU Langone Health Human Subjects Protection Program Policies and Procedures
- Federal regulations relevant to the IRB
New members are required to complete the Initial Education requirement (discussed in the next section) prior to serving as primary reviewer.

**Initial Education**
All new IRB members will complete the following web-based training:

1. NYU Langone Health Human Subjects Training Module; and the
2. The Ethical Research Oversight Course (E-ROC) by Public Responsibility in Research Organization or IRB Member Module—“What Every New IRB Member Needs to Know” at the CITI site.

**Continuing Education**
To ensure that oversight of human research is ethically grounded and that the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB. Educational activities include, but are not limited to:

- in-service training at IRB meetings
- review of appropriate publications
- identification and dissemination by the IRB Director of new information that might affect the human research protection program, including emerging laws, regulations, policies, procedures, and ethical and scientific issues to IRB members via email, mail, or during IRB meetings
- unlimited access to the IRB Office resource library
- Completion of The Ethical Research Oversight Course (E-ROC) by Public Responsibility in Research Organization or IRB Member Module—“What Every New IRB Member Needs to Know” at the CITI site once every three (3) years

The IO will provide support and send as many members of the IRB as possible to attend the annual PRIM&R/ARENA conference and/or regional OHRP conferences on human research protections.

**IRB Office Staff Training**
All new IRB Office staff will meet with the respective IRB Associate Director for a formal introduction to the IRB and staff members’ responsibilities. At this session, the new staff will be given an IRB Handbook that includes:

- The Belmont Report
- NYU Langone Health Human Subjects Protection Program Policies and Procedures
- Federal regulations relevant to the IRB

The IRB Office staff is required to complete the entire CITI Course in the Protection of Human Research Subjects once every three (3) years and the NYU Langone Health Human Subjects Training module. Staff will be expected to attend PRIM&R or OHRP training at least annually.

The IRB Office staff will be expected to become CIP-certified within a two-year period of employment.

**6.8. Liability Coverage for IRB Members**
The NYU Langone Health’s insurance coverage applies to NYU Langone Health employees, any person authorized to act on behalf of the NYUGSoM IRB or the NYU Winthrop IRB, and any person who acts within the scope of their employment or authorized activity on behalf of NYU Langone Health.

**6.9. Review of IRB Member Performance**
IRB members’ performance will be reviewed on an annual basis by the respective IRB Chairs and IRB
Director. Formal feedback based upon this evaluation will be provided to IRB members in writing with an opportunity to discuss in person. Members who are not acting in accordance with the IRB mission or policies and procedures, or IRB members who have an undue number of absences, will be removed.

6.10. IRB Member Conflicts of Interest

IRB members and consultants will not participate in any IRB action, including the initial and continuing review of any project, in which the member has a conflicting financial or other interest, except to provide information requested by the IRB. IRB members are expected to self-identify conflicting interests. A primary reviewer or expedited reviewer with a conflict of interest must notify the IRB Office staff, and the IRB Office staff will, in turn, re-assign the protocol to another IRB member.

An IRB member is considered to have a conflicting interest when the IRB member or an immediate family member (defined as having a relationship to a person, whether by blood, law, or marriage, as a spouse, parent, child, grandparent, grandchild, stepchild, or sibling) of the IRB member:

- has an involvement in (or is directly supervising) a research project being reviewed by the IRB;
- is the project director, or a member of the research team;
- has a financial interest (for example, a financial interest in the sponsor or the product or service being tested) in the research whose value cannot be readily determined or whose value may be affected by the outcome of the research;
- has a financial interest in the research with value that exceeds $10,000 or 5% ownership of any single entity when aggregated for the IRB member and their immediate family;
- has received or will receive any compensation whose value may be affected by the outcome of the study;
- has a proprietary interest in the research (property or other financial interest in the research including, but not limited to, a patent, trademark, copyright or licensing agreement);
- has received payments from the sponsor that exceed $10,000 in one year when aggregated for the IRB member and their immediate family;
- is an executive or director of the agency or company sponsoring the research; and/or
- any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

IRB members who have a conflicting interest in a research study will be excused from the meeting room when the IRB reviews the research, except when otherwise requested to provide information to the IRB. The IRB Chair will allow for Board discussion to commence upon the conflicted member’s removal from the meeting. The conflicted member is not counted toward the quorum and his/her absence during the discussion and vote on the protocol will be noted in the IRB meeting minutes, with an indication that a conflict of interest was the reason for the absence.

If the conflict of interest status of an IRB member changes during the course of a study, the IRB member is required to declare such conflict to the IRB Chair and/or IRB Director.

6.11. Reporting and Investigation of Allegations of Undue Influence

If an IRB Chair, IRB member, or IRB Office staff member feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the IO, who can determine corrective action, depending on the circumstances.

The official receiving the report or his/her designee will conduct a thorough investigation and corrective action will be taken to prevent additional occurrences.
7. **IRB Records**

The IRB will prepare and maintain adequate documentation, in printed form or electronically, of the IRB’s activities.

IRB records will include continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in 45 CFR 46.108(f)(1), and copies of all correspondence between the IRB and investigators. Statements of significant new findings provided to subjects must be maintained with the related research proposal and, when reviewed at an IRB meeting, such statements must be documented in the minutes.

Documentation of verified exemptions consists of the reviewer’s written concurrence that the activity described in the investigator’s request satisfies the conditions of the cited exemption category.

IRB records for initial and continuing review by the expedited procedure must include: the specific permissible category; a description of action taken by the reviewer, and any determinations required by the regulations and protocol-specific findings supporting those determinations. IRB records must also document the rationale for an expedited review's determination under 45 CFR 46.110(b)(1)(i) that research appearing on the expedited review list described in 45 CFR 46.110(a) is more than Minimal Risk.

IRB records must document any determinations required by the federal regulations and protocol-specific findings supporting those determinations.

All records must be accessible for inspection and copying by authorized representatives of the FDA, OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

IRB records must also include documentation of the responsibilities that NYU Langone Health and the IRB will undertake to ensure compliance with the requirements of 45 CFR 46.

7.1. **IRB Records**

Records that will be maintained by the IRB include, but are not limited to:

- Written IRB operating procedures
- IRB membership rosters
- IRB training records. For the NYUGSoM IRB, the NYUGSoM IRB Education Coordinator maintains accurate records listing research investigators, IRB members, and IRB Office staff that have fulfilled the institution’s human subject training requirements. For NYU Winthrop’s IRB, these are maintained by the Associate, IRB Systems. Electronic copies of documentation are maintained in the official IRB records located in the IRB Office.
- IRB correspondence (other than protocol related)
- IRB Study Files for each study. Documents included in Study Files are listed in Section 7.2 (IRB Study Files) below.
- Documentation of Emergency Exemption from Prospective IRB Approval. (21 CFR 56.104(c))
- Documentation of Exceptions from Informed Consent Requirements for Emergency Use of a Test Article ((21 CFR 50.23)
- Documentation of verified exemptions (including documentation of initial and continuing review)
- Documentation of convened IRB meetings minutes
- Documentation of review by an external/another institution’s IRB when appropriate
- Documentation of cooperative review agreements, e.g. Memoranda of Understanding (MOUs)
- Federal Wide Assurances (FWAs), Protocol violations submitted to the IRB, Quality assurance reviews

Documentation that must be maintained for studies reviewed by external IRBs includes:

- On-line access to all applicable protocol documents
- MOU/agreements of IRB services
- Workflow/SOPs
7.2. **IRB Study Files**

The NYU Langone Health IRBs maintain Study Files in an electronic system ("Research Navigator") that holds complete records for each human research study that was active as of November 2013 or later. Previous records are kept in an electronic documents archive for at least three years, or in a combination of the archive system and the current electronic system. Research Navigator issues each study a unique study number which is used throughout the institution to refer to the study throughout its entire operational life. Research Navigator maintains all submission forms, study-related documents and all official communications to and from the IRB to study staff. Additionally, each study team shall keep copies of these files in the Principal Investigator’s project file.

Study Files include (but are not limited to):

- Protocol and all other documents submitted as part of a new protocol application;
- Protocol and all other documents submitted as part of a request for continuing review/termination of research application. This also includes progress reports, statements of significant new findings provided to subjects, reports of injuries to subjects;
- Documents submitted and reviewed after the study has been approved, including reports of modifications to research/amendments and adverse event reports;
- Copy of IRB-approved consent form;
- DHHS-approved sample consent form document and protocol, when they exist;
- IRB reviewer forms (when expedited review procedures are used) and scientific reviewer forms (where applicable);
- Documentation of type of IRB review;
- For expedited review, documentation of any determinations required by the regulations and protocol- specific findings supporting those determinations, including:
  - waiver or alteration of the consent process
  - research involving pregnant women, fetuses, and neonates
  - research involving prisoners
  - research involving children
  - research involving persons with impaired cognitive function;
- Documentation of all IRB review actions;
- Notification of expiration of IRB approval to the Principal Investigator and instructions for submitting relevant continuing review materials;
- Notification of suspension of research;
- Correspondence pertaining to appeals;
- Copies of approval letters and forms that describe what Principal Investigator must have before beginning the study;
- IRB correspondence to and from study investigators;
- All other IRB correspondence related to the research;
- For studies of medical devices, a report of prior investigations;
- Reports of Unanticipated Problems involving risk to subjects or others and adverse events; and
- A log of each submission’s administrative history and communications within Research Navigator that take place between the IRB and the study team.

7.3. **Minutes of an IRB Meeting**

Documentation of proceedings at a convened IRB meeting must be written and available for review by the next regularly scheduled IRB meeting date. After ratification of the minutes by the Board members, if it is determined that revisions/corrections are necessary, the minutes will be amended and presented at the following IRB meeting.

A copy of the IRB-approved minutes for each IRB meeting must be distributed to the Institutional Official and NYU Langone Health’s Office of General Counsel upon ratification by the IRB.
Minutes of IRB meetings must contain sufficient detail to show:

- The basis for requiring changes in research.
- The basis for disapproving research.
- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
- The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area.
- Attendance at the meetings, including documentation of those members or alternate members who are participating through videoconference or teleconference, and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions.
- Alternate members attending the meeting and for whom they are substituting.
- Names of consultants present.
- Name of investigators present.
- Names of guests present.
- The initial attendance list shall include those members present at the beginning of the meeting. The minutes will indicate, by name, those members who enter or leave the meeting. The vote on each action will reflect those members present for the vote on that item.
- Business items discussed.
- Continuing education.
- Actions taken by the IRB including those involving full Board review. The IRB must use the minutes to notify IRB members of actions taken through expedited review and those studies that have been determined to be Exempt from IRB review.
- Separate deliberations, actions, and votes for each protocol undergoing initial review, continuing review, or review of modifications by the convened IRB.
- Documentation that the research meets each of the required criteria [45 CFR 46.116(d)] along with protocol-specific information containing justification as to why the IRB considers the research to meet each criterion when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain informed consent.
- Documentation that the research meets each of the required criteria [45 CFR 46.117(c)] along with protocol-specific information justifying why the IRB considers the research to meet each criterion when the requirements for written documentation of consent are waived.
- When approving research that involves populations covered by Subparts B, C, or D of 45 CFR 46, the minutes will document the IRB’s protocol-specific justifications and findings regarding the determinations stated in the Subparts or the IRB’s agreement with the findings and justifications as presented by the investigator on IRB forms.
- The vote on actions, including the number of members voting for, against, and abstaining. Number of those excused, and number of those recused.
- Notations indicating an IRB member’s conflicting interest with the research under review, as defined by NYU Langone Health policy (see: Conflicts of Interest).
- and further that the conflicted IRB member was not present during the deliberations or voting on the proposal (and that the quorum was maintained).
- A written summary of the discussion of controversial issues and their resolution.
- Review of additional safeguards to protect vulnerable populations if entered as study subjects when this is not otherwise documented in IRB records.
- For initial and continuing review, the frequency of continuing review of each proposal, as determined by the IRB, including identifications of research that warrants review more often than annually and the basis for that determination.
- Risk level of initial and continuing approved protocols.
- Review of interim reports, e.g. Unanticipated Problems or safety reports; amendments; report of violation/deviations; serious or continuing non-compliance; suspensions/terminations, etc.
- Review of Data and Safety Monitoring Board (DSMB) summary.
- Review of Plans for Data and Safety Monitoring.
- Documentation, as required by 45 CFR 164(i)(2), indicating the approval of a waiver or alteration of the HIPAA Authorization.
- Relevant information provided by consultants will be documented in the minutes or in a report provided by the consultant.
- The rationale for significant risk/non-significant risk device determinations.
- Determinations of conflict of interest management plans and that the IRB found it acceptable.
- Identification of any research for which there is need for verification from sources other than the Principal Investigator that no material changes are made in the research.
- A list of research approved since the last meeting utilizing expedited review procedures.

7.4. Membership Rosters
A membership list of IRB members will be maintained and must identify members sufficiently to describe each member’s chief anticipated contributions to IRB deliberations. The list must contain the following information about members (IRB Membership Roster).

- Name
- Earned degrees
- Affiliated or non-affiliated status (“non-affiliated” would mean that neither the member him/herself nor an immediate family member of the member is affiliated with NYUGSoM, NYU Winthrop, or any other part of NYU Langone Health)
- Status as scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist). For purposes of this roster, IRB members with research experience are designated as scientists (including student members). Research experience includes training in research (e.g., doctoral degrees with a research-based thesis) and previous or current conduct of research. Students undergoing training in research fields will be designated as scientists
- Indications of experience, such as board certifications or licenses sufficient to describe each member’s chief anticipated contributions to IRB deliberations
- Representative capacities of each IRB member; including naming the IRB member prisoner representative (as required by Subpart C), and naming the IRB members knowledgeable about or experienced in working with children, pregnant women, cognitively impaired individuals, and other vulnerable populations locally involved in research
- Role within the IRB (Chair, Co-Chair, etc.)
- Voting status (Any ex officio members are non-voting members)
- Alternate status, including the name of the member he/she alternates with
- Relationship (e.g., employment) between the individual IRB member and NYU Langone Health

The responsible IRB Office must keep the IRB membership list current.

7.5. Documentation of Exemptions
Documentation of verified exemptions consists of the reviewer’s citation of a specific exemption category and written concurrence that that activity described in the investigator’s request for exemption satisfies the conditions of the cited exemption category (see: Categories of Research Permission for Exemptions). The Exempt determination is reported at the next convened IRB meeting and documented in the IRB meeting minutes.

7.6. Documentation of Expedited Reviews
IRB records for initial and continuing review of a study by the expedited procedure must include: the specific permissible category; documentation of determination that the activity described by the investigator satisfies all of the criteria for approval under expedited review (see: Categories of Research Eligible for Expedited Review); the approval period; any determinations required by the federal regulations including protocol-specific findings supporting those determinations (such as waiver or
7.7. Access to IRB Records
The IRB has policies and procedures to protect the confidentiality of research information.
- Digital IRB records are maintained on password-protected, secure hardware.
- Ordinarily, access to IRB records is limited to the IRB Director, IRB Chairs, IRB members, IRB Administrators, IRB Office staff, authorized institutional officials, and officials of federal and state regulatory agencies (OHRP, FDA, etc.). Research investigators are provided reasonable access to files related to their research. Appropriate accreditation bodies are provided access and may recommend additional procedures for maintaining security of IRB records. All other access to IRB records is limited to those who have legitimate need for them, as determined by the IO and IRB Director.
- Records are accessible for inspection and copying by authorized representatives of regulatory agencies during regular business hours.
- Records may not be removed from the IRB Office; however, the IRB Office staff will provide copies of records for authorized personnel if requested.
- All other access to IRB Study Files is prohibited.

7.8. Records Retention Requirements
“Retention” refers to the storage of records of inactive/closed/terminated/exempt/not-human-subjects-research studies and past IRB Board meeting minutes.

IRB records are stored as described above.

Records pertaining to conducted research must be retained for at least three (3) years after completion of the research. IRB records not associated with research or for protocols cancelled without subject enrollment will be retained at the facility for at least three (3) years after closure.

Physical records associated with closed or terminated studies shall, after the three-(3) year retention period expires, be electronically scanned and thereafter shredded or otherwise destroyed in accordance with institutional policy.

Electronic records must be retained for at least three (3) years on the IRB’s current production systems.

7.9. Written Policies and Procedures
This document details the policies and federal regulations governing research involving human subjects, and further sets forth the requirements for submitting research proposals for review by the NYU Langone Health IRBs.

These Policies and Procedures are frequently updated. The NYU Langone Health IRB Directors will keep the NYU Langone Health research community apprised of any new information that may affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues. Such notification may be given via electronic mail, displayed on the NYUGSoM and NYU Winthrop IRBs’ websites and via the NYU Langone Health Office of Science and Research’s (OSR’s) web-based newsletter. The Policies and Procedures will be available for download through the NYUGSoM and NYU Winthrop IRBs’ websites.

8. IRB Review Process
These procedures and guidelines apply to all research involving human subjects, regardless of sponsorship and performance site, conducted under at or under the auspices of NYU Langone Health and at any unaffiliated institutions under the jurisdiction of the NYU Langone Health IRBs.
8.1. Human Subjects Research Determination
The Principal Investigator is responsible for making the initial determination as to whether an activity constitutes human subjects research. The Principal Investigator should make this determination based on the definitions of “human subjects research” (see: Definitions). For guidance on whether an activity constitutes human subjects research, Principal Investigators should use the "Self-Certification Form for Determining Whether Your Proposed Activity is Research Involving Human Subjects" on the NYUGSoM and NYU Winthrop IRB websites.

The Principal Investigator will be held responsible by the applicable NYU Langone Health IRB to make the proper human subjects research determination. As such, Principal Investigators are urged to request a confirmation that an activity does not constitute human subjects research from the IRB Office. The request may be made verbally, by telephone, via electronic mail or through a formal written communication. All requests must include sufficient documentation of the research activity to support the determination.

Within the IRB Office, determination of whether an activity constitutes human subjects research may be made by experienced members of the IRB Office staff or any member of the IRB. Determinations will analyze whether the activity meets the definitions of “research” and involves “human subjects,” using the Checklist for Human subjects research Determination. The IRB Office staff will respond to the Principal Investigators’ formal requests for determination of human subjects research status in writing. A copy of the submitted materials and determination correspondence will be kept on file in the IRB Office.

8.2. Exempt Research
All research involving human subjects must be approved by the IRB. However, certain categories of research (i.e., “Exempt research”) do not require review and approval by a convened IRB. Exempt research is reviewed, determined and approved by an IRB Chair, or designee of the Chair, and is further subject to institutional review. Research cannot be approved by the institution if it has been disapproved by the IRB.

Reviewers will use the Checklist for Exempt Determination to determine and document whether or not the research protocol meets the Exempt criteria.

A determination of exemption from IRB review does not equate to an exemption from the HIPAA requirement for Authorization or Waiver of Authorization when the research involves a Covered Entity’s protected health information (“PHI”). Researchers who receive an exemption determination but whose research involves PHI must still (1) submit a HIPAA Authorization form (or a request for waiver of HIPAA Authorization), or (2) if applicable, submit a HIPAA form for conducting research involving decedents’ information or research using a Limited Data Set. Researchers who wish to review PHI (e.g., medical records) to prepare a research protocol must submit the appropriate HIPAA form for IRB approval.

Limitations on Research Subjects; Vulnerable Populations

Children
Research involving survey or interview procedures or observations of public behavior involving children will not be determined Exempt, except if the research involves observations of public behavior when the investigator does not participate in the activities being observed (see: Child.)

Prisoners
Research involving prisoners will not be determined Exempt. IRB review is required.

Categories of Research Permissible for Exemption
The categories of research permissible for exemption are described in the federal regulations at 45 CFR 46.104(d). The IRB Office staff and IRB members are required to use the Checklist for
Note Regarding Broad Consent:

In the new Common Rule, "Broad Consent" is an (optional) alternative consent process for use only for the storage, maintenance, and secondary use of identifiable private information or identifiable biospecimens for future, yet-to-be-specified research. To utilize "Broad Consent," the study team and/or the unit/biorepository responsible for the storage of the identifiable data/biospecimens are required to:

- identify the types of research that may be conducted with the data/biospecimens,
- record and track who has agreed to or refused consent, and
- to track the terms of consent to determine whether proposed future secondary research use falls within the scope of the identified types of research

NYUGSoM and NYU Winthrop IRB Process

At this time, the NYU Langone Health HRPP and IRBs will not mandate nor implement the institutional use of Broad Consent, as the tracking requirements may be burdensome. Exemption categories 7 and 8, which rely on Broad Consent, will not be applied when the IRB reviews Exempt research.

NYU Langone Health will continue to support study teams seeking subject permission for the collection and storage of identifiable private information/biospecimens for future secondary use research through the following processes:

- Study-specific consent and comprehensive IRB review
- IRB waiver of consent (as eligible) and comprehensive IRB review
- Exemption #4
- De-identification to remove the research activity from Common Rule purview and not require IRB review or consent

Only the IRB may deem a research project to be Exempt from IRB review. Research activities that are not regulated by the FDA (see: FDA Exemptions) in which the only involvement of human subjects will be in one or more of the eight categories found in 45 CFR 46.104(d) (see: 45 CFR 46 Exemptions) are Exempt from federal regulations, but still require IRB registration and review.

FDA Exemptions

The following categories of clinical investigations are not regulated by DHHS or another federal agency and are exempt from the requirements of IRB review prior to commencement of the investigation:

- Emergency use of a Test Article, provided that such emergency use is reported to the IRB within five working days of such use. Any subsequent use of the Test Article at the institution is subject to IRB review [21 CFR 56.104(c)]; and
- Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture [21 CFR 56.104(d)].

How to Submit an Exemption Application

Any initial application for Exemption of human subjects research must be submitted electronically via the NYU Langone Health IRB’s Research Navigator eSubmission system with the following documentation:
• a summary of the research;
• a description of the research procedures;
• consent documents (if applicable);
• plan for privacy and confidentiality;
• plan for dissemination of findings;
• a copy of the proposal if the research is externally funded, and
• expected date of research completion.

The IRB Chair (or designee) reviews all requests for exemptions and determines whether the request meets the criteria for Exempt research. The IRB Chair may designate an IRB member to review requests for exemptions submitted to the IRB. The IRB Chair selects designees who are qualified to review this category of submission based on their expertise of the protocol content and knowledge of regulations pertaining to research. If a designated reviewer to consider requests for exemptions is not available, the IRB Chair reviews the requests. Individuals involved in making the determination of an IRB Exempt status of a proposed research project cannot be involved in the proposed research, nor can they have any apparent conflict of interest.

The IRB reviewer’s determination on the request for Exempt research is documented by the Exemption Determination Form to be completed by the reviewer. The IRB reviewer verifies on the form whether the submission meets the definition for “research” or “clinical investigation”. If the request meets the definitions of both human subject and research, the reviewer indicates whether the request for exemption was approved or denied, and if approved, the rationale for the determination and exemption category under which it was permitted. Determinations of Exempt studies are communicated to the IRB at the next convened meeting after the approval of exemption is made.

The decision must be communicated in writing to the Principal Investigator and the IRB. Documentation must include the specific categories justifying the exemption.

Investigators will be given feedback as to the qualification of the application for Exempt research status through the eSubmission system. Upon the IRB’s completion of the review, the IRB Office staff will inform the Principal Investigator of the results of the review via electronic mail.

**Additional Protections**

Although NYU Langone Health research that is deemed by an IRB to be Exempt research is not covered by the federal regulations, such research is not exempt from NYU Langone Health policies on the responsible conduct of research or the ethical guidelines of the Belmont Report. The individual making the determination of exemption will use the NYU Langone Health Checklist for Exemption Determination to determine whether to require additional protections for subjects (including specifics of the informed consent procedures) in keeping with NYU Langone Health institutional policies and/or the ethical guidelines of the Belmont Report.

**8.3. Expedited Review of Research**

The IRB may use the expedited review procedure to review the following:

(A) some or all of the research appearing on the categorical list below (see: Categories of Research Eligible for Expedited Review) and unless the reviewer determines that the study involves more than Minimal Risk;
(B) minor changes in previously approved research during the period (of one year or less) for which approval is authorized; or
(C) for new research approved after January 21, 2019, research for which limited IRB review is a condition of exemption under 45 CFR 46.104(d)(2)(iii), d(3)(i) (c), and (d)(7) and (8).

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (i) the level of risks to subjects; (ii) the research design or methodology (e.g., an addition of a procedure...
Under an expedited review procedure, the review may be carried out by an IRB Chair or by one or more IRB reviewers designated by the IRB Chair. For expedited review purposes, the reviewers designated by the NYUGSoM IRB Chair will consist of the IRB Director, IRB Associate Director and the IRB Research Analysts (“Expedited Reviewers”). An IRB Chair may also designate the IRB Vice Chair(s) to assist the designees in review of expedited reviews. The IRB Chair or IRB Director may appoint other designees from among the members of the IRB when a particular field of expertise is required for an expedited review. Expedited Reviewers at NYU Winthrop are appointed by the NYU Winthrop IRB Chair and IRB Director among IRB committee members and IRB Office staff. The Expedited Reviewer(s) may, at their discretion, forward expedited reviews to the IRB Chair or IRB Vice Chair(s) when additional review is needed in order to evaluate Minimal Risk status and determine expedited status. On an annual basis, the IRB Chairs will designate a list of IRB members eligible to conduct expedited review, and the IRB Office will select Expedited Reviewers from that list. IRB members eligible to conduct expedited review must have served on the IRB for at least three (3) months.

When reviewing research under an expedited review procedure, the IRB Chair, or designees, should receive and review all documentation that would normally be submitted for a Full-Board review including the complete protocol, a Continuation review form summarizing the research to date (including modifications and Adverse Events), as applicable, notes from the pre-screening conducted by the IRB Office staff, and the current consent documentation. The IRB Chair or designees shall determine the regulatory criteria for use of such a review procedure by using the Reviewers Checklist.

If the research clearly qualifies for expedited review, the reviewer shall conduct the expedited review. If the research does not clearly qualify for expedited review, the reviewer shall refer the application to the IRB for Full Board review at its next convened meeting.

The reviewer(s) conducting the initial or continuing review will complete the appropriate Institutional Review Board Protocol Review Checklist in order to determine whether the research meets the expedited procedure criteria and, if so, whether the research meets the regulatory criteria for approval. If the research does not meet the criteria for expedited review, then the reviewer will indicate that the research requires Full Board review by the IRB and the protocol will be placed on the next agenda for an IRB meeting.

**For studies approved after January 21, 2019:** if the reviewer determines that research appearing on the expedited review list is more than Minimal Risk, he/she will provide documentation of their rationale for the determination.

In reviewing the research, the Expedited Reviewers will follow the Review Procedures described in Review Process and may exercise all of the authorities of the IRB except for disapproval of the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth below.

Expedited Reviewers will indicate approval, required modifications or disapproval within Research Navigator. If modifications are required, the reviewer will inform the Principal Investigator (either via Research Navigator or via electronic mail). If the modifications are minor, the reviewer(s) may determine if the Principal Investigator has sufficiently addressed the modifications. If the modifications are major and have been reviewed by the IRB Chair or IRB Vice Chair, the reviewer(s) may send the review back to the IRB Chair or Vice Chair (s) for further review. Upon the discretion of the Expedited Reviewer(s) and/or the IRB Chair or IRB Vice Chair, the protocol may be submitted to the IRB for Full Board review.

In the event that expedited review is carried out by more than one IRB member and the Expedited
Reviewers disagree on the resolution of the application, the IRB Director and/or IRB Chair may make a final determination. Upon the discretion of the IRB Director or IRB Chair, the protocol will be submitted to the IRB for review.

**Categories of Research Eligible for Expedited Review**

[63 FR 60364-60367, November 9, 1998]

Inclusion on the list of Research Categories below does not mean that the activities are to be deemed to be of Minimal Risk. Rather, it means that the research activity is eligible for review through the expedited review procedure to determine whether the specific proposed research involves no more than Minimal Risk to human subjects.

- The categories in this list apply regardless of the age of subjects, except as noted.
- The expedited review procedure may not be used where identification of the subjects and/or subjects’ responses would reasonably place them at risk of criminal or civil liability, or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- The expedited review procedure may not be used for classified research involving human subjects.
- The standard requirements for informed consent (or waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

Research Categories one (1) through seven (7) below pertain to both initial and continuing IRB review:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. However, research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the drug is not eligible for expedited review.
   (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared and/or approved for marketing, and the medical device is being used in accordance with its cleared/approved status.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   - from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   - from other adults and children, taking into consideration the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency in which blood samples will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period, and collection may not occur more frequently than 2 times per week.
   - Children are defined in the DHHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” [45 CFR 46.402(a)]

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include, *inter alia*: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and sub gingival dental plaque and calculus,
provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings, and (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, such devices must be cleared and/or approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include, inter alia: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography, and (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. See Categories of Research Permissible for Exemption and [45 CFR 46 101(b)(4)]. This listing refers only to research that is not Exempt.

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies. Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not Exempt.

8. Continuing review of research previously approved by the convened IRB as follows:

   o a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of subjects; or
   o b. where no subjects have been enrolled and no additional risks have been identified, or
   o c. where the remaining research activities are limited to data analysis.

Note: For categories 8(a) and 8(b) the following applicability criteria apply:

(1) the remaining activities must be Minimal Risk;

(2) if identification of the subjects or their responses will reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal; and

(3) the research may not be classified research. For category 8b, the only applicability criterion is that the research may not be classified research.
For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the Principal Investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.

9. Continuing review of research that is not conducted under an investigational new drug application (IND) or investigational device exemption (IDE) where categories two (2) through eight (8) above do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than Minimal Risk and no additional risks have been identified.

Note: Under Category (9), an expedited review procedure may be used for continuing review of research not conducted under an IND application or IDE where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than Minimal Risk and no additional risks have been identified. The determination that "no additional risks have been identified" does not need to be made by the convened IRB.

If a research protocol has been initially approved through a Full-Board review procedure, the continuing review may not be performed under the expedited review procedure unless such protocol falls within the purview of categories 8 or 9, above. If the protocol was initially targeted for Full Board review but was determined to meet the expedited review criteria outlined above, the reviewer(s) will document that an erroneous review had previously taken place and process the expedited review in accordance with this Policy. The Principal Investigator will be notified of the change in status through electronic mail correspondence.

How to Submit an Expedited Review
The submission should be made via Research Navigator and include the following documentation:

- a summary of the research;
- description of the research procedures;
- consent documents (if applicable);
- plan for privacy and confidentiality;
- plan for dissemination of findings;
- a copy of the proposal if the research is externally funded;
- a protocol;
- a current CV for each investigator or other study staff listed on the study; and
- a financial disclosure form for each team member listed on the study.

Informing the IRB
All members of the IRB will be apprised of all expedited review approvals by means of the agenda for the next scheduled Full Board meeting. The expedited review approvals will be made available for any optional review at the request of any IRB member.

8.4. Convened IRB Meetings
Except where eligible for the expedited review procedure, the IRB must review proposed research at convened meetings (also known as “Full-Board” meetings) at which a quorum is present.

Schedule of IRB Meetings
In general, the NYU Langone IRB meets on the first, second, third and fourth Tuesday of each month (for Boards A, B, C and D, respectively). A special Board E is available to hold ad hoc/emergency meetings; these may be called at any time by an IRB Chair or the IRB Director and they are held via telephone.
The schedule for the IRB may change as needed due to holidays or lack of quorum.

**Quorum**

A quorum consists of a simple majority of the voting membership, including at least one member whose primary concern is in a non-scientific area. If research involving an FDA-regulated article is involved, a licensed physician must be included in the quorum. The IRB Chair, with the assistance of the IRB Office staff, will confirm that an appropriate quorum is present before calling the meeting to order. The IRB Chair will be responsible in ensuring that the IRB meetings remain appropriately convened.

A quorum must be present when voting occurs. The IRB Coordinator takes note of arrivals and departures of all members and notifies the IRB Chair if a quorum is not present. If a quorum is not maintained, the proposal must be tabled or the meeting must be terminated. All members present at a convened meeting have full voting rights, except in the case of a conflict of interest (see IRB Member Conflicts of Interest).

In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

While it is preferred that IRB members be physically present at the meeting, if a voting member cannot be physically present at the convened meeting, he/she may be considered present, participate and vote via teleconference or videoconference. In such cases, the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions.

Opinions of absent IRB members that are transmitted by mail, telephone, facsimile or e-mail may be considered by the attending IRB members but may not be counted as votes or to satisfy the quorum for convened meetings.

It is generally expected that at least one IRB member unaffiliated with NYU Langone Health and at least one member who represents the general perspective of subjects (the same individual can serve in both capacities) will be present at all convened IRB meetings. Although the IRB may, on occasion, meet without this representation, individuals serving in this capacity must be present for at least 80% of the IRB meetings.

**Pre-Meeting Distribution of Documents**

Review and meeting materials are available electronically via Research Navigator prior to each IRB meeting.

**Meeting Procedures**

The IRB Chair, or Vice-Chair in the event that the IRB Chair is absent, will call the meeting to order, once it has been determined that a quorum is in place. The Chair or Vice-Chair will remind IRB members to recuse themselves from the discussion and vote by leaving the room where there is a conflict. The IRB will review and discuss the IRB minutes from the prior meeting and determine if there are any revisions/corrections to be made. If there are no changes to be made, the minutes from the prior meeting will be accepted as presented and considered final. If it is determined that revisions/corrections are necessary, the minutes will be amended and presented at the following IRB meeting.

The IRB reviews all submissions for initial and continuing review, as well as requests for modifications. The primary and secondary reviewer present an overview of the research (including the study goals, design, procedures, safety procedures, and qualifications of the investigators) and lead the IRB through the completion of the regulatory criteria for approval in the Institutional Review Board - Protocol Review/Initial Review checklist appropriate for the type of review (e.g., initial, continuing, amendment).

In order for the research to be approved, it must receive the approval of a majority of those voting
At the discretion of the IRB, the Principal Investigator may be invited to the IRB meeting to answer questions about his/her proposed or ongoing research. The Principal Investigator may not be present for the discussion or vote on their research.

The IRB Office staff is responsible for recording the proceedings and for taking minutes at each IRB meeting.

**Guests**

Guests may be permitted to attend IRB meetings at the discretion of the IRB Chair and the IRB Director. Guests may not participate in any discussions occurring at the meeting unless requested by the IRB and must sign the IRB’s Confidentiality Agreement to attend.

**Primary Reviewers**

The IRB Office staff assigns a primary and secondary reviewer for all protocols requiring initial Full Board review, continuing Full Board review, and for all protocols requiring Full Board review of modifications to previously approved research. When making reviewer assignments, IRB Office staff will take into consideration the vulnerable populations involved in the research and the scientific or scholarly expertise required to review the research. Such protocols will then be assigned to at least one IRB member who has the appropriate expertise.

If the IRB Office staff cannot identify a primary reviewer with appropriate expertise, the IRB Chair or the IRB Director will solicit consultants from NYU Langone Health or the general community with competence in such specialized areas to assist in the review of the issues or protocols requiring appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB (see: Use of Consultants (Outside Reviewers)).

Prior to the convened IRB meeting, each protocol application (including background information, project protocol, and informed consent) is reviewed in depth by the assigned Primary reviewer(s). All other IRB members receive copies of aforementioned with the exception of the protocol and/or investigators brochure. They are expected to have reviewed all provided material in order to have a meaningful discussion of the presented information during the convened IRB meeting.

At the meeting, the Primary and Secondary Reviewers present an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators. The Primary and Secondary Reviewers, along with the IRB members, then complete the regulatory criteria for approval located in the Reviewer’s Checklists appropriate for the type of review (e.g., initial, continuing, amendment). Both primary reviewers and other IRB members who are not assigned as primary reviewers of proposed studies that require copies of protocols and/or any documentation may access these materials via Research Navigator. Further, upon request, copies of minutes and or study materials can be obtained in hard or electronic format by putting in a request to the IRB Office.

**8.5. Review Process**

**Submitting Electronically to the IRB (eSubmission)**

The IRB uses an electronic research administration system made up of several modules and collectively called “Research Navigator,” as updated from time to time.

All submissions must be made to the applicable NYU Langone Health IRB via Research Navigator. Initially, a study profile must be completed in the MyStudies module. This module issues the IRB Study Number. Once the MyStudies study profile is complete, any member of the study team may submit the study for initial review. The submission process executes an initial electronic review of the study and makes draft submissions in all of the appropriate OSR review office systems – including the IRB’s module,
Upon creation of an IRB/Research Navigator submission, the IRB Office is notified electronically and a pre-submission review is conducted by IRB Office staff. If, upon review of the IRB/Research Navigator submission, all required materials and information appear to have been received, the study’s Principal Investigator is notified via email to log into IRB/Research Navigator and confirm through the system an attestation that the submitted application is complete and accurate, and then formally submit their application to the IRB via electronic signature.

The Principal Investigator’s signature is considered valid based on the use of their confidential NYU Langone Health Kerberos ID and password used to log in into the system. It is against NYU Langone Health institutional policy to share a Kerberos password with anyone. During the electronic submission process, the Principal Investigator will be required to submit an attestation to the accuracy of the study submission, the fitness of their study staff, etc.

Initial review submissions also require review and approval of the proposed research by the Principal Investigator’s department chair and any of the department chair’s delegates “Proxies” they have designated for the review and approval of research. The department chair and Proxies are electronically notified of the initial submission, and may review and approve the study. Final IRB approval is withheld until department chair approval is received.

**eSubmission Contingency Process**

When IRB/Research Navigator is unavailable for an extended time for any reason, one of the following alternative methods for submitting and receiving approval/acknowledgement of a study submission may be used:

- **Manual (Written) Submission**
  
  If a time-critical submission must be made, a request for manual review of the submission can be made by the study team by contacting the IRB Office and requesting by email the MS Word submission form appropriate to the review type from the IRB/Research Navigator system. The IRB Office will email this form to the study team for completion. The submission form is then sent back electronically along with electronic copies of all necessary study-related materials for the IRB to review and approve. Any submission-related correspondence including requests for clarification or corrections, and final approval will be handled via email. A scanned signature of the study’s Principal Investigator and department chair may be required to secure review.

  If email is also unavailable, the IRB can receive written (printed and manually signed) copies of the necessary documents to review and approve. The IRB will return a written (printed and manually signed) decision letter.

- **Making the Submission System Whole**
  
  If an alternative submission is utilized, once the IRB/Research Navigator system is back online, the IRB Office will work with the study team to ensure that the electronic submission record for the study incorporates the complete review record, including all materials and issued decision letters along with a public comment as to the ‘make-up’ nature of the electronic record. This record will be placed on an IRB meeting agenda and reported to the next available Board as necessary. NYU Langone Health’s IT department may be called upon to update IRB/Research Navigator submission dates to match the actual dates of submission, review, approval, etc.

- **Delayed Submission**
  
  The IRB may ask the study team to delay their submission until such time as the IRB/Research Navigator system is once again available. The final decision is up to the Principal Investigator.

**IRB Office Pre-review**

Prior to being placed on an IRB Full Board meeting agenda, new protocol Full Board review applications are screened by the IRB Office staff for completeness and accuracy, using the appropriate Pre Review...
Checklist and ensuring regulatory compliance. The IRB Office staff may request additional information and/or request clarification on substantive issues from the Principal Investigator and any assigned primary study contact (such as a research coordinator. Principal Investigators will submit all requests for review, responses to review (etc.) via IRB/Research Navigator unless otherwise instructed.

The IRB Office staff will correct consent form deficiencies (typically limited to editorial changes) and will recommend protocol revisions via Word/track-changes. The IRB Office staff will check for completeness and accuracy of submissions and further identify the pertinent issues for the IRB Board, and will identify and/or clarify any substantive questions and deficiencies before the protocol is added to an agenda for Full Board review. Changes required by the IRB Office staff will be incorporated within the applicable IRB/Research Navigator electronic submission record for full review.

Only complete submissions will be placed on the IRB agenda for review. The Principal Investigator and any assigned primary study contact will be informed electronically via the eSubmission system (IRB/Research Navigator) if materials are missing or require substantive changes.

In-Person Consultations
In the case of a Principal Investigator who is submitting a protocol for the first time or a Principal Investigator who may not be well-versed in the protocol submission procedures, individualized IRB consultations can be arranged.

Specific questions about the IRB Policies and Procedures, determination of whether a particular protocol is human research or not, and what particular forms are required for a particular study can be submitted in writing to the IRB Office for information and/or clarification. Individual appointments with an IRB Office staff member can also be arranged and are strongly recommended for first-time submissions.

Meeting Materials Received for the Initial Review of Research
Each IRB member will have electronic access via IRB/Research Navigator to the following documentation, as applicable:

- complete IRB protocol application form;
- protocol summary;
- proposed consent / parental permission / assent form(s);
- recruitment materials;
- subject information;
- investigators’ curriculum vitae (CV); and
- data collection instruments (including all surveys and questionnaires).

At least one primary reviewer must review:

- any relevant grant applications;
- the sponsor’s protocol (when one exists);
- the investigator’s brochure (when one exists);
- the DHHS-approved sample informed consent document (when one exists);
- the complete DHHS-approved protocol (when one exists); and
- the Principal Investigator’s current CV or other documentation evidencing qualifications.

If an IRB member requires additional information to complete the review, that member may contact the Principal Investigator directly or may contact the IRB Office to make the request of the Principal Investigator.

Protocol reviewers will use the Reviewer’s Checklists as a guide to completing their review.

When a protocol is reviewed by the expedited procedure process, reviewers are provided with and expected to review all information that the convened IRB would have received. For expedited review
If an IRB member, consultant, Chair or other reviewer has a conflict of interest in the research undergoing review, he/she cannot participate in any IRB action, except to provide information requested by the IRB. It is the IRB member’s responsibility to self-identify conflicts of interests (See IRB Member Conflict of Interest).

Possible IRB Actions Taken by Vote

IRB members will discuss the study and make determinations regarding category of risk, risk/benefit issues, and whether informed consent procedures are adequate. The IRB will then vote and may take one of the following actions. All actions taken will be recorded in the IRB meeting minutes.

Approved
The study is approved as submitted. The research may begin upon receipt of the IRB’s written approval and assuming any other required approvals for beginning the research are obtained).

Approved with Conditions (Conditionally Approved)
The research is approved by the IRB with conditions if, given scope and nature of the conditions, the IRB is able to make all of the determinations required for approval (i.e., approval criteria and any applicable special determinations (e.g., waivers, alterations, vulnerable population determinations, etc.), and based on the assumption that the conditions will be satisfied. Any time the IRB cannot make one or more of the determinations required for approval, the IRB may not issue an approval with conditions for the study.

The IRB may require the following as conditions of its approval of research:

- Confirmation of specific assumptions or understanding on the part of the IRB regarding how the research will be conducted (e.g., confirmation that research excludes children);
- Submission of additional documentation (e.g., certificate of training);
- Precise language changes to the study, consent, or other study documents; or
- Substantive changes to the study, consent, or other study documents along with clearly stated parameters that the changes must satisfy.

When the IRB approves research with conditions, the conditions will be documented in the IRB meeting minutes, and the IRB will notify the Principal Investigator of its approval subject to the conditions being satisfied. The written notification will identify the specific conditions that need to be addressed. The research cannot begin until verification by the IRB that the conditions have been satisfied and IRB final approval letter is sent.

When the convened IRB approves research with conditions, the IRB may designate the IRB Chair (and/or other qualified individual(s)) to review responsive materials from the Principal Investigator and determine that the conditions have been satisfied. If the conditions have not been satisfied, or are only partially satisfied, the responsive materials must be referred to the convened IRB for review.

After verification, the following will be documented in the IRB records and written communication to the Principal Investigator:

- The date when verification was made that all IRB conditions have been satisfied (i.e., the “effective date”);
- For initial approval, the date when approval becomes effective (i.e., the date on which the Principal Investigator’s response has been accepted as satisfactory); and
- The date by which continuing review must occur.

Deferred for Substantive Issues
Substantive issues regarding the research and/or consent form must be addressed. This action is taken if substantial modification or clarification is required, or insufficient information is provided to judge the protocol application adequately (e.g., the risks and benefits cannot be assessed with the information provided). IRB approval of the proposed research will not be issued by the convened IRB until subsequent review of the requested material that is submitted by the Principal Investigator.
If the application is deferred the following will occur:

- The IRB Office informs the Principal Investigator in writing of the IRB’s decision, setting forth the IRB’s questions and concerns.
- The Principal Investigator’s response is sent to the IRB Office.
- In order to receive approval for a deferred protocol, the protocol must be submitted for Full Board IRB review at a subsequent, convened meeting of the same IRB. The IRB Office will provide to the IRB members the Principal Investigator’s response, the revised protocol and/or consent with highlighted changes, all original submission materials (inclusive of changes, if any were required), and the previous IRB written decision (relayed to the Principal Investigator by the IRB Office) signed by the Principal Investigator. The deferred protocol is then placed on the agenda for the following meeting.
- The amended protocol application is given full IRB review.
- The outcome of the IRB’s deliberations is once again communicated to the Principal Investigator in writing.
- The IRB’s determination concerning the subsequent amended submission will be documented in the minutes of that meeting.

Disapproved

Questions and issues surrounding the research are of such a magnitude that the IRB determines approval of the study is unwarranted. If the IRB disapproves a study, the Principal Investigator will be notified in writing of such decision, the reasons for the decision, and be notified of the opportunity to appeal the decision. Approval of a previously disapproved protocol requires full IRB review (see: Appeal of IRB Decisions).

Approval in Principle [45 CFR 46.118]

There are two circumstances in which the IRB may grant approval required by a sponsoring agency without having reviewed all of the study procedures and consent documents:

- If study procedures are to be developed during the course of the research, but human subjects approval is required by the sponsoring agency.
- If the involvement of human subjects depends on the outcomes of work with animal subjects.

The IRB may then grant approval without having reviewed the, as yet undeveloped, recruitment, consent, and intervention materials. If the proposal is funded, the Principal Investigator must submit such materials for approval at least sixty (60) days before recruiting human subjects into the study, or into any pilot studies or pre-tests. Approval in Principle is granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects.

Appeals

Should the IRB make a decision the Principal Investigator believes to be unduly restrictive, the investigator may appeal to the full IRB (see: Appeal of IRB Decisions).

Determination of Risk

Concurrent with the initial and continuing review process, the IRB will make a determination with respect to the risks associated with the research. Risks associated with the research will be classified as either “minimal” or “greater than minimal” based on the “absolute” interpretation of Minimal Risk. The meeting minutes will reflect the IRB’s determination regarding risk levels.

Period of Approval

Concurrent with the initial and continuing review process, the IRB will make a determination with respect to the frequency of review of the research. All protocols will be reviewed by the IRB at intervals appropriate to the IRB’s determination of the degree of risk, but no less than once per year. In certain circumstances, a shorter review interval (e.g. bi-annually, quarterly, or after accrual of a specific number of subjects) may be required. The meeting minutes will reflect the IRB’s determination regarding review
Review More Often Than Annually

Unless specifically waived by the IRB, research that meets any of the following criteria will require review more often than annually:

- Significant risk to research subjects (e.g., death, permanent or long lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the subjects;
- Involvement of especially vulnerable populations likely to be subject to coercion (e.g., institutionalized psychiatric patients, incarcerated minors); or
- A history of serious or continuing non-compliance on the part of the Principal Investigator.

The following factors will also be considered when determining which studies require review more frequently than on an annual basis:

- The probability and magnitude of anticipated risks to subjects;
- The likely medical condition of the proposed subjects;
- The overall qualifications of the Principal Investigator and other members of the research team;
- The specific experience of the Principal Investigator and other members of the research team in conducting similar research;
- The nature and frequency of Adverse Events observed in similar research at this and other institutions;
- The novelty of the research, thereby increasing the possibility of unanticipated Adverse Events; and
- Any other factors that the IRB deems relevant.

In circumstances where the IRB mandates an approval period of less than one year, the IRB may define the review period (1) with a time interval, or (2) in circumstances where a specified number of subjects were studied or enrolled in the study. If a specified number of subjects were studied or enrolled in the study, it is understood that the approval period in no case may exceed one year. Further, the number of subjects studied or enrolled in the study will determine the approval period only when the specified number of subjects were studied or enrolled in the study for less than one year.

Independent Verification Regarding Material Changes

Protecting the rights and welfare of subjects often requires the IRB to independently verify information about various aspects of the study utilizing sources other than the Principal Investigator. Independent verification includes, but is not limited to:

- Adverse Event reporting;
- information in the scientific literature;
- reports of drug toxicity;
- drug approval status; and
- confirmation that no material changes occurred during the IRB-designated approval period.

The IRB will determine the need for verification from outside sources on a case-by-case basis based upon the following criteria:

- Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.
- Protocols conducted by Principal Investigators who have previously failed to comply with federal regulations and/or the requirements or determinations of the IRB.
- Protocols randomly selected for internal audit.
- Any other instance in which the IRB deems verification from outside sources is relevant.

The following factors will also be considered when determining whether or not a study requires
independent verification:

- The probability and magnitude of anticipated risks to subjects.
- The likely medical condition of the proposed subjects.
- The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed.

In making independent verification determinations, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period, may retrospectively require such verification at the time of continuing review, review of amendments and/or Unanticipated Problems, or may require such verification at any time during the approval period in the light of new information.

If any material changes have occurred without IRB review and approval, the IRB will decide the corrective action to be taken.

**Consent Monitoring**

In reviewing the adequacy of informed consent procedures for proposed research, the IRB may on occasion determine that special monitoring of the consent process by an impartial observer (a “consent monitor”) is required in order to ensure that the approved consent process is being followed and to ensure that subjects are truly giving informed consent.

Such monitoring may be particularly warranted for:

- high risk studies;
- studies that involve particularly complicated procedures or interventions;
- studies involving highly vulnerable populations (e.g., ICU patients, children);
- studies involving study staff with minimal experience in administering consent to potential study subjects; or
- other situations when the IRB has concerns that consent process is not being conducted appropriately.

Monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular investigator or a research project.

If the IRB determines that consent monitoring is required, the IRB Chair and the IRB Director will develop a monitoring plan and submit it to the IRB for approval. The consent monitoring may be conducted by IRB Office staff, IRB members, or another party, either affiliated or unaffiliated with the institution. The Principal Investigator will be notified of the IRB’s determination and the reasons for the determination. Arrangements will be made with the Principal Investigator for the monitoring of the consent process for a specified number of subjects. When observing the consent process, the monitor will determine whether the:

- informed consent process was appropriately completed and documented;
- subject had sufficient time to consider study participation;
- consent process involved coercion or undue influence;
- information was accurate and conveyed in understandable language; and
- subjects appeared to understand the information and gave their voluntary consent.

Following the monitoring, a report of the findings will be submitted to the IRB, which will determine the appropriate action to be taken.

**Significant New Findings**

During the course of research, significant new knowledge or findings about the medication or test article and/or the condition under study may develop. The Principal Investigator must report any significant new findings to the IRB and the IRB will review them with regard to the impact on the subjects’ rights and welfare. Since the new knowledge or findings may affect the risks or benefits to subjects or subjects’ willingness to continue in the research, the IRB may require, during the ongoing review process, that the
Principal Investigator contact the currently enrolled subjects to inform them of the new information. The IRB will communicate this to the Principal Investigator. The informed consent should be updated and the IRB may require that the currently enrolled subjects be re-consented, acknowledging receipt of this new information and for affirming their continued participation.

Other Committee Approvals

The Principal Investigator is required to secure the approval of other research committees and institutional committees (if applicable) as may be required by the institution prior to initiation of research activities. For instance, research that involves recruitment of human subjects at NYU Health and Hospitals – Bellevue will require the approval of the BRCC after the study is approved by the NYU Langone Health IRB or their designated IRB of record. In addition, a billing plan approved by NYU Langone Health’s CRSU may be required. The Principal Investigator is responsible for submitting the required materials to the appropriate committees required by the institution and securing their approval.

For NYU Langone Health studies, the IRB requires documentation of approval from the following committees (as applicable) prior to issuing IRB approval: Business Conflict of Interest Committee, Institutional Biosafety Committee, ESCRO, and the Radiation Safety Committee. The IRB Director or designee may serve as a member of all of these ancillary committees to secure timely communication of any modifications resulting in a protocol’s review.

In the application for new protocol review, NYU Langone Health Principal Investigators are required to indicate institutional support required for the research, including, as applicable:

- Laboratory
- Medicine
- Pharmacy
- Radiology
- Nuclear Medicine
- Nursing
- Psychiatry
- Outpatient
- Surgery
- Other

For any that are indicated, a letter of support or collaboration must be included and the relevant Department Chair must sign the form.

Reporting IRB Actions

All IRB actions are communicated directly (electronically via IRB/Research Navigator or by electronic mail) to the Principal Investigator and designated principal contact person for the study within five to seven (5-7) working days of the IRB’s determination via a template letter prepared by the IRB Office staff and signed by the IRB Director. When approving a protocol, the IRB will forward notification of approval along with a copy of the approved consent form. The approval will contain date(s) of the study approval and the expiration date. When deferring a protocol, the IRB notification will include the modifications required for approval along with the reasoning for requiring such modifications. When disapproving, terminating or suspending a protocol, the IRB notification will include the reasoning behind such decision.

A copy of letters to Principal Investigators and other correspondence are maintained by the IRB electronically in IRB/Research Navigator’s study files.

The IRB reports its findings and actions to NYU Langone Health in the form of the IRB meeting minutes, which are distributed to the NYU Langone Health IO. Such findings are stored electronically in IRB/Research Navigator.
8.6. Continuing Review of Active Protocols

The IRB will conduct a continuing review of ongoing research at intervals that are appropriate to the level of risk for each research protocol, but not less than once per year except as described in this section below under Expedited Continuing Review, continuing review must occur as long as the research remains active for long-term follow-up of subjects, even when the research is permanently closed to the enrollment of new subjects and all subjects have completed all research-related interventions. Continuing review of research must occur, even when the remaining research activities are limited to the analysis of private identifiable information.

Approval Period

Determination of the approval period for a study is made by the IRB on a protocol-by-protocol basis. For each initial and continuing review approval, the IRB will indicate an approval period with an approval expiration date specified. IRB approval is considered to have lapsed at midnight on the expiration date of the approval. For a study approved by a convened IRB, the approval period starts on the date that the IRB conducts its final review of the study; that is, the date that the convened IRB approved the research or the date the convened IRB verified the conditions have been met if the research was approved with conditions. For a study approved under expedited review, the approval period begins on the date the IRB Chair or IRB member(s) designated by the IRB Chair gives final approval to the protocol.

The approval date(s) and approval expiration date are clearly noted on all IRB notifications sent to the Principal Investigator and must be strictly adhered to. Principal Investigators should allow sufficient time for development and review of renewal submissions.

Review of a change in a protocol ordinarily does not alter the date by which continuing review must occur. This is because continuing review is review of the full protocol, not simply a change to it.

No grace periods extending the conduct of research beyond the expiration date of IRB approval will be permitted. Therefore, continuing review and re-approval of research must occur by midnight of the date when IRB approval expires.

Routine expiration reminder notices will be sent electronically either through IRB/Research Navigator or via electronic email to the Principal Investigator and their indicated primary study contact in advance of the approval expiration date and following lapse of IRB approval of a protocol; however, it is the Principal Investigator’s responsibility to ensure that the continuing review of ongoing research is approved prior to the expiration date. By federal regulation, no extension past that date can be granted.

IRB approved studies must be conducted in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB.

Continuing Review Process

Investigators are responsible for timely submission of continuing review materials. The following must be submitted to the IRB for continuing review:

- the current consent document;
- any newly proposed consent document; and
- Disclosures of Financial Interest forms (NYU Langone Health form).

In conducting continuing review of research that is ineligible for expedited review, all IRB members are provided with and review the application and all of the above-referenced material. The primary reviewer and IRB Chair will also receive a copy of the most recent protocol version. At the convened IRB Board meeting, the primary Reviewer will lead the IRB through the completion of the regulatory criteria for approval in the Reviewer’s Checklists.

IRB Office staff will attend the convened meetings, and will retrieve any additional related materials the IRB Board members request.
In the case of research eligible for expedited review, the IRB members may request the IRB Office staff to provide them with any additional materials required for the review.

Review of currently approved or newly proposed consent documents must occur during the scheduled continuing review of research by the IRB, but informed consent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent document.

A new protocol version that has not been previously approved by the IRB will not be accepted at the time of continuing review. Any new protocol/protocol amendment must be submitted through a modification request in IRB/Research Navigator with all accompanying materials and must be approved before reviewing the continuation.

**Expedited Continuing Review**

In conducting a continuing review of research that initially qualified for expedited review, the reviewers will receive all of the above-referenced materials. The reviewer(s) will complete the “Reviewers Checklist” to determine whether the research meets the criteria allowing continuing review using the expedited procedure and, if so, whether the research continues to meet the regulatory criteria for approval.

Generally, if research did not qualify for expedited review at the time of initial review, it will not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories (8) and (9) at 63 FR 60364-60367 (see: Categories of Research Eligible for Expedited Review). It is also possible that research activities that previously qualified for expedited review in accordance with 45 CFR 46.110 changed or will change, such that expedited IRB review would no longer be permitted for continuing review.

For new studies submitted and approved by NYU Langone Health IRBs (including those duly authorized by NYU Langone Health) after January 21, 2019, the following applies:

Continuing review of research is not required under federal regulations in the following circumstances [45 CFR 46.109(f)(1):]

1. Research determined eligible for expedited review in accordance with 45 CFR 46.110;
2. Research reviewed by the IRB in accordance with the limited IRB review described in 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);
3. Research that has progressed to the point that it involves only one or both of the following, and which are part of the IRB-approved study:
   a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
   b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

This does NOT apply to research involving an FDA-regulated test article in a clinical investigation using human subjects, as defined by FDA regulations (“FDA-regulated research”). Continuing review is still required for FDA-regulated research.

An annual notice will be sent to Principal Investigators as a reminder that IRB oversight is still in place, and that modifications, reportable events, and termination/study closure reports must still be submitted to the IRB.

The NYU Langone Health IRB will, however, require continuing review for non-FDA-regulated research if the research meets at least one of the following criteria*:

- The research involves inclusion of vulnerable populations;
- The research involves deception;
- The study has multiple phases/compartments and not all are available/developed at the time of initial review of the protocol;
Interventional studies involving an FDA-approved drug or device (see Section 8.5, Expedited Research Category 1);

The research involves sensitive information that presents increased risk to employability, insurability, social stigmatization, criminal or civil liability;

The research is an interventional study deemed to fall under Expedited Research Category 9).

*Does not apply to research reviewed by the IRB in accordance with the limited IRB review process under 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(c), or d(7) or d(8) Continuing review will not be required for those studies.

**Lapse in IRB Approval**

The IRB and Principal Investigators must plan ahead in order to meet required continuing review dates. If the IRB has not reviewed and approved a research study by the end of the approval period specified by the IRB, all research activities must cease, including recruitment and enrollment of subjects, consent, interventions, interactions, and data collection, unless the IRB concludes that it is in the best interests of individual subjects to continue participation in the research interventions or interactions. This will occur even if the Principal Investigator has provided the continuing review information before the expiration date.

Therefore, Principal Investigators must allow sufficient time for IRB review before the expiration date.

An expiration letter (or electronic mail) will be sent to Principal Investigators by the last date of the approval period.

Failure to submit continuing review information on time is considered non-compliance and will be handled according to the non-compliance policy (see: Non-Compliance).

- If the study is FDA-regulated, the IRB Director and IRB Chair must follow FDA requirements set forth in 21 CFR 56.108(b)(3) in reaching their decision.

- The sponsoring agency, private sponsor, or other federal agencies must be informed of any lapse of IRB Approval of research via the appropriate institutional business unit (for NYU Langone Health, through the Office of Sponsored Programs Administration).

Once suspended, IRB review and re-approval must occur prior to re-initiation of the research.

The continuation of research after expiration of IRB approval is a violation of the federal regulations. If the IRB has not reviewed and approved a research study by the study’s current expiration date, i.e., IRB approval has expired, research activities must cease. No new subjects may be enrolled in the study.

However, the IRB may find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions.

**Procedure for Obtaining Approval to Continue Subject Participation After Lapse in IRB Approval**

Once IRB approval lapses for a study, all research activity must cease. However, the Principal Investigator may submit in writing requests to the IRB to approve individual subjects in a study to continue participating in research interventions or interactions if stopping their participation would cause harm. The procedure for obtaining approval to continue subject participation after expiration of IRB approval is as follows:

- The Principal Investigator will submit to the IRB Chair a written list of research subjects for whom stopping of the research would cause harm.
- The IRB Chair will review written requests from investigators who wish to continue research with existing subjects in research procedures.
- The IRB Chair will determine which subjects, if any, may continue with the study. The IRB Chair will further determine the specific procedures that may continue to be performed when ceasing such procedures will harm the subject.
8.7. Modification of an Approved Protocol

Principal Investigators may wish to modify or amend their approved applications. Principal Investigators must seek IRB approval before making any changes in approved research—even though the changes are planned for the period for which IRB approval has already been given. A change may be implemented without IRB approval only when the change is necessary to eliminate an immediate hazard to the subject (in which case the IRB must then be notified at once).

Modifications may be approved if they are within the scope of what the IRB originally authorized. For example, if a researcher wishes to add a population to an existing study, but not alter the study procedures or purpose, a modification request is usually appropriate. Likewise, modifying a procedure without changing the study’s purpose or study population may also be appropriate.

Principal Investigators must electronically submit via IRB/Research Navigator all necessary materials necessary to inform the IRB about the changes in the status of their study, including:

- revised protocol application or sponsor’s protocol (if applicable);
- revised approved consent/parental permission/assent documents (if applicable) or other documentation that would be provided to subjects when such information might relate to their willingness to continue to participate in the study;
- revised or additional recruitment materials;
- any other relevant documents provided by the Principal Investigator; and
- an investigator’s current curriculum vitae or other documentation evidencing qualifications (if applicable).

The Principal Investigator must electronically submit all revised materials in Microsoft Word format, noting changes via highlight or “Track Changes”.

All changes must be accompanied by a detailed summary of the changes and a rationale (as applicable).

IRB Office staff will determine whether the proposed changes may be approved through an expedited review process, if the changes are minor, or whether the modification warrants Full Board review. The reviewer(s) using the expedited procedure has the ultimate responsibility to determine that the proposed changes may be approved through the expedited review procedure and, if not, must refer the protocol for Full Board review.

**Expedited Review of Protocol Modifications**

The IRB may use expedited review procedures to review minor changes in ongoing previously-approved research during the period for which approval is authorized. An expedited review may be carried out by the IRB Chair and/or designee(s) among the IRB. Minor changes/modifications would not include the addition of procedures involving more than Minimal Risk to subjects or changes that do not fall in categories (1)-(7) of research that could be reviewed using the expedited procedure. (See: [Categories of Research Eligible for Expedited Review](#))

The reviewer(s) complete the **Checklist for Amendment Review Determination** to determine whether the modifications meet the criteria allowing review using the expedited procedure, and if so, whether the research with the proposed modifications meets the regulatory criteria for approval.

**Full Board Review of Protocol Modifications**

When a proposed change in a research study is not minor (e.g., procedures involving increased risk or discomfort are to be added), then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects. In such a case, the IRB should be promptly informed of the change following its implementation and should review the change to
determine that it is consistent with ensuring the subjects' continued welfare.

Major changes/modifications would include the addition of procedures involving more than Minimal Risk to subjects or changes that do not fall in categories (1)-(7) of research that could be reviewed using the expedited procedure (see: Categories of Research Eligible for Expedited Review).

All IRB members review all documents provided electronically by the Principal Investigator.

At the convened meeting, the primary reviewer presents an overview of the modifications and leads the IRB through the completion of the regulatory criteria for approval.

When the IRB reviews modifications to previously approved research, the IRB will consider whether information about those modifications might relate to subjects’ willingness to continue to take part in the research and if so, whether to provide that information to subjects.

**Closure of Studies**

The completion or termination of the study is a change in activity and must be reported to the IRB. Although subjects will no longer be "at risk" under the study, a final report to the IRB allows it to close its files as well as providing information that may be used by the IRB in the evaluation and approval of related studies.

Applications for study closures must be submitted to the IRB electronically via IRB/Research Navigator. The Principal Investigator must submit a final report with the closure application. IRB Office staff will review the closure application for completeness and will determine how to notify the IRB. Closure applications will be reviewed, noted, and the final report will be included on the next IRB meeting agenda.

**8.8. Unanticipated Problems**

Federal regulations require organizations to have written policies and procedures to ensure the prompt reporting of Unanticipated Problems involving risks to subjects or others to the IRB, appropriate institutional officials, and regulatory agencies and departments.

*NOTE: For simplicity, Unanticipated Problems involving risks to subjects or others will be referred to as “Unanticipated Problems” in this Policy.*

This Policy requires that all Unanticipated Problems (as defined below) be reported to the NYU Langone Health IRB. Requirements to report Unanticipated Problems to regulatory agencies and institutional officials are covered in Section 13.0 (Reporting to Regulatory Agencies and Institutional Officials). Principal Investigator Holds are typically not considered an Unanticipated Problem but must be reported to the assigned IRB as referenced under Section 12.3. A Hold is not considered to be a reportable event under this Policy and thus should not be handled under this Section.

Events which direct harm to subjects are referred to as “Adverse Events”. Although Adverse Events occur most commonly in the context of biomedical research, Adverse Events can occur in the context of social and behavioral research. Only unanticipated Adverse Events that are related to the research need to be reported. If a research subject dies while participating in a study, the death does not have to be reported if the investigator is positive it was not study-related.

**Definitions**

Unanticipated Problem Involving Risks to Subjects or Others

(Original Problem)

Any event, incident, experience, outcome, or new information that (1) was unforeseen and (2) indicates that the research procedures caused harm to subjects or others or indicates that subjects or others are at increased risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
Adverse Event
Any physical, psychological or social harm occurring to subjects during the course of participating in research, whether or not it is related to participation in the research. An Adverse Event can be any unfavorable or unintended event that is temporally related to the research. Examples of Adverse Events include: abnormal laboratory findings, nightmares, broken wrist, upper respiratory tract infection, nausea and vomiting, and other symptoms or diseases. Although Adverse Events occur most commonly in the context of biomedical research, Adverse Events can occur in the context of social and behavioral research.

Unanticipated
An event is “Unanticipated” when its nature, frequency, specificity and severity are not expected, given the research procedures described in the protocol-related documents and characteristics of the subject population being studied, and are not accurately reflected in the informed consent document, protocol and/or investigator’s brochure.

Related to the Research
An event is “Related to the research procedures” if in the opinion of the Principal Investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current subjects.

Reporting Requirements
All Unanticipated Problems, meaning those that are serious, unexpected, and related to the research activity, must be reported to the NYU Langone Health IRB. Not all Unanticipated Problems involve direct harm to subjects. Events can occur which are unexpected and result in new circumstances that increased the risk of harm to subjects without directly harming them. In addition, the event may have presented unanticipated risks to others (e.g., the sexual partners of the subjects, individuals the subject may come in contact with, family members, research personnel, etc.) in addition to the subjects. In each case, even if the event did not cause any detectable harm or adverse effect to subjects or others, they nevertheless represent Unanticipated Problems and should be promptly reported under this Policy.

Principal Investigators must report to the IRB as soon as possible, but in all cases within ten (10) working days of becoming aware of and/or receipt of information about any of the following:

- Adverse Events which, in the opinion of the Principal Investigator, are both unexpected and Related to the research. The IRB only requires Unanticipated Adverse Events and Serious Adverse Events that are Related to the research to be reported to the IRB.

- Unanticipated Problem Related to the research that exposes individuals other than the research subjects (e.g., investigators, research assistants, students, the public, etc.) to potential risk.

- Information that indicates a change to the risks or potential benefits of the research. For example:
  - an interim analysis or safety monitoring report indicates that frequency or magnitude of harms or benefits may be different than those initially presented to the IRB, or
  - a paper is published from another study that shows that the risks or potential benefits of the Principal Investigator’s research may be different than initially presented to the IRB.

- A breach of confidentiality, including the loss of digital storage devices that contained research data.

- Change in subject’s status during the course of their participation in a study that might affect their eligibility to remain in the study. Examples: Incarceration of a subject in a protocol not approved to enroll prisoners; pregnancy during research participation; children who reach the age of majority (in New York State, age 18) during study participation.
• Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research subject. For clarity, the NYU Langone Health IRBs do not require reporting of unintentional or intentional changes to the IRB-approved protocol (protocol deviations) unless the deviation was made due to concerns of subject safety or rises to the level of a protocol deviation.

• Complaint of a subject or subject's family member when the complaint indicates unexpected risks or the complaint cannot be resolved by the research team.

• Protocol violation. A protocol violation refers to an accidental or unintentional change to the IRB-approved protocol that harmed subjects or others or that indicates subjects or others may be at increased risk of harm. Examples: receipt of wrong dose of study medication.

• Event that requires prompt reporting to the study sponsor.

• Sponsor-imposed suspension of the research based on risk.

If the Unanticipated Problem is a subject's death, the Principal Investigator should report such event to the IRB no later than five (5) calendar days of becoming aware, whether or not causality (relatedness to the research) has been determined.

The IRB will accept other reports when the Principal Investigator is unsure whether the event should be reported. The Principal Investigator should first contact the IRB Office by email or telephone to determine if the reporting is necessary under this Policy.

Study staff should report the above events electronically using IRB/Research Navigator. The IRB/Research Navigator submission is titled Reportable New Information.

If the event requires immediate intervention to prevent serious harm to subjects or others, the investigator may act accordingly to prevent harm and then must report the event within five (5) days.

Investigators must report all other possible Unanticipated Problems occurring at the local research site and non-local research sites to the IRB as soon as possible but no later than ten (10) business days from the date of the event or from the date the investigator is notified of the event.

Problems occurring within thirty (30) days after subjects' active participation or treatment must be reported according to the above schedule.

Investigators or the study team must report possible Unanticipated Problems to the IRB Office in writing using the Unanticipated Problem Reporting Form. The written report should contain the following:

• detailed information about the possible Unanticipated Problems, including relevant dates
• any corrective action, planned or already taken, to ensure that the possible Unanticipated Problems is corrected and will not occur again
• an assessment of whether any subjects or others were placed at risk as a result of the event or suffered any physical, social, or psychological harm and any plan to address these consequences
• any other relevant information
• any other information requested by the IRB Office

A report of a possible Unanticipated Problem involving risks to subjects or others will be immediately forwarded by IRB Office staff to the IRB Chair if the IRB Office staff believes that immediate intervention may be required to protect subjects or others from serious harm.

Upon receipt of a report of a possible Unanticipated Problem from someone other than the investigator or study staff, the IRB director will notify the Principal Investigator on the study when appropriate.
RNI Pre-Review

- When a Reportable New Information (RNI) submission is made in IRB/Research Navigator, the IRB Office staff checks the submission for completeness and requests additional information from the Principal Investigator or designated primary study contact person as needed. Any corrections and requests for information are made through IRB/Research Navigator, which will indicate the date, and documented.

- An IRB Manager (or in the case of NYU Winthrop, the IRB Chair, Vice-Chair, or designated IRB member) reviews the RNI submission and all supporting documents provided by the Principal Investigator and determines how to proceed. Reviewed documents will include:
  1. the currently approved protocol;
  2. the currently approved consent document;
  3. previous reports of Unanticipated Problems involving risks to subjects or others; and
  4. investigator’s brochure, if one exists.

- The IRB Manager, IRB Chair, Vice-Chair or designated IRB member (as applicable) may determine that (1) the reported event is not an Unanticipated Problem and that no further action is needed; (2) the event is an Unanticipated Problem but with no more than minimal risk; (3) the event is an Unanticipated Problem which should be referred to the IRB Chair or IRB Director or designated reviewer; or (4) the event is an Unanticipated Problem that should be referred to a convened IRB.

- If the IRB Manager, IRB Chair, Vice-Chair or designated IRB member (as applicable) determines that either (1) the reported information was foreseen/expected and (2) no subjects or others were harmed AND subjects or others are not at increased risk of harm, they will indicate in the RNI record that the problem is not an Unanticipated Problem. The determination is communicated to the Principal Investigator and no further action is taken.

- If the IRB Manager, IRB Chair, Vice-Chair or designated IRB member (as applicable) considers that the problem is an Unanticipated Problem, but that the risk is no more than minimal (e.g., using an outdated consent form to consent subject but with no difference other than IRB approval date), they may direct further action which will be documented and communicated to the Principal Investigator.

- The IRB Manager, IRB Chair, Vice-Chair or designated IRB member (as applicable) may determine that the event is an Unanticipated Problem that is greater than minimal risk and may affect the safety of subjects. If the IRB Manager, IRB Chair, Vice-Chair, or designated IRB member believes that additional review is necessary, he/she may forward the RNI and all supporting documentation to the IRB Chair or designee (such as an IRB member who has appropriate expertise to review the event) and IRB Director, or refer the RNI to a convened IRB meeting.

  The IRB Chair (or designee) and IRB Director may direct suspension of the research to ensure protection of the rights and welfare of subjects pending completion of review. Suspension directives made by the IRB Chair or IRB Director must be reported to a meeting of the convened IRB.

RNI Review by IRB Chair or Designee and IRB Director

If an RNI is referred to the IRB Chair or designee and IRB Director, they will be provided with a copy of the RNI and supporting documents, including the currently approved protocol, and consent form. The IRB Chair (or designee) has authority to require submission of more detailed contextual information by the Principal Investigator, the study sponsor, the study coordinating center, or Data
Safety Monitoring Board/Data Monitoring Committee (DSMB/DMC) about any Adverse Event occurring in a research protocol as a condition of the continuation of the IRB’s approval of the research.

After reviewing all of the materials, the IRB Chair or designee in consultation with the IRB Director may then take appropriate action depending on the nature of the risk involved, including requesting that the protocol or the consent form be modified, if applicable. The results of this review will be documented in the protocol record, communicated to the Principal Investigator, reported to the convened IRB, and referred to the IRB Office to be handled according the reporting procedures as may be appropriate (see: Reporting to Regulatory Agencies and Institutional Officials). The IRB Chair and IRB Director may also determine the RNI should be reviewed by a convened IRB.

**RNI Review by Convened IRB**

- If the RNI is referred to a convened IRB, all IRB members are provided for review prior to the meeting a copy of the RNI and supporting documents, such as the currently approved protocol, consent form, and RNI report. The convened IRB may require the Principal Investigator to provide more detailed information, or require the study sponsor, coordinating center, or DSMB/DMC to do so.

- The convened IRB will make findings and recommendations based on the following considerations:

  1. Whether the reported event is an Unanticipated Problem involving risks to subjects or others according to the definition in this Policy;
  2. What action in response to the report is appropriate;
  3. Whether suspension or termination of approval is warranted; and
  4. Whether further reporting of the Unanticipated Problem to institutional and/or federal officials is required. If the convened IRB finds that further reporting is necessary, the procedures in Section 13.0 will be followed.

- If the convened IRB determines that the event is not an Unanticipated Problem, the results of the review are recorded in the protocol record and the IRB meeting minutes, and communicated to the Principal Investigator. The IRB may recommend any of the following actions:

  1. No further action;
  2. Requiring modifications to the protocol;
  3. Revising the continuing review timetable;
  4. Modifying the consent process;
  5. Modifying the consent document;
  6. Providing additional information to current subjects (e.g. whenever the information may relate to the subject’s willingness to continue participation);
  7. Providing additional information to past subjects;
  8. Requiring additional training of the Principal Investigator and/or study staff; and/or
  9. Other actions appropriate for the local context.

- If the convened IRB considers the event to represent an Unanticipated Problem, the IRB may recommend the following actions:

  1. Requesting modification of the protocol;
  2. Requesting modification of the information disclosed during the consent process;
  3. Providing additional information to current subjects (This must be done whenever the information may relate to the subject’s willingness to continue participation);
  4. Providing additional information to past subjects;
  5. Requiring current subjects to re-consent to participation;
  6. Alteration of the frequency of continuing review;
  7. Observation of the research or the consent process;
  8. Requiring additional training of the Principal Investigator and/or study staff;
9. Notification of investigators at other sites;
10. Termination or suspension of the research according to Complaints, Non-Compliance, and Suspension or Termination of IRB Approval of Research;
11. Obtaining additional information;
12. Referral to other organizational entities (e.g., legal counsel, risk management, institutional official); and/or
13. Other actions appropriate for the local context.

The results of the convened IRB review are recorded in the IRB meeting minutes, protocol record, communicated to the Principal Investigator and referred to the IRB Office to be handled according the reporting procedures (see: Reporting to Regulatory Agencies and Institutional Officials).

8.9. Further Review/Approval of IRB Actions by Others within the Institution

Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution; however, those officials may not authorize research if it has been not been approved by the IRB [45 CFR 46.112]. There are no required institutional reviews after the IRB grants its approval, but the institution reserves the right to subject research reviewed by the IRB to further review.

8.10. Appeal of IRB Decisions

The Principal Investigator may appeal an IRB decision in writing. The NYU Langone Health IRBs will reconsider appeal(s) of a disapproved new protocol submission. All appeals of the disapproval must be addressed to the IRB Chairperson and should be accompanied by a letter from the Principal Investigator detailing the reason for the appeal. The Principal Investigator should be prepared to attend the meeting of the appropriate convened IRB to address issues raised by the Board.

If the IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator may appeal, in writing, for review by the convened IRB. The Principal Investigator may first discuss the matter with the IRB Chair or the IRB Director, taking care to explain the reasons for believing that the proposed procedures are in compliance with NYU Langone Health IRB policy and with federal regulations. If the issue cannot first be resolved satisfactorily by negotiation, the Principal Investigator may submit a written appeal the decision of the IRB. In either case, after one appeal, the IRB will consider additional appeals made by the Principal Investigator and re-reviews only if based upon new information; that is, if there is any new substantive information that would affect the IRB’s decision and that has not been previously presented. Appeals must be in writing and addressed to the IRB Director, who will discuss with the IRB Chair whether the appeal warrants review by a convened Board. The IRB will notify the Principal Investigator of the determination.

8.11. Sponsored Research Contracts

NYU Langone Health requires that all of its funded human subjects research must be reviewed and approved by the NYU Langone Health IRB, or another duly authorized IRB. Proposals to be submitted for external funding by a non-industry funding source are sent to the NYU Langone Health Office of Sponsored Programs (SPA) along with the Proposal Transmittal Form. SPA office staff review the submission form to determine if the “human subjects” box is checked. If it is checked for “human subjects”, a date for approval must also be provided and is noted in the SPA system. If the human subjects box is not checked the SPA staff review the abstract or the statement of work to determine if the project involves human subjects and the box was not checked. On occasion, SPA office staff will contact the IRB (or other affected compliance offices) to determine appropriate follow up action. If it is determined that the proposed research involves human subjects the Principal Investigator is advised to submit the proposal to the IRB Office.
Contracts associated with human subjects research will be reviewed for the following by both the SPA contracts unit and the NYU Langone Health IRB:

- consistency between the contract(s) and the informed consent form approved by the IRB;
- that the contract indicates that the NYU Langone Health Principal Investigator will follow the protocol, applicable regulations and its ethical standards;
- that the contract defines who will be responsible for research related injuries;
- if the sponsor will monitor the conduct of the research, the contract states that if the study monitor uncovers information that could affect the safety of subjects or their willingness to continue participation, influence the conduct of the study, or alter the IRB’s approval to continue the study, the sponsor will make sure that the information is communicated to the Principal Investigator and IRB;
- that the contract indicates that, if the sponsor discovers results that could affect the safety or medical care of study subjects, the sponsor will make sure the Principal Investigator and IRB are notified.

8.12. IRB Fee Policy and Schedule
A fee will be required for all new, continuing review, and protocol amendment reviews of industry sponsored studies reviewed by the NYU Langone Health IRB.

IRB fees are applied even if subjects are never enrolled, the study terminates before milestones are met, expenditures exceed revenue, or a contract is never finalized.

These fees should be included as a line item in the budget of the formal contract as an upfront and non-refundable item negotiated through the responsible department of the institution (in the case of NYU Langone Health industry-funded clinical research, the Clinical Research Support Unit).

8.13. The Rights of Research Subjects

IRB Policy
It is the policy of the NYU Langone Health IRBs to provide information to the community regarding the rights of research volunteers who participate in NYU Langone Health research.

- The IRB will require that a telephone contact number be provided to each subject consented to participate in research. The contact number should appear on every informed consent document along with a statement about whom the subject may contact regarding questions (i.e., if the subject needs additional information), concerns, or complaints regarding his/her rights as a research subject. This information is included in the NYU Langone Health IRB Informed Consent template in the section entitled Contact Person(s).

- The NYUGSOM IRB has provided the community with a section on the NYUGSOM IRB website that provides potential and current research subjects additional information regarding participation in a research study. The website is located at https://med.nyu.edu/research/office-science-research/clinical-research/prospective-current-study-participants

- The IRB maintains a mechanism to receive complaints from subjects or others in a confidential manner.

- A brochure for research volunteers is available entitled, “Thinking About Enrolling in a Clinical Trial?” found in Resources for Prospective and Current Study Participants and includes the following:
  - a lay definition of research and research personnel
  - a discussion of potential risks and benefits of research
  - what information should be made available in an informed consent
Repsentatives from the NYUGSoM IRB participate in community outreach activities such as speaking engagements to patient support groups.

The NYUGSoM IRB actively recruits community members for service on the panels through community outreach programs and organizations.

The NYUGSoM IRB and Clinical and Translational Science Institute (CTSI) Research Participant Advocates respond to inquiries, complaints, and requests for information from patients, research subjects, and community members.

The Patient Advisory Council for Research (PACR), which consists of patients from NYU Langone Health, provides regular feedback on the following: (1) ways to make research projects more patient-friendly, (2) how best to engage patients in clinical trials and health research, (3) how best to advertise studies, and (4) concerns and potential challenges around study recruitment and retention.

The applicable IRB Director and IO will evaluate the effectiveness and impact of the NYU Langone Health IRBs’ outreach activities on an annual basis or more often. The evaluation will entail both auditing of the informed consent process, interviewing and surveying research subjects that have been enrolled in research studies.

The oversight function of the outreach program will become part of a continuous Quality Improvement program that will support the maintenance of higher standards of human subjects protections. In order to formally evaluate its outreach activities, the IRB Associate Director will determine:

- the specific community outreach activities being used
- whether or not these community outreach activities have an evaluative component, and if so what, if any, changes in the outreach activities have resulted from these evaluations

The NYUGSoM IRB Associate Director in collaboration with the CTSI’s Community Engagement and Population Health Research program (CEPHR) will administer surveys annually to determine the adequacy of outreach activities. The survey will assess:

- the scope, the content and the adequacy of outreach activities and resources
- whether the research community is using the NYUGSoM and NYU Winthrop IRB website resource for prospective and current research subjects
- whether the NYU Langone Health research community is using other educational materials to inform prospective subjects about their rights and welfare as research subjects
- whether additional resources are needed to improve subject outreach activities

The results of the survey will be used to establish both the adequacy of current outreach activities and any additional resources that may be needed to meet the needs of the NYU Langone Health research community regarding subject outreach.

**Review Process**

**Principal Investigator Responsibilities**

The Principal Investigator is responsible for assuring the informed consent document contains the IRB phone number for subjects to call if they have questions regarding their rights as a volunteer for research. If the IRB has waived the documentation of informed consent, it is the Principal Investigator’s responsibility to provide the IRB phone number to the subject by other means.

The Principal Investigator may request copies of the community outreach brochures for distribution to subjects.

**IRB Committee Responsibilities**
The IRB Committee, Chair, or Executive Committee Member will review each informed consent document to assure that the IRB phone number is included with a statement that the subject may call if they have any questions regarding their rights as a volunteer for research.

**IRB Office Responsibilities**

The IRB Office staff will assure during the administrative review of proposed NYU Langone Health research that each informed consent document contains the IRB phone number for subjects to call if they have questions regarding their rights as a research volunteer. If the Principal Investigator is requesting a waiver of documentation of informed consent, the IRB Office staff will request information from the Principal Investigator regarding the method of informing the subjects of the IRB phone number for questions.

**Administrative Responsibilities**

The IRB Director will evaluate the outreach activities on an annual basis and make adjustments to the program as appropriate.

### 9. Criteria for IRB Approval of Research

In order for the IRB to approve human subjects research it must determine that the following requirements are satisfied:

- **Risks to subjects are minimized:** (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- **Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.** In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- **Selection of subjects is equitable.** In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- **Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [45 CFR §46.116].**
- **Informed consent will be appropriately documented, in accordance with, and to the extent required by [45 CFR §46.117].**
- **When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.**
- **When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**
- **When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.**

For purposes of conducting the limited IRB review, the IRB need not make the determinations bulleted above, and shall make the following determinations:

- If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
9.1. **Risk/Benefit Assessment**

One of the major responsibilities of the IRB is to conduct a risk/benefit assessment of the proposed human subjects research. The goal of the assessment is to ensure that the risks to research subjects posed by participation in the research are justified by the anticipated benefits to the subjects or society. Toward that end, the IRB must:

- judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies asking any person to undertake the risks; and
- disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

The assessment of the risks and benefits of proposed research involves a series of steps:

- Identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research.
- Determine whether the risks will be minimized to the extent possible.
- Identify the probable benefits to be derived from the research.
- Determine whether the risks are reasonable in relation to the benefits to subjects, if any, and assess the importance of the knowledge to be gained.
- Ensure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits.

Risks to subjects are minimized:

- by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and
- whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Risks to subjects must be reasonable in relation to anticipated benefits, if any, and to the importance of the knowledge that may reasonably be expected to result.

- In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research—as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research.
- The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

**Scientific Merit**

In order to assess the risks and benefits of the proposed research, the IRB must determine that the science is adequate to provide sufficient benefit to justify the risks, including:

- the research uses procedures consistent with sound research design;
- the research design is sound enough to reasonably expect the research to answer its proposed question; and
- the knowledge expected to result from this research is sufficiently important to justify the risk.

For research that is funded externally or is internally funded (such as through local research award programs) the IRB may take into account that the research will be going through a peer review process. For departments that conduct scientific merit review, departmental scientific review is documented by the signature of the administrative official responsible for the Principal Investigator’s research unit on new protocol applications. In cases where the proposed research is not funded and there is no departmental scientific review, the IRB relies on the knowledge and disciplinary expertise of its members and alternates or consults with other researchers on or off campus for scientific merit review.

The IRB will require documentation demonstrating that the following questions were considered during the scientific review:
Does the research use procedures consistent with sound research design?

Is the research design sound enough to reasonably expect the research to answer its proposed question?

For research that is subject to ICH-GCP guideline (E6):

- Policies and procedures include the evaluation of the available nonclinical and clinical information on an investigational product is adequate to support the proposed clinical trial.
- Clinical trials must be scientifically sound and described in a clear, detailed protocol.

**Other Considerations**

In assessing the benefits of the research, the IRB must also review:

- the qualifications of the research team, including their technical and scientific expertise, as well as their knowledge and understanding of their obligation to protect the rights and welfare of research subjects; and
- the adequacy of the resources necessary for human research protection, care of research subjects, and safety during the conduct of the research.

### 9.2. Selection of Subjects is Equitable

The IRB will review the inclusion/exclusion criteria for the research to ensure equitable selection of subjects. In making this assessment the IRB takes into account the purposes of the research and the setting in which the research will be conducted, and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, fetuses, pregnant women, human in vitro fertilization, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged (see: Vulnerable Populations).

**Recruitment of Subjects**

The Principal Investigator will provide the IRB with all recruiting materials to be used in identifying subjects for the IRB’s review, including:

- the information contained in the advertisement (including web-based sites)
- the mode of its communication
- the final copy of printed advertisements
- the final audio/video taped advertisements

The IRB must approve any and all advertisements prior to posting and/or distribution. The advertising material must be accurate, should not be coercive or unduly optimistic, or create undue influence to the subject to participate. The content of the advertisement should be limited to the information the prospective subjects need to determine their eligibility and interest in participation.

The IRB will review:

- the information contained in the advertisement
- the mode of its communication
- the final copy of printed advertisements
- the final audio/video taped advertisements

The IRB reviews advertising to ensure that advertisements do not:

- make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation;
- state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol;
- make claims, either explicitly or implicitly, that the test article is known to be equivalent or
superior to any other drug, biologic or device;
- use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational;
- promise “free medical treatment,” when the intent is only to say subjects would not be charged for taking part in the investigation;
- include exculpatory language; and
- emphasize the payment or the amount to be paid, by such means as larger or bold type.

The IRB determines that advertisements are limited to the information prospective subjects need to determine their eligibility and interest, such as:

- the name and address of the clinical investigator or research facility;
- the condition under study or the purpose of the research;
- in summary form, the criteria that would be used to determine eligibility for the study;
- a brief list of participation benefits (if any);
- the time or other commitment required of the subjects;
- the location of the research and the person or office to contact for further information;
- a clear statement that this is research and not treatment;
- a brief list of potential benefits (e.g. no cost of health exam); and
- advertisements will not include reimbursement/compensation for participation in a trial offered by a sponsor to involve a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

This information should be submitted to the IRB with the initial application or as an addendum to the protocol.

Once approved by the IRB, an advertisement cannot be altered or manipulated in any way without prior IRB approval.

9.3. Informed Consent

The IRB will ensure that informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 and 21 CFR 50.20. In addition, the IRB will ensure that informed consent will be appropriately documented in accordance with, and to the extent required by [45 CFR 46.117] and [21 CFR 50.27].

For detailed IRB policies on informed consent (see: Informed Consent).

9.4. Data Safety Monitoring

The IRB will review the data safety monitoring plan for protocols involving more than minimal risk during initial review and at the time of continuing review. The initial plan submitted to the IRB should describe the procedures for safety monitoring, reporting of Unanticipated Problems involving risks to subjects or others, descriptions of interim safety reviews and the procedures planned for transmitting the results to the IRB. This description should include information regarding an independent Data and Safety Monitoring Board (DSMB), if one exists, or an explanation why an independent data safety monitor is not necessary.

The IRB determines that the safety monitoring plan makes adequate provision for monitoring the reactions of subjects and the collection of data to ensure the safety of subjects. The overall elements of the monitoring plan may vary depending on the potential risks, complexity, and nature of the research study. The method and degree of monitoring needed is related to the degree of risk involved. Monitoring may be conducted in various ways or by various individuals or groups, depending on the size and scope of the research effort. These exist on a continuum from monitoring by the Principal Investigator in a small, low risk study to the establishment of an independent DSMB for a large phase III clinical trial.

The factors the IRB will consider in determining whether the safety monitoring plan is adequate for the
research are as follows:

- Monitoring is commensurate with the nature, complexity, size and risk involved.
- Monitoring is timely. Frequency should commensurate with risk. Conclusions are reported to the IRB.
- For low risk studies, continuous, close monitoring by the study Principal Investigator or an independent individual may be an adequate and appropriate format for monitoring, with prompt reporting of problems to the IRB, study sponsor and regulatory bodies as appropriate.
- For studies using only an individual safety monitor, the plan must include:
  - parameters to be assessed;
  - mechanism to assess the critical efficacy endpoints at intervals in order to determine when to continue, modify, or stop a study;
  - frequency of monitoring; and
  - procedures for reporting to the IRB.
- For studies using a DSMB, the plan must include:
  - the name of the DSMB;
  - where appropriate, is independent from the study sponsor;
  - availability of written reports;
  - composition of the monitoring group (if a group is to be used): the DSMB should include experts in all scientific disciplines needed to interpret the data and ensure patient safety. Clinical trial experts, biostatisticians, bioethicists, and clinicians knowledgeable about the disease and treatment under study should be part of the monitoring group or be available if warranted;
  - frequency and content of meeting reports; and
  - the frequency and character of monitoring meetings (e.g., open or closed, public or private).

In general, it is desirable for a DSMB to be established by the study regulatory sponsor for research that is blinded, involves multiple sites, involves vulnerable subjects, or employs high-risk interventions. For some studies, the National Institutes of Health (NIH) require a DSMB. The IRB has the authority to require a DSMB as a condition for approval of research where it determines that such monitoring is needed. When DSMBs are utilized, IRBs conducting continuing review of research may rely on a current statement from the DSMB indicating that it has and will continue to review study-wide Adverse Events, interim findings, and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB.

9.5. Privacy and Confidentiality

The IRB will determine whether adequate procedures are in place to protect the privacy of subjects and to maintain the confidentiality of the research data.

Definitions

Privacy means having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Confidentiality means the methods used to ensure that information obtained by researchers about their subjects is not improperly divulged.

Private Information refers to information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Identifiable Information means information where the identity of the subject is or may readily be ascertained by the
Privacy
The IRB must determine whether the activities in the research constitute a violation of privacy. In order to make that determination, the IRB must obtain information regarding how the investigators obtain access to subjects or subjects’ information and the subjects expectations of privacy in the situation. The Principal Investigator must have appropriate authorization to access the subjects or the subjects’ information. In developing strategies for the protection of subjects’ privacy, consideration should be given to:

- methods used to identify and contact potential subjects;
- settings in which an individual will be interacting with an investigator;
- appropriateness of all personnel present for research activities;
- methods used to obtain information about subjects and the nature of the requested information;
- information that is obtained about individuals other than the “target subjects,” and whether such individuals meet the regulatory definition of “human participant” (e.g., a subject provides information about a family member for a survey); and
- how to access the minimum amount of information necessary to complete the study.

Confidentiality
Confidentiality and anonymity are not the same. If anyone, including the investigator, can readily ascertain the identity of the subjects from the data, then the research is not anonymous and the IRB must determine if appropriate protections are in place to minimize the likelihood that the information will be inappropriately divulged. The level of confidentiality protections should be commensurate with the potential of harm from inappropriate disclosure.

At the time of initial review, the IRB ensures that the privacy and confidentiality of research subjects is protected. The IRB assesses whether there are adequate provisions to protect subject privacy and maintain confidentiality. The IRB does this through the evaluation of the methods used to obtain information:

- about subjects;
- about individuals who may be recruited to participate in studies;
- the use of personally identifiable records; and
- the methods to protect the confidentiality of research data.

The Principal Investigator should provide the information regarding the privacy and confidentiality of research subjects at the time of initial review through the completion of the protocol application, any necessary Health Insurance Portability and Accountability Act (HIPAA) authorization forms, research protocol, and/or other submitted, applicable materials. The IRB will review all information received from the Principal Investigator and determine whether or not the privacy and confidentiality of research subjects is sufficiently protected. In some cases, the IRB may also require that a Certificate of Confidentiality be obtained to additionally protect research data (see: Certificate of Confidentiality).

In reviewing confidentiality protections, the IRB shall consider the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research. It shall evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections.

9.6. Vulnerable Populations
If vulnerable populations are likely to be involved in the research, at the time of initial review, the IRB will consider the scientific and ethical reasons for including vulnerable subjects in the research and will determine if appropriate additional safeguards are in place to protect the rights and welfare of such
9.7. Special Requirements for Research Funded by the Department of Defense

If the research is supported by the United States Department of Defense (DoD), (1) it must be reviewed and conducted in compliance with the Common Rule, adopted at part 219 of title 32 CFR, and FDA regulations on human subjects research, and (2) also must comport with DoD Instruction (DoDI) 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,” including all references included therein. These additional requirements apply to any human subjects research that is conducted, reviewed, approved, overseen, supported, managed or otherwise contractually subject to applicable regulations by DoD, or that uses DoD property, facility or assets (“DoD-Supported Research”).

Excerpts and summaries of DoDI 3216.02 requirements are included below for ease of reference, but in the event of any conflict between provisions of this policy and any regulations or guidance provided by the DoD or its components, such regulations or guidance shall control. The complete DoDI 3216.02 is available at [www.dtic.mil/whs/directives/corres/pdf/321602p.pdf] and is incorporated by reference in full into this Policy.

Following IRB review, non-Exempt research protocols covered by these requirements must also be reviewed administratively by the DoD Human Research Protections Office (HRPO) before the activities that involve human subjects can begin (e.g., human subject recruitment and data collection) [DoDI 3216.02, enclosure 3, para 4c2]. No such research may begin until such approval by DoD has been received in writing.

**Minimal Risk – [DoDI 3216.02, enclosure 3, para 6b]**

The definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

**Military Personnel as Subjects and Undue Influence – [DoDI 3216.02, enclosure 3, para 7e1]**

Service members shall follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty and for approving off-duty employment or activities. Superiors (e.g., military and civilian supervisors, unit officers, and noncommissioned officers (NCOs)) are prohibited from influencing the decisions of their subordinates (e.g., junior enlisted personnel and equivalent civilians) regarding participation as subjects in research involving human subjects. Superiors of service members in the chain of command shall not be present at any human subject recruitment sessions or during the consent process in which members of units under their command are afforded the opportunity to participate as research subjects. When applicable, the superiors so excluded shall be afforded the opportunity to participate as research subjects in a separate recruitment session. For research involving service members as human subjects that has been determined to be greater than minimal risk and when recruitment occurs in a group setting, the IRB shall appoint an ombudsman who is not associated in any way with the research. The ombudsman shall be present during the recruitment in order to monitor that the voluntary involvement or recruitment of service members is clearly and adequately stressed and that the information provided about the research is clear, adequate, and accurate. For any other research involving service members, the IRB shall determine when it is appropriate to appoint an ombudsman.

**Education and Training – [DoDI 3216.02, enclosure 3, para 5]**
For initial and continuing research ethics education and training for all personnel who conduct, review, approve, oversee, support, or manage human subjects research, there may be specific DoD educational requirements or certification required. The IRB will assess, prior to issuance of IRB approval, whether all personnel have met any DoD training requirements that apply to the research.

The DoD Component may evaluate institution-specific education and training policies to ensure the personnel are qualified to perform the research, based on the complexity and risk of the research.

**Appointment of a Research Monitor – [DoDI 3216.02, enclosure 3, para 8]**

The IRB requires appointment of a research monitor for research involving human subjects that involve more than Minimal Risk and comparable DoD-Supported Research. The IRB or organizational official can require a research monitor for a portion of the research or studies involving no more than Minimal Risk if appropriate. The research monitor is appointed by name. There may be more than one research monitor (e.g., if different skills or experience are necessary). The monitor may be an ombudsman or a member of the DSMB.

The duties of the research monitor are determined on the basis of specific risks or concerns about the research. The research monitor may perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and reports of Unanticipated Problems involving risks to subjects or others, and oversee data matching, data collection and analysis) and report observations and findings to the IRB or a designated official. They should have expertise consonant with the nature of the risk(s) identified within the research protocol and must be independent of the team conducting the research.

The research monitor may discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study. The research monitor has the authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor’s report. Research monitors must promptly report their observations and findings to the IRB or other designated official.

The IRB must approve a written summary of the monitors’ duties, authorities, and responsibilities. The IRB or institution’s HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.

**Additional protections for pregnant women, prisoners, and children (Subparts B, C and D of 45 CFR 46) – [DoDI 3216.02, enclosure 3 para 7]**

DoD-Supported Research involving pregnant women, prisoners, and children are subject to additional protections set forth in the DHHS Common Rule at 45 CFR 46, Subparts B, C and D. DoD-Supported Research involving other vulnerable populations, such as research involving human subjects and investigators in supervisor-subordinate relationships, human subjects with decisional or mental impairments, human subjects with a physical disability, or any other kind of subjects in circumstances that may warrant provision of additional protections.

- Pregnant Women, Fetuses and Neonates as Subjects in DoD-Supported Research
  - For purposes of applying 45 CFR 46 Subpart B to DoD-Supported Research, the phrase “biomedical knowledge” shall be replaced with “generalizable knowledge.”
  - The applicability of Subpart B is limited to research involving pregnant women as subjects in research that is more than Minimal Risk and includes interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as subjects.
  - Fetal research must comply with the 42 USC sections 289g-289g-2.

- Children as Subjects in DoD-Supported Research
The exemption for research involving survey or interview procedures or observation of public behavior does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

- Treatment of Detainees
  - Research involving a detainee as a human subject is prohibited, except for research activities covered by IND or IDE when it is for the purpose of diagnosis or treatment of a medical condition in a patient.

- Prisoners as Subjects in DoD-Supported Research
  - Research involving prisoners cannot be reviewed by the IRB through an expedited review procedure.
  - When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum.
  - In addition to allowable categories of research on prisoners in 45 CFR Part 46 Subpart C, epidemiological research is also allowable when:
    - The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
    - The research presents no more than minimal risk.
    - The research presents no more than an inconvenience to the human subject.
    - Prisoners are not a particular focus of the research.

- When a previously-enrolled human subject becomes a prisoner and the relevant protocol was not approved by IRB in accordance with these additional protections, the Principal Investigator shall promptly notify the IRB. If the Principal Investigator asserts to the IRB that it is in the best interest of the prisoner-subject to continue to participate in the research while a prisoner, the IRB Chair may determine that the prisoner-subject may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the IO and DoD Component office review the IRB’s approval to change the research protocol. Otherwise, the IRB Chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol. The convened IRB, upon receipt of notification that a previously enrolled human subject has become a prisoner, shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-subject can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-subject’s confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human subjects from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-subject to continue to participate in the research. This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects.

Limitation of Waivers and Exceptions from Informed Consent - [DoDI 3216.02, enclosure 3, paras 9 and 13]

In accordance with 10 USC section 980, “research involving a human being as an experimental subject” is an activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction. This activity does not include activities that are not considered research involving human subjects, Exempt categories of research, and research involving the collection or study of existing data, documents, records, or specimens from living individuals.
For research involving a human being as an “experimental subject,” informed consent must be obtained in advance from the experiment subject or the subject’s legal representative if the subject cannot consent; if consent is obtained from the legal representative, the research must intend to benefit the individual subject, which shall be determined by the IRB.

The IRB may not waive these requirements, unless the requirement for informed consent is waived by the Assistant Secretary of Defense for Research and Engineering or such person’s delegate when all of the following are met:

- The research is necessary to advance the development of a medical product for the Military Services;
- The research may directly benefit the individual experimental subject; and
- The research is conducted in compliance with all other applicable laws and regulations.

If the research does not involve a human being as an experimental subject, the IRB may waive the consent process in accordance with its Policies and Procedures.

For classified research, waivers of consent are prohibited.

**Limitations on Compensation for U.S. Military Personnel - [DoDI 3216.02, para 11; Dual Compensation Act and 24 U.S.C. 30]**

The Dual Compensation Act prohibits an individual from receiving pay from more than one position for more than an aggregate of forty (40) hours of work in one calendar week. This prohibition applies to employees paid from either appropriated or non-appropriated funds, or a combination thereof, and includes temporary, part-time and intermittent appointments. This law is not applicable to enlisted off-duty military personnel in relation to their military duty.

When research involves U.S. military personnel, limitations on dual compensation include:

- Federal personnel (civil servants or service members) participating as human subjects in DoD-Supported Research while on duty and non-federal personnel may be compensated for blood draws for research up to fifty U.S. dollars ($50) for each blood draw.
- Federal personnel are prohibited from receiving pay or compensation for general research participation during duty hours, even if the research is not federally funded or conducted.
- Non-federal personnel participating as human subjects in DoD-Supported Research may be compensated for research participation other than blood draws in a reasonable amount, as approved by the IRB according to local prevailing rates and the nature of the research. Federal personnel may be compensated for general research participation only if the federal personnel is involved in the research when not on duty in the same way as human subjects who are not federal personnel (i.e., compensated for participating in a reasonable amount as approved by the IRB according to prevailing rates and the nature of the research). However, payment to off-duty federal personnel for general research participation may not come directly from a federal source.

**Requirement for Reporting – [DoDI 3216.02, enclosure 3, para 4b4]**

NYU Langone Health shall promptly (no longer than within 30 days) notify the DoD Human Research Protection Program (DoD HRPP) office and appropriate sponsor(s) of the following:

- When significant changes to the research protocol are approved by the IRB;
- The results of the IRB continuing review, if the IRB used to review and approve the research changes to a different IRB;
- When the institution is notified by any federal department or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-Supported Research protocol;
- All Unanticipated Problems involving risks to subjects or others, suspensions, terminations, and serious or continuing noncompliance of IRB approval regarding DoD-Supported Research involving human subjects;
All suspensions or terminations of IRB approval of previously approved DoD-Supported Research protocols; and
The initiation and results of investigations of alleged non-compliance with human subjects protections with respect to DoD-Supported Research.

Recordkeeping Requirements - [DoDI 3216.02, para 15]
Recordkeeping requirements for DoD-Supported Research with human subjects may be longer than the Common Rule’s requirement. The DoD may require that records be submitted to the DoD for archiving.

Records maintained that document compliance or non-compliance with DoD requirements shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD Component.

Classified research - [DoDI 3216.02, enclosure 3, para 13]
The involvement of classified information in research involving human subjects may be limited to information needed for IRB approval and oversight of the research; information needed to inform the human subjects during the consent process; and information provided by the human subjects during the course of the research. Secretary of Defense approval is required for all classified non-exempt DoD-Supported Research involving human subjects.

Waivers of informed consent are prohibited for this type of research.

Informed consent procedures shall include:
- Identification of the DoD as the supporting institution of the research, unless the research involves no more than minimal risk. The Secretary of Defense may grant an exception to this requirement on the grounds that providing this information could compromise intelligence sources or methods; and
- A statement that the research involving human subjects is classified and an explanation of the impact of the classification.

The IRB approval process shall meet the following requirements:

- IRB review will be conducted using a Full Board review. Use of an expedited review procedure is prohibited.
- At least one non-affiliated IRB member shall be a non-federal employee.
- Any IRB member who disagrees with a majority decision to approve a project may appeal the decision to the Secretary of Defense.
- The IRB shall determine whether potential human subjects need access to classified information to make a valid, informed consent decision.

Disclosure or use of classified information must comply with all applicable law.

Additional Requirements for DoD Sponsored Research

For non-Exempt research involving human subjects, the IRB must consider the scientific merit of the research. The IRB may rely on outside experts to provide an evaluation of scientific merit. [DoDI3216.02, enclosure 3, para 4b2.]

When conducting research in a foreign country, the IRB shall consider the cultural sensitivities in the setting where the research will take place and shall require that the Principal Investigator has all necessary approvals and permissions to conduct research in that country in accordance with applicable law. [DoDI3216.02, enclosure 3, para 4c2e.]

Disclosure regarding the provisions for research-related injury follow the requirements of the DoD Component. [DoDI 3216.02, enclosure 3, para 10.]

Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD after the research protocol is reviewed and approved by the IRB.

When conducting multi-site research, a formal agreement between the participating organizations is required to specify the roles and responsibilities of each party.
Responsibilities

The Principal Investigator must ensure compliance with all additional DoD requirements for human subject protection, including any necessary approvals from DoD following IRB approval prior to starting the research. It also is the responsibility of the IRB to ensure that all additional requirements by DoD Components for human subject protection have been met before IRB approval of the research project.

10. Informed Consent

Prior to any study participation, informed consent must be sought from each prospective subject or the subject’s Legally Authorized Representative, in accordance with 45 CFR §46.116. In addition, the informed consent discussion must be appropriately documented, in accordance with 45 CFR §46.117. The IRB must approve both the informed consent process and documentation of informed consent.

10.1. Informed Consent Process

No investigator may involve a human subject in research without obtaining the legally effective informed consent of the subject or the subject’s Legally Authorized Representative unless a waiver of consent has been approved by the IRB in accordance with Waiver or Alteration of Informed Consent in this Policy. In general, the IRB considers individuals who are unable to consent for their own clinical care to be unable to consent for research participation. Tools or instruments such as the Mini Mental Exam can also be used to determine capability to consent.

Consent must always be sought under circumstances that:

- provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate; and
- minimize the possibility of coercion or undue influence.

The IRB will consider where the consent process will take place and the individual who will be obtaining consent (e.g. the Principal Investigator, collaborator, or qualified designee) in its determination regarding the appropriateness of the consent process. When the potential subject’s understanding of the research may be impaired due to the timing, location, or individuals participating in the proposed consent process, the IRB will require an alternative process.

The information that is given to the subject or the representative must be in language understandable to the subject or the representative.

The following applies to all studies submitted and approved by NYU Langone Health IRBs (including those that are duly authorized by NYU Langone Health to review NYU Langone Health studies):

No informed consent, whether oral or written, may include exculpatory language through which the subject or the Legally Authorized Representative is made to waive or appear to waive any of the subject’s legal rights.

A person knowledgeable about the consenting process and the research to be conducted (i.e.: a member of the project’s research team) must obtain the informed consent, and must be able to answer questions about the study.

If someone other than the Principal Investigator conducts the interview and obtains consent, the Principal Investigator needs to formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity.

The following additional requirements apply to new studies submitted and approved by NYU
The prospective subject or the Legally Authorized Representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or Legally Authorized Representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Informed consent in general must present information relating to the research in sufficient detail, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or Legally Authorized Representative’s understanding of the reasons why one might or might not want to participate.

10.2. Definitions

**Legally Authorized Representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research. See [Legally Authorized Representatives](#).

**Legal Guardian** means a person appointed by a court of appropriate jurisdiction.

10.3. Basic Requirements

The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for by the federal regulations and the IRB. Investigators are required to obtain legally effective informed consent from a subject or the subject’s Legally Authorized Representative. When informed consent is required, it must be sought prospectively, and properly documented.

The informed consent process involves three key features:

- disclosing to the prospective human subject information needed to make an informed decision in addition to following the requirements pertaining to consent covered by ICH-GCP (see “ICH-GCP Guidance”);
- facilitating the understanding of what has been disclosed; and
- promoting the voluntariness of the decision about whether or not to participate in the research.

Informed consent is more than just a signature on a form. It is a process of information exchange to include reading and signing the informed consent document. The informed consent process is the critical communication link between the prospective human subject and an investigator, beginning with the initial approach of an investigator and continuing through the completion of the research study. Investigators must have received the appropriate training and be knowledgeable about the study protocol in order that they may answer questions to help provide understanding to the study subject or potential study subject.

The exchange of information between the investigator and study subject can occur via one or more of the following modes of communication, among others: face to face contact, mail, telephone; or fax.

Sample or draft consent documents may be developed by a study sponsor or cooperative study group. However, the IRB-of-record is the final authority on the content of the consent documents that is presented to the prospective study subjects.
These informed consent requirements are not intended to preempt any applicable federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed for informed consent to be legally effective, or any additional safeguards required by the institution for certain categories of individuals.

10.4. Basic Elements of Informed Consent

Informed consent must be sought from each potential subject or the subject's Legally Authorized Representative, in accordance with, and to the extent required by [45 CFR 46.116] and [21 CFR 50.25].

The basic elements of informed consent are:

- a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; a description of any reasonably foreseeable risks or discomforts to the subject;
- a description of any benefits to the subject or to others which may reasonably be expected from the research;
- a statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;
- for research involving more than Minimal Risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available;
- an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
- for FDA-regulated studies, the possibility that the FDA may inspect the records needs to be included in the statement regarding subject confidentiality;
- an explanation of whom to contact to voice concerns or complaints about the research; and
- contact information for the IRB to obtain answers to questions about the research; to voice concerns or complaints about the research; to obtain answers to questions about their rights as a research subject; in the event the research staff could not be reached; and in the event the subject wishes to talk to someone other than the research staff.

Additional elements of informed consent to be applied, as appropriate, are:

- a statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable. (For example: Include when the research involves investigational test articles or other procedures in which the risks to subjects is not well known.);
- a statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. (For example: Include when the research involves pregnant women or women of childbearing potential and the risk to fetuses of the drugs, devices, or other procedures involved in the research is not well known.);
- anticipated circumstances under which the subject's participation may be terminated by the Principal Investigator without regard to the subject's consent. (For example: Include when there are anticipated circumstances under which the Principal Investigator may terminate participation of a subject.);
- any additional costs to the subject that may result from participation in the research. (For example: Include when it is anticipated that subjects may have additional costs.);
- the consequences of a subject's decision to withdraw from the research. (For example: Include when withdrawal from the research is associated with adverse consequences.);
- procedures for orderly termination of participation by the subject. (For example: Include when the protocol describes such procedures.)
- a statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject. (For example: Include when the research is long term and interim information is likely to be developed during the conduct of the research.);
- the approximate number of subjects involved in the study. (For example: Include when the research involves more than minimal risk.);
- for studies submitted and approved by NYU Langone Health IRBs (including those duly authorized by NYU Langone Health) on or after January 21, 2019 [45 CFR 46.116(b)(9)]: one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
  ○ a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the Legally Authorized Representative, if this might be a possibility; or
  ○ a statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies;
- for studies submitted and approved by NYU Langone Health IRBs (including those duly authorized by NYU Langone Health) on or after January 21, 2019 [45 CFR 46.116(c)], a statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- for studies submitted and approved by NYU Langone Health IRBs (including those duly authorized by NYU Langone Health) on or after January 21, 2019 [45 CFR 46.116(c)], a statement regarding whether clinically relevant results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- for studies submitted and approved by NYU Langone Health IRBs (including those duly authorized by NYU Langone Health) on or after January 21, 2019 [45 CFR 46.116(c)], for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Additional elements of informed consent to be applied when the research is subject to ICH-GCP (E6) are:

- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject in addition to inclusion of any benefits or risks associated with alternatives; and
- a statement indicating that the monitor, the auditor, the IRBs, and the regulatory authority will be granted direct access to the subject's original medical records for verification of clinical trial procedures or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written consent form, the subject or the subject’s Legally Acceptable Representative is authorizing such access. [ICH-GCP]

The NYU Langone Health IRBs are not implementing broad consent (allowable under the 2018 Common Rule) at this time.

10.5. **Subject Withdrawal or Termination**

For a variety of reasons, a subject enrolled in a research study may decide to withdraw from the research, or an investigator may decide to terminate a subject’s participation in research regardless of whether the subject wishes to continue participating. Principal Investigators must plan for the possibility that subjects will withdraw from research and include a discussion, in the research protocol/research plan and consent document, of what withdrawal will mean and how it will be handled.
When seeking informed consent from subjects, the following information regarding data retention and use must be included:

- **For FDA-regulated clinical trials**, when a subject withdraws from a study, the data collected on the subject to the point of withdrawal remain part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

- **For research not subject to FDA regulations**, the Principal Investigator should inform subjects whether the Principal Investigator intends to either: (1) retain and analyze already collected data relating to the subject up to the time of subject withdrawal; or (2) honor a research subject’s request that the Principal Investigator destroy the subject’s data or that the Principal Investigator exclude the subject’s data from any analysis.

When a subject’s withdrawal request is limited to discontinuation of the primary interventional component of a research study, research activities involving other types of participation for which the subject previously gave consent may continue. Investigators should ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between study-related interventions and procedures and continued follow-up in person, by phone, or via records review, of data and address the maintenance of privacy and confidentiality of the subject's information.

If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up as described in the previous paragraph, the investigator must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original consent document). IRB approval of consent documents for these purposes is required.

If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up, the investigator must not access or gather private information about the subject for purposes related to the study. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.

### 10.6. Waiver or Alteration of Informed Consent

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement for informed consent, provided the IRB finds and documents that all the following conditions are met [45 CFR 46.116(f)]:

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practicably be carried out without the waiver or alteration;
- whenever appropriate, the subjects must be provided with additional pertinent information after participation;
- **for new research submitted and approved by NYU Langone Health IRBs (including those duly authorized by NYU Langone Health) after January 19, 2019**: if the research involves using identifiable private information or identifiable biospecimens, the IRB must additionally find that the research could not be practically carried out without using such information or biospecimens in an identifiable format

OR

- if the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - public benefit or service programs;
  - procedures for obtaining benefits or services under those programs;
  - possible changes in or alternatives to those programs or procedures; or
The given consent [Informed consent] may be obtained in these ways and reviewed a form to be completed by the Principal Investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. The IRB must find and document that the protocol reflects that the information will be obtained in these ways and review a form to be completed by the Principal Investigator.

In addition, the following applies to new research submitted and approved by NYU Langone Health IRBs (including those duly authorized by NYU Langone Health) after January 19, 2019 [45 CFR 46.116(g)]:

The IRB may approve a research protocol in which information or biospecimens will be obtained for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without requiring the informed consent of the prospective subject or their Legally Authorized Representative or a waiver of consent, if, through the protocol: (1) the Principal Investigator will obtain information through oral or written communication with the prospective subject or Legally Authorized Representative; or (2) the Principal Investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. The IRB must find and document that the protocol reflects that the information will be obtained in these ways and review a form to be completed by the Principal Investigator.

Note: Informed consent cannot be waived under these criteria for FDA-regulated research. Note that some research involving FDA-regulated products is not FDA-regulated and that some research that does not involve FDA-related products is FDA-regulated. Exceptions from the FDA requirements for informed consent may be waived for emergency situations [21 CFR 50.23] or for emergency research [21 CFR 50.24].

10.7. Documentation of Informed Consent (Signed Consent)

Informed consent must be appropriately documented, in accordance with, and to the extent required by [45 CFR 46.117] or [21 CFR 50.27]. Informed consent is documented by the use of a written informed consent form approved by the IRB and signed and dated by the subject or the subject's Legally Authorized Representative at the time of consent. A copy of the signed and dated informed consent form must be given to the person signing the informed consent form; that is, either the subject or his/her Legally Authorized Representative).

The consent form may be either of the following approved by the IRB:

[pre-2018 Common Rule]

- A written consent document that embodies the elements of informed consent may be read to the subject or the subject's Legally Authorized Representative, but the subject or representative must be given adequate opportunity to read it before it is signed; or

- A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's Legally Authorized Representative. When this method is used:
  - a witness to the oral presentation is required; and
  - the IRB must approve a written summary of what is to be reviewed with the subject or representative. The long form English IRB-approved consent document may be used as the required written summary; and
  - the witness must sign both the short form attesting to the adequacy of the consent process and a copy of the summary. The subject may only sign the short form; and
  - for subjects who do not speak English, the witness must be conversant in both English and the language of the subject.
  - the person actually obtaining consent must sign a copy of the summary; and
[2018 Common Rule]

- A written informed consent form that meets the requirements of informed consent. The subject or the subject’s Legally Authorized Representative must be given adequate opportunity to read the informed consent form before it is signed. Alternatively, this form may be read to the subject or the subject’s Legally Authorized Representative; or

- A short form written informed consent form stating that the elements of informed consent have been presented orally to the subject or the subject’s Legally Authorized Representative and that key information required by 45 CFR 46.116(a)(5)(i) was presented first to the subject before any other information (if any) was provided. When the short form written consent method is used:
  - a witness to the oral presentation is required; and
  - the IRB must approve a written summary of what is reviewed with the subject or Legally Authorized Representative. The long form English IRB-approved consent document may be used as the required written summary; and
  - the witness must sign both the short form and a copy of the summary. The witness is attesting to the adequacy of the consent process. The subject may only sign the short form;
  - for subjects who do not speak English, the witness must be conversant in both English and the language of the subject.
  - the person actually obtaining consent must sign a copy of the summary; and
  - a copy of the summary must be given to the subject or Legally Authorized Representative, in addition to a copy of the short form.

More guidance on the documentation of and consenting process for non-English speaking subjects may be found in this Policy, Section 10.12, Consent and Language Barriers.

### 10.8 Waiver of Documentation of Informed Consent (Waiver of Signed Consent)

The IRB may waive the requirement for the Principal Investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated, or

  *Note: Subjects must be asked whether they want documentation linking them with the research, and their wishes must govern. Example: domestic violence research where the principal risk is discovery by the abuser that the subject is talking to researchers.*

- The research presents no more than Minimal Risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Procedures such as non-sensitive surveys, questionnaires and interviews generally do not require written consent when conducted by non-researchers; or

- **For new studies submitted and approved by NYU Langone Health IRBs (including those duly authorized by NYU Langone Health) after January 21, 2019 only:** If the subjects or Legally Authorized Representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than Minimal Risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the IRB grants a waiver of the requirement for signed consent, the Principal Investigator must provide in the application materials a written summary of the information to be communicated to the
10.9. Review and Approval of the Informed Consent Form
The IRB is responsible for the review and approval of the informed consent form prepared by the Principal Investigator. The wording on the informed consent form must contain all of the required elements and meet all other requirements as described in this Section. If the wording of the informed consent has been initially prepared by an external entity (e.g., a pharmaceutical company or a cooperative study group, including National Cancer Institute (NCI) groups) other than by the Principal Investigator, the Principal Investigator must prepare the consent using the institutional IRB consent template.

IRB approval of the consent form language must be documented through the use of a certification stamp on each page that indicates the date of the most recent IRB approval of the document and the expiration date. If the consent form is amended during the protocol approval period, the form must bear the approval date of the amendment rather than the date of the approved protocol.

10.10. Parental Permission and Assent
For policies on parental permission and assent in research involving children, see: Parental Permission and Assent.

10.11. Surrogate Consent
Any use of surrogate consent requires prior approval by the IRB. See Persons who Lack Capacity to Provide Informed Consent for Research and Surrogate Consent.

10.12. Consent and Language Barriers

Consent Documentation
If a study subject does not clearly understand the information presented at the signing of the consent document or in subsequent discussions, his/her consent may not be informed, and therefore, not effective.

Documentation of consent for studies where non-English-speaking subjects are enrolled (either planned or unexpectedly) is required if the IRB has not granted a Waiver of Documentation of Informed Consent. In these cases, there are two methods of documenting consent: use of a short form for when a non-English-speaking subject is encountered unexpectedly, or use of a fully translated informed consent document when enrollment of non-English-speaking subjects is planned.

Translated Long Form
For studies where non-English-speaking subjects are anticipated or planned to be included, researchers should submit to the IRB both English language and translated consent forms. The IRB will request an explanation of the translations and evidence of the comparability of the English and non-English consent forms. The IRB may consult with language experts or require a "back-translation" into English. The translation should provide documentation to verify the accuracy of the translation and back-translation. When non-English-speaking subjects enroll, they and the witness sign the translated document. The subjects are given a copy of the signed translated consent document.

Short Form
If a non-English-speaking subject is enrolled unexpectedly and there is not an existing IRB-approved long form informed consent document available in the prospective subject’s language, the Principal
Use of Interpreters in the Consent Process

NYU Langone Health strongly recommends use of a certified medical interpreter to assist in the consent discussion with non-English-speaking prospective subjects. Using a non-certified interpreter for the consent discussion may increase the risk that the quality of the informed consent discussion will later be called into question in the event of complications with the subject.

NYU Langone Health recognizes, however, that the use of a certified medical interpreter may not always be possible. In cases where the researcher is fluent in the subject’s language, the researcher may conduct the informed consent process with use of either method of documentation of consent as noted in this Policy’s section on Documentation of Informed Consent (Signed Consent).

Researchers should consider the level of complexity and level of study risk (as determined by the IRB) when deciding whether a non-certified interpreter will be used to facilitate the consent discussion. For example, a non-certified interpreter who is bilingual in both English and the subject’s language may be adequate for a minimal risk study that measures subjects’ movements and heart rate but involves no other intervention.

- **When the short form written consent method is used (i.e., there is no translated full consent document):**

  If the person obtaining consent is not fluent in the prospective subject’s language, an interpreter will be necessary to deliver information in the IRB-approved consent form and/or script and to facilitate the consent discussion. The interpreter assisting with presentation of the information and obtaining consent should be someone who is independent of the subject (i.e., not a family member). Whenever possible, interpreters should be provided copies of the short form written consent and the IRB-approved consent script well before the consent discussion with the subject; ideally, 24 to 48 hours prior.

  If the short form process is used with an interpreter, a witness is required and must be available to sign the short form consent document. The person who serves as the witness must be conversant in both English and the subject’s language. The interpreter may serve as the witness. If the interpreter also serves as the witness, she/he may sign the short form consent document and script or the full translated consent form as the witness and should note “Interpreter” under the signature line. The person obtaining consent must document that the “short form” process was used in the progress notes of the subject’s medical record, including the name of the interpreter.

  If, however, the person obtaining consent is fluent in the subject’s language, he or she may deliver the information, but a separate witness is required to observe the consent process and attest to the adequacy of the consent process (see Documentation of Informed Consent).

- **When a long form is used (i.e., translated full consent document):**

  If the person obtaining consent is not fluent in the prospective subject’s language, an interpreter independent of the subject should be used to facilitate the discussion. The consent form should be signed
by the witness to the consent process. The person who serves as the witness must be conversant in both English and the subject’s language. The interpreter may serve as the witness.

If the person obtaining consent fluently speaks the prospective subject's language, and there is a translated consent form in the subject’s language, the researcher may conduct the consent process and sign the required documents as both the researcher and the interpreter. A witness to the consent process will not be required.

**NOTE:** If the consent process is conducted remotely (see the IRB’s guidance on e-consent) and the interpreter also serves as witness to the consent process, they may provide their interpreter license number as their signature on the short-form or long form consent document regardless of whether the short form or long form consent process is used.

**Braille Consent**

For blind subjects who read Braille, the IRB may approve a consent document prepared in Braille. In order to assure itself that a Braille consent document is accurate, the IRB may require a transcription into print text or review of the document by an IRB member or other person who reads Braille. If possible, the subject will sign the Braille consent; otherwise verbal consent will be obtained, witnessed and documented as described in Oral Consent below.

**Oral Consent**

When subjects are unable to read a written consent form (such as blind or illiterate subjects), the IRB may approve an oral consent process, provided the subject (1) retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally and (2) is able to indicate approval or disapproval to study entry.

For research that is no more than Minimal Risk, documentation of consent may be waived according to the criteria in Waiver of Documentation of Informed Consent (Waiver of Signed Consent).

For greater than Minimal Risk research, the consent form must be read to the subjects and the subjects must be given an opportunity to ask questions. An audiotape approved by the IRB may be used. If capable of doing so, the subject signs, or marks an X to signify consent. If that is not possible, the subject will provide verbal consent. The person obtaining consent and a witness will sign the written study consent form with a statement that documents that an oral process was used and, if necessary, that the subject gave verbal consent. The consent process should also be documented in the medical record or in accord with the institution’s policy on documentation of informed consent. Signed copies of the consent form are given to the subject and, whenever possible, these documents should be provided to the subject on audio or video tape.

Sometimes a subject understands English but does not read or write English. An impartial witness should document that the subject understands the research and the consent process and consented to participate.

**10.13. Waiver of Informed Consent for Planned Emergency Research**

A request for an exception from informed consent of research subjects may be granted by the IRB for FDA-regulated planned research in an emergency setting if the IRB, with the written concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation, finds and documents each of the following:

- **Life-Threatening Situation.** The human subjects are in a life-threatening situation, which means, for purposes of this Policy, diseases or conditions in which the likelihood of death is high unless the course of the disease or condition is interrupted. An individual is not considered to be in a life-
threatening situation when the situation is not emergent. For example, research involving an individual who has been in a coma for a long period of time and whose condition is not rapidly deteriorating is not considered planned emergency research. In that case, the research intervention requires consent by a Legally Authorized Representative or appropriate surrogate of the subject. See Persons who Lack Capacity to Provide Informed Consent for Research and Surrogate Consent.

- Available Treatments Unproven or Unsatisfactory. Available treatments are unproven or unsatisfactory, and the collection of additional valid scientific evidence is necessary to determine the safety and effectiveness of particular study interventions and/or test articles.

- Informed Consent Not Feasible. Obtaining informed consent is not feasible because:
  - The subjects will not be able to give their informed consent as a result of their medical condition;
  - The practicable treatment window does not allow time to get prospective consent, and the intervention under investigation must be administered before obtaining consent from a subject's Legally Authorized Representative or appropriate surrogate is feasible; and
  - There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.

- Prospect of Direct Benefit. Participation in the research holds out the prospect of direct benefit to the subjects because:
  - They are in life-threatening situations that necessitate intervention;
  - Appropriate animal and/or other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and
  - Risks associated with the investigation are reasonable in relation to what is known about the medical conditions of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

- Impracticable Without Waiver. The clinical investigation could not practicably be carried out without the waiver of consent.

- Defined Therapeutic Window. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence.

- Informed Consent Procedures and Documents. The informed consent procedures and informed consent documents are consistent with the requirements of 21 CFR § 50.25. These procedures and documents are to be used with subjects or their Legally Authorized Representative or appropriate surrogate in situations where use of such procedures and documents is feasible.

- Right to Object: The procedures in place provide an opportunity for a Legally Authorized Representative or family member to object to a subject's enrollment and/or continued participation in the study. [21 CFR § 50.24(a)(6) and (7)(v)]. If such Legally Authorized Representative or family member objects to the subject's continued participation, consent should be considered to have been withdrawn and the investigator must immediately notify the IRB.

Additional Subject Protections

Additional protections for subjects will be provided, including the following:
  - Consultation with representatives of the community(ies) in which the clinical investigation will be conducted and from which the subjects will be drawn;
  - Public disclosure to the community(ies) in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the research and its risks and expected benefits;
  - Public disclosure of sufficient information following completion of the protocol to apprise the community(ies) and investigators of the study, including the demographic characteristics of the research population, and its results; and
Informed Consent Requirement

In addition, if obtaining informed consent is not feasible and a Legally Authorized Representative is not reasonably available, the Principal Investigator must, if feasible, attempt to contact within the therapeutic window the subject's family member who is not a Legally Authorized Representative, and ask whether he or she objects to the subject's participation in the research [21 CFR 50.24(a)(6)]. The Principal Investigator will notify the IRB as soon as is reasonable of such objection to participation, and the IRB will follow appropriate steps. Additionally, the Principal Investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

The IRB is responsible for ensuring that the Principal Investigator has procedures in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a Legally Authorized Representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation, and other information contained in the informed consent document.

The IRB will also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a Legally Authorized Representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a Legally Authorized Representative or family member is told about the clinical investigation and the subject's condition improves, the subject must also be informed as soon as feasible. If a subject is entered into a clinical investigation without consent and the subject dies before a Legally Authorized Representative or family member can be contacted, information about the clinical investigation must be provided to the subject's Legally Authorized Representative or family member, if feasible.

Documentation

If the IRB determines that it cannot approve a clinical investigation because the investigation does not meet the above criteria or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the Principal Investigator and to the sponsor of the clinical investigation. The sponsor of the clinical investigation must promptly disclose this information to FDA and to the sponsor's clinical investigators who are participating, or are asked to participate, in this or a substantially equivalent clinical investigation of the sponsor, and to other IRBs that have been, or are, asked to review this or a substantially equivalent investigation by that sponsor.

The IRB determinations and documentation are to be retained by the IRB for at least three (3) years after completion of the clinical investigation, and the records shall be accessible for inspection and copying by the FDA.

IND / IDE Requirements

Protocols where an exception to the informed consent requirement under this section are granted must be performed under a separate investigational new drug application (IND) or investigational device exemption
(IDE) that clearly identifies such protocols as including subjects who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for investigations under this section may not be submitted as amendments.

NYU Langone Health Requirements

In addition to IRB approval, planned emergency research conducted by or at NYU Langone Health that involves the waiver of informed consent is subject to the institutional requirements set forth in NYU Langone Health’s Policy on Planned Emergency Research (HSR Policy #6).

10.14. Posting of Clinical Trial Consent Form

For any Clinical Trial conducted or supported by a federal department or agency that is submitted and approved by the NYU Langone Health IRBs (including those duly authorized by NYU Langone Health) on or after January 21, 2019, one copy of the IRB-approved informed consent form that was used to enroll subjects must be posted by the awardee or the federal department or agency Component conducting the trial on a publicly available federal website that will be established as a repository for such informed consent forms [45 CFR 46.116(h)]. “Clinical Trial” is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

The Principal Investigator must ensure that the last IRB-approved informed consent form is posted on the federal website after the clinical trial is closed to recruitment, and no later than sixty (60) days after the last study visit by the last subject, as required by the protocol.

If the federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a federal website (e.g. confidential commercial information), such federal department or agency may permit or require redactions to the information posted.

11. Vulnerable Populations

When some or all of the subjects in a protocol are likely to be vulnerable to coercion or undue influence, the IRB should include additional safeguards to protect the rights and welfare of these subjects. Some of the vulnerable populations that might be involved in research include children, pregnant women, fetuses, neonates, prisoners, or adults who lack the ability to consent, students, employees, or homeless persons.

If the IRB reviews research that involves categories of subjects vulnerable to coercion or undue influence, the review process will include one or more individuals who are knowledgeable about or experienced in working with these subject populations will be included in the review process.
[45 CFR 46] has additional subparts designed to provide extra protections for vulnerable populations which also have additional requirements for IRBs:

<table>
<thead>
<tr>
<th>Subpart B</th>
<th>Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research</th>
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<tbody>
<tr>
<td>Subpart C</td>
<td>Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects</td>
</tr>
<tr>
<td>Subpart D</td>
<td>Additional Protections for Children Involved as Subjects in Research</td>
</tr>
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Under each IRB’s FWA (NYUGSoM, NYU Winthrop, duly authorized external IRB), the subparts apply to all research regardless of funding source.

Researchers conducting human subjects research must check with the IRB to determine applicability of and how to apply the subparts.

11.1. PI Responsibilities
The Principal Investigator is responsible for identifying the potential for enrolling vulnerable subjects in the research proposal at initial review and for providing justification for including vulnerable populations in the research. For example, the Principal Investigator is responsible for identifying patients who are at risk for impaired decisional capacity as a consequence of psychiatric illness, and who are being asked to participate in a research study with greater than Minimal Risk.

11.2. IRB Responsibilities
- The IRB shall include representation, either as members or ad hoc consultants, individual(s) interested in or who have experience with the vulnerable populations involved in a research proposal.
- The IRB reviews the PI’s justifications for including vulnerable populations in the research to assess appropriateness of the research proposal.
- The IRB must ensure that additional safeguards have been included in each study to protect the rights and welfare of vulnerable subjects as needed at the time of initial review of the research proposal.
- Information reviewed as part of the continuing review process should include the number of subjects considered as members of specific vulnerable populations.
- For studies that do not have or are not required to have a Data and Safety Monitoring Board (DSMB) or a Data Monitoring Committee and have entered vulnerable subjects, the IRB needs to carefully review the safety monitoring plan.
- The IRB should be knowledgeable about and experienced in working with populations who are vulnerable to coercion and undue influence. If the IRB requires additional qualification or expertise to review a protocol, it should obtain consultation.

Initial Review of Research Proposal
- The Principal Investigator should identify the potential to enroll vulnerable subjects in the proposed research at initial review and provide the justification for their inclusion in the study.
- The IRB will evaluate the proposed plan for consent of the specific vulnerable populations involved. If the research involves adults unable to consent, the IRB evaluates the proposed plan for permission of Legally Authorized Representatives.
- The IRB evaluates and approves the proposed plan for the assent of subjects.
- The IRB evaluates the research to determine the need for additional protections and consider the use of a DSMB or data monitoring committee as appropriate.
- The Principal Investigator should provide appropriate safeguards to protect the subject’s rights and welfare, which may include the addition of an independent monitor. The independent
monitor is a qualified individual not involved in the research study who will determine the subject’s capacity to provide voluntary informed consent.

- Examples of studies that warrant independent monitoring include those involving schizophrenic patients who will be exposed to placebo, and/or drug washout, and/or treatment with agents that are not approved by the Food and Drug Administration (FDA). Populations requiring independent monitoring would include individuals with schizophrenia, other psychotic disorders or conditions characterized by lack of reality testing (i.e., psychosis). Populations not usually requiring independent monitoring would include those with substance use disorders.
- The IRB will assess the adequacy of additional protections for vulnerable populations provided by the Principal Investigator.

**Continuing Review and Monitoring**
At continuing review, the Principal Investigator should identify the number of vulnerable subjects enrolled and any that needed an independent monitor in the study progress report.

**11.3. Research Involving Children**
The following applies to all research involving children, regardless of funding source. The requirements in this section are consistent with [Subpart D of 45 CFR 46], which applies to DHHS-funded research and [Subpart D of 21 CFR 50], which applies to FDA-regulated research involving children.

**Definitions**

**Child**
Under DHHS and FDA regulations, "children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

When research is conducted in New York State, persons who meet the above definition are all individuals under 18 years of age with the following exceptions:

- Individuals between 16 and 18 years of age adjudicated as emancipated by a probate court
- All individuals under 18 years of age, if the research procedures are limited to:
  - HIV testing, counseling, and treatment;
  - Outpatient mental health services;
  - Testing or treatment for sexually transmitted diseases;
  - Treatment or rehabilitation for alcohol or drug dependence; and/or
  - Abortion counseling and treatment.
- All individuals between 16 and 18 years of age, if the research procedures are limited to inpatient mental health services

**NOTE:** For research conducted in jurisdictions other than New York State, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The Office of General Counsel may be consulted for assistance with regard to the laws in other jurisdictions.

**Guardian**
Under DHHS and FDA regulations, “guardian” means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. When research is conducted in New York State, the persons who meet the definition of guardian are court-appointed guardians with the authority to consent to major medical, psychiatric or surgical treatment with specific authorization to consent to research.

**NOTE:** For research conducted in jurisdictions other than New York State, the research must comply with the laws regarding guardianship in all relevant jurisdictions. The Office of General Counsel may be consulted to assistance with regard to the laws in other jurisdictions.
Assent means a child’s affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.

Permission means the agreement of parent(s) or legal guardian to the participation of their child or ward in research.

Parent means a child’s biological or adoptive parent.

Allowable Categories
Research on children must be reviewed and categorized by the IRB into one of the following groups:

1. Research that does not involve physical or emotional risk greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk). [45 CFR 46.404]
   - Requires assent of the child.
   - Requires permission of either both parents, or legal guardian, unless one parent is deceased, unknown, incompetent, or not reasonably available; or only one parent has legal responsibility for the care and custody of the child.
   - The IRB may determine that the permission of one parent is sufficient, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

2. Research involving greater than Minimal Risk but presenting the prospect of direct benefit to the individual subject. [45 CFR 46.405]
   - The risk must be justified by the anticipated benefit to the subjects.
   - Requires assent of the child.
   - Requires permission of either both parents, or legal guardian, unless one parent is deceased, unknown, incompetent, or not reasonably available; or only one parent has legal responsibility for the care and custody of the child.
   - The IRB may determine that the permission of one parent is sufficient, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

3. Research involving greater than Minimal Risk with no reasonable prospect of direct benefit to the individual subject, but is likely to yield generalizable knowledge about the subject’s disorder or condition. [45 CFR 46.406]
   - The risk represents a minor increase over Minimal Risk.
   - The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
   - Requires permission of either both parents, or legal guardian, unless one parent is deceased, unknown, incompetent, or not reasonably available; or only one parent has legal responsibility for the care and custody of the child.
   - Requires assent of the child.

4. Research that is not otherwise approvable but which presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children. [45 CFR 46.407]
   - Federally-funded research in this category must be approved by the Secretary of Health and Human Services, and requires consent of either both parents, or legal guardian.
   - FDA-regulated research in this category must be approved by the Commissioner of Food and Drugs.
   - For non-federally-funded research and non-FDA research, IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law).
on the recommendation of the panel, the IRB may approve the research based on either:

- That the research in fact satisfies the conditions of the previous categories, as applicable; or

- The following:
  - the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
  - the research will be conducted in accord with sound ethical principles; and
  - informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this Policy manual.

**Parental Permission and Assent**

**Parental Permission**

In accordance with [45 CFR 46.408(b)] and [21 CFR 50.55(e)], the IRB must determine that adequate provisions have been made for soliciting the permission of each child's parents or guardians. Permission from both parents is required for all research to be conducted with children unless: (1) one parent is deceased, unknown, incompetent, or not reasonably available; or (2) when only one parent has legal responsibility for the care and custody of the child; or (3) the research falls under 1 and 2 above and the IRB has determined that the permission of one parent is sufficient.

Parents or guardians must be provided with the basic elements of consent as stated in [45 CFR 46.116(a)(1-8)] and [21 CFR 50.25(a)(1-8)] and any additional elements the IRB deems necessary.

The IRB may find that the permission of one parent is sufficient for research to be conducted under [45 CFR 46.404] (21 CFR 50.51) or [45 CFR 46.405] (21 CFR 50.52). The IRB's determination of whether consent must be obtained from one or both parents will be documented in the consent checklist when a protocol receives expedited review, and in meeting minutes when reviewed by the convened IRB.

Consent from both parents is required for research to be conducted under [45 CFR 46.406] (21 CFR 50.53) and [45 CFR 46.407] (21 CFR 50.54) unless:

- one parent is deceased, unknown, incompetent, or not reasonably available; or
- when only one parent has legal responsibility for the care and custody of the child

The IRB may waive the requirement for obtaining consent from a parent or legal guardian for research that is not FDA-regulated if both of the following are true: (1) the research meets the provisions for waiver in [45 CFR 46.116(d)(1-4)]; or the IRB determines that the research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), and (2) an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and the waiver is not inconsistent with federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, as well as their age, maturity, status, and condition.

Parental permission may not be waived for research covered by the FDA regulations.

Permission from parents or legal guardians must be documented in accordance with and to the extent required by Parental Permission and Assent.

**Assent from Children**

Because “assent” means a child’s affirmative agreement to participate in research [45 CFR 46.402(b)], where a child’s assent is required, the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. The IRB has the discretion to judge children’s capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis.
When reviewing the proposed assent procedure and the form and content of the information conveyed to prospective subjects, the IRB should take into account the nature of the proposed research activity and the ages, maturity, and psychological state of the children involved. For example, for research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should likewise include information similar to what would be provided for informed consent by adults or for parental permission. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.

The IRB presumes that children ages 7 and older should be given an opportunity to provide assent. Generally, oral assent through the use of a script should be obtained from children 7-11 years of age. Written assent using a written document for the children to sign may be sought for older children. If the child’s assent is not obtained the Principal Investigator may either re-approach the child at a later time or not enroll the child.

At times, there may be inconsistency between parent permission and child assent. Usually a "no" from the child overrides a "yes" from a parent, but a child typically cannot decide to be in research over the objections of a parent. There may be individual exceptions to these guidelines (such as when the use of an experimental treatment for a life-threatening disease is being considered). The general idea, however, is that children should not be forced to be research subjects, even when their parents consent to it.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

Even when the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances detailed in the Waiver of Informed Consent.

**The Assent Form**

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

The assent form should be drafted in a way that is age appropriate and study-specific, taking into account the typical child’s experience and level of understanding, and the document should be composed in a way that treats the child respectfully and conveys the essential information about the study. The assent form should:

- tell why the research is being conducted;
- describe what will happen and how long or how often;
- say it is up to the child to participate and that it is okay to say no;
- explain if it will hurt and if so for how long and how often;
- say what the child’s other choices are;
- describe any good things that might happen;
- say whether there is any compensation for participating; and
- ask for questions.

For younger children, the document should be limited to one page if possible. Illustrations and larger type make a form easier for young children to understand and read. Studies involving older children or adolescents should include more information and may use more complex language.
Children who are Wards

Children who are wards of the State or any other agency, institution, or entity can be included in research involving greater than Minimal Risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, only if such research is:

- related to their status as wards; or
- conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research meets the condition(s) above, an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in loco parentis.

The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Re-Consent Upon Reaching Age of Majority

If the IRB determines that a child’s assent is required under the federal regulations, the IRB must also determine whether re-consent is required when the subject reaches the age of legal majority during study participation in order for research-required interactions or interventions to continue. The NYU Langone Health IRB will require re-consent when a research subject who was a minor and entered the study with parental or guardian consent reaches the age of majority (in New York State, age 18) while continuing in the research. Re-consent is also necessary if previously collected biospecimens are still being utilized or if those subjects’ medical records will continue to be accessed/reviewed.

11.4. Research Involving Pregnant Women, Human Fetuses and Neonates

Definitions

Dead Fetus
means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

Delivery
refers to a complete separation of the fetus from the woman by expulsion or extraction or any other means.

Fetus
means the product of conception from implantation until delivery.

Neonate
means a newborn.

Nonviable neonate
means a neonate after delivery that, although living, is not viable.

Pregnancy
encompasses the period of time from implantation until delivery. A woman is assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results
of a pregnancy test are negative or until delivery.

**Viable**
as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

**Research Involving Pregnant Women or Fetuses**
For DHHS-funded research in addition to non-funded DHHS research, [45 CFR Subpart B] applies to all research involving pregnant women. Under [45 CFR Subpart B], pregnant women or fetuses may be involved in research funded by DHHS if all of the following conditions are met:

- Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risk to pregnant women and fetuses.
- The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.
- Any risk is the least possible for achieving the objectives of the research.
- If the research holds out the prospect of direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, then the consent of the pregnant woman must be obtained in accord with the provisions for informed consent.
- If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father must be obtained in accord with the provisions for informed consent, except that the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Each individual providing consent under previous two elements of this Section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
- For children who are pregnant, assent and permission are obtained in accord with the provisions of permission and assent under Parental Permission and Assent.
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- Individuals engaged in the research will have no part in determining the viability of a neonate.

DHHS-funded research that falls in this category must be approved by the Secretary of Health and Human Services. If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates, and the research is not approvable under the above provisions, then the research will be sent to OHRP for DHHS review.

**Research Involving Neonates**
The following Policies and Procedures apply to all research involving neonates, regardless of funding source.

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

- Where scientifically appropriate, predclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
- Each individual providing consent is fully informed regarding the reasonably foreseeable
impact of the research on the neonate.

- Individuals engaged in the research will have no part in determining the viability of a neonate.
- The requirements set forth in Neonates of Uncertain Viability or Nonviable Neonates (see below in this Section) have been met as applicable.

**Neonates of Uncertain Viability**

Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met.

The IRB determines that:

- The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
- The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and
- The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's Legally Authorized Representative is obtained in accord with the provisions of permission and assent, except that the consent of the father or his Legally Authorized Representative need not be obtained if the pregnancy resulted from rape or incest.

**Nonviable Neonates**

After delivery, nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met:

- Vital functions of the neonate will not be artificially maintained.
- The research will not terminate the heartbeat or respiration of the neonate.
- There will be no added risk to the neonate resulting from the research.
- The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.
- The legally effective informed consent of both parents of the neonate is obtained in accord with the provisions of permission and assent, except that the waiver and alteration of the provisions of permission and assent do not apply.

However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a Legally Authorized Representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

**Viable Neonates**

A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of IRB Review Process and Research Involving Children.

**Research Involving, After Delivery, the Placenta, the Dead Fetus or Fetal Material**

Research involving the placenta, the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus after delivery, must be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

If information associated with material described above in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to
those individuals, those individuals are research subjects and all pertinent sections of this manual are applicable.

**Research Not Otherwise Approvable**

If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and the research is not approvable under the above provisions, then the IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the IRB may approve the research based on either:

- that the research in fact satisfies the conditions of *Research Involving Pregnant Women or Fetuses*, as applicable; or

- the following:
  - the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
  - the research will be conducted in accord with sound ethical principles, and
  - informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this Policy manual.

**11.5. Research Involving Prisoners**

Prisoners are another of the three classes that are deemed so vulnerable to exploitation in research that there are special rules in the federal regulations protecting them. In the past, prisoners were viewed as a convenient research population, due to their being housed in a single location, constituting a large and relatively stable population, and living a routine life. Unfortunately, all the things that make prisoners a convenient research population also make prisoners ripe for exploitation.

The concern that Subpart C, and this Policy based on Subpart C, attempt to address is whether prisoners have any real choice in participation in research, or whether incarceration could affect their ability to make a truly voluntary, uncoerced decision to participate as subjects in research, prohibiting free choice. It is the purpose of this Policy to provide additional safeguards for the protection of prisoners involved in research activities to which this Subpart is applicable. [45 CFR 46.302]

The following Policy applies to all biomedical and behavioral research involving prisoners as subjects, regardless of funding source. The requirements in this section are consistent with [Subpart C of 45 CFR 46], which applies to DHHS-funded research.

Even though the IRB may approve a research protocol involving prisoners as subjects according to this Policy, Principal Investigators are still subject to any applicable state or local laws such as, in New York State, the Administrative Regulations of the New York Department of Corrections. [45 CFR 46.301]

**Definitions**

**Prisoner**

Means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
Minimal Risk means, for research involving prisoners, the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons [45 CFR 46.303(d); 21 CFR 50.3(o)]. This differs from the definition as stated in 45 CFR 46.102(i) and 21 CFR 50.3(k).

**Composition of the IRB**

In addition to satisfying the general requirements detailed in the IRB section of this Policy manual, when reviewing research involving prisoners, the IRB must also meet the following requirements:

- A majority of the IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership on the IRB; and
- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

**Additional Duties of the IRB**

In addition to all other responsibilities prescribed for IRB in the Institutional Review Board and NYU Langone Health IRB Review Process sections of this Policy manual (Sections 5 and 8), the IRB will review research involving prisoners and approve such research only if it finds that:

- the research falls into one of the following permitted categories [45 CFR 46.306]:
  - study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
  - study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
  - research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or
  - research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

- any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

- the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

- procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the Principal Investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

- the information is presented in language which is understandable to the subject population;

- adequate assurance exists that a parole board will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

- where the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing subjects of this fact.

**Certification to HHS**

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Under [45 CFR 46.305(c)], the institution responsible for conducting research involving prisoners that is supported by HHS shall certify to the Secretary (through OHRP) that the IRB has made the seven findings required under [45 CFR 46.305(a)]. For all HHS conducted or supported research, the NYU Langone Health IRB will send to OHRP a certification letter to this effect, which will also include the name and address of the institution and specifically identify the research protocol in question and any relevant HHS grant application or protocol. HHS conducted or supported research involving prisoners as subjects may not proceed until OHRP issues its approval in writing to the NYU Langone Health IRB on behalf of the Secretary under [45 CFR 46.306(a)(2)].

Under its authority at [45 CFR 46.115(b)], OHRP requires that the institution responsible for the conduct of the proposed research also submit to OHRP a copy of the research proposal so that OHRP can determine whether the proposed research involves one of the categories of research permissible under [45 CFR 46.306(a)(2)], and if so, which one.

The term "research proposal" as used above includes the IRB-approved protocol, any relevant HHS grant application or proposal, any IRB application forms required by the IRB, and any other information requested or required by the IRB to be considered during initial IRB review.

The above requirement does not apply to research that is not HHS conducted or supported.

Incarceration of Enrolled Subjects
If a subject becomes a prisoner while enrolled in a research study that was not reviewed according to Subpart C, the Principal Investigator must promptly notify the IRB and the IRB shall:

1. Confirm that the subject meets the definition of a prisoner.
2. Consult with the Principal Investigator to determine if it is in the best interests of the subject to continue participation in the study, in part or in full, and if so, if there are specific study activities which are in the best interests of the subject and should continue until the IRB is able to review the research study under Subpart C.
3. If the subject should continue, one of two options are available:
   a. Keep the subject enrolled in the study and review the research under Subpart C. If some of the requirements of Subpart C cannot be met or are not applicable (e.g., procedures for the selection of subjects within the prison), but it is in the best interests of the subject to remain in the study, keep the subject enrolled and inform OHRP of the decision along with the justification.
   b. Remove the subject from the study and keep the subject on the study intervention under an alternate mechanism such as compassionate use, off label use, etc.
4. If a subject is incarcerated temporarily while enrolled in a study:
   a. If the temporary incarceration has no effect on the study (i.e., there is no need for study activities to take place during the temporary incarceration), keep the subject enrolled.
   b. If the temporary incarceration has an effect on the study, follow the above guidance.

Requirements of the Prisoner Representative
For research reviewed by the convened IRBs involving prisoners:

The prisoner representative must be a voting member of the IRB.
The prisoner representative must review research involving prisoners and must receive all materials pertaining to the research (same as primary reviewers).
The prisoner representative must be present at a convened meeting when the research involving prisoners is reviewed. If the prisoner representative is not present, research involving prisoners cannot be reviewed or approved.
The prisoner representative must present his/her review either orally or in writing at the convened meeting of the IRB when the research involving prisoners is reviewed.
Minor modifications to previously approved research may be reviewed using the expedited procedure described below, using either of the two procedures described based on the type of modification.
Substantial modifications reviewed by the convened IRBs must use the same procedures for initial review including the responsibility of the prisoner representative.

Continuing review—must use the same procedures for initial review including the responsibility of the prisoner representative.

For research reviewed by the expedited procedure involving interaction with prisoners (including obtaining consent from prisoners):

- Research involving prisoners involving interaction with prisoners (including obtaining consent from prisoners) may be reviewed by the expedited procedure, if a determination is made that the research is Minimal Risk for the prison population being studied or included.
- The prisoner representative must concur with the determination of Minimal Risk.
- The prisoner representative must review the research as a reviewer or consultant. This may be as the sole reviewer of in addition to another reviewer or in place of another reviewer as appropriate.
- Review of modifications and continuing review must use the same procedures for initial review using this expedited process including the responsibility of the prisoner representative.

For research reviewed by the expedited procedure that does not involve interaction with prisoners (e.g. research involving existing data or record review):

- Research involving prisoners that does not involve interaction with prisoners may be reviewed by the expedited procedure, if a determination is made that the research is Minimal Risk for the prison population being studied or included.
- The prisoner representative may review the research as a reviewer or consultant if designated by the IRB chair, but review by the prisoner representative is not required.
- Review of modification and continuing review must use the same procedures for initial review using this expedited process including the responsibility of the prisoner representative.

**Waiver for Epidemiology Research**

The Secretary of DHHS has waived the applicability of [45 CFR 46.305(a)(l)] and [46.306(a)(2)] for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

- Studies in which the sole purposes are:
  - to describe the prevalence or incidence of a disease by identifying all cases, or
  - to study potential risk factor associations for a disease, and
  - where the IRB has approved the research and fulfilled its duties under [45 CFR 46.305(a)(2)–(7)] and determined and documented that:
    - the research presents no more than Minimal Risk and no more than inconvenience to the prisoner-subjects, and
    - prisoners are not a particular focus of the research.

The specific type of epidemiological research subject to the waiver should involve no more than Minimal Risk and no more than inconvenience to the human subjects. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in [45 CFR 46.306(a)(2)].

The range of studies to which the waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than Minimal Risk to the subjects.

In order for a study to be approved under this waiver, the IRB would need to ensure that, among other things, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
11.6. Persons who Lack Capacity to Provide Informed Consent for Research and Surrogate Consent

Individuals with reduced or impaired decision-making capacity may not be able to understand or appreciate information necessary to make a voluntary and informed decision about participating in research. Such individuals may be vulnerable to coercion and undue influence. This Policy is designed to protect the rights and welfare of these individuals, while also facilitating research into the very conditions and disorders which affect them.

This Policy applies to all research involving individuals 18 years of age or older who lack or who may lack the capacity to make a voluntary and informed decision to participate in research. This Policy applies to all such research regardless of funding source. Any research involving individuals who lack or who may lack capacity also must comply with applicable law, including those relating to assessment of capacity, authority to make health care decisions on behalf of another individual, and research involving persons living in an institution.

General Requirements for Surrogate Consent

Obtaining research informed consent from a representative of a subject who is 18 years of age or older rather than directly from the subject ("surrogate consent") requires prior approval of the IRB. Surrogate consent may be used only for such individuals who lack capacity to provide their own consent. Surrogate consent may be provided only by the subject’s Legally Authorized Representative (as defined in Section Legally Authorized Representatives).

Approval Criteria for Research Involving Use of Surrogate Consent

The IRB may approve use of surrogate consent only for studies that have the prospect of direct benefit to subjects directly or will answer a scientific question that will further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of the studied population, thereby benefitting those similarly situated in the future. Within this framework, the IRB may approve use of surrogate consent for research only if the research belongs to one of the following categories.

1. Research involving interventions or procedures that are considered minimal risk and present the prospect of direct benefit to the individual subject. The IRB may approve such studies if the risks are reasonable in relation to the prospective benefits. For new protocols, this is the only category of research involving surrogate consent that may be eligible for expedited review, subject to all other requirements as described in IRB Policies and Procedures, Expedited Review of Research.

2. Research involving interventions or procedures that are considered minimal risk and have no prospect of direct benefit to the individual subject, but are likely to yield generalizable knowledge about the subject’s disorder or condition. The IRB may approve such studies if important to advance to the scientific knowledge of a medical condition that affects the research population, and if the risks are reasonable in relation to such importance. For research in this category, the disorder, condition or factor that prevents the individual from having capacity to consent must be an intrinsic characteristic of the research population such that the research could not otherwise be conducted on subjects who have capacity.

3. Research involving interventions or procedures that are considered a minor increase over minimal risk but present the prospect of direct benefit to the individual subject. The IRB may approve such studies only if the risks are reasonable in relation to the prospective benefits, if the potential benefits are similar to those available in the standard clinical or treatment setting, and if the risk-benefit ratio is favorable to subjects.

4. Research involving interventions or procedures that are considered a minor increase.
over minimal risk and have no prospect of direct benefit to the individual subject, but are likely to yield generalizable knowledge about the subject’s disorder or condition. The IRB may approve such studies if vitally important to advance the scientific knowledge of a medical condition that affects the research population, and if the risks are reasonable in relation to such vital importance. For research in this category, the disorder, condition or factor that prevents the individual from having capacity to consent must be an intrinsic characteristic of the research population such that the research could not otherwise be conducted on subjects who have capacity.

5. Research involving interventions or procedures that are considered a more than a minor increase over minimal risk but present the prospect of direct benefit to the individual subject. The IRB may approve such studies only if the risks are reasonable in relation to the prospective benefits, if the potential benefits are similar to those available in the standard clinical or treatment setting, and if the risk-benefit ratio is favorable to subjects. Such ratios are less favorable when the risk is substantially more than a minor increase over minimal risk. Such ratios are more favorable when the prospect of direct benefit is more certain, or the benefit is expected to be more frequent or more significant.

In order to determine whether an intervention or procedure is a “minor increase over minimal risk” or if research is “vitally important,” the IRB will apply, as appropriate, principles for reviewing research involving children under federal regulations and applicable IRB policies.

A “minor increase over minimal risk” means that the increase in the probability and magnitude of harm is only slightly more than minimal risk, any potential harms associated with the procedure will be transient and reversible in consideration of the nature of the harm, and there is no or an extremely small probability that subjects will experience significant pain, discomfort, stress or harm.

Research is “vitally important” if there is clear and significant evidence that the use of such a procedure or intervention presents a reasonable opportunity to further the understanding of the etiologist, prevention, diagnosis, pathophysiology, or alleviation or treatment of a condition or disorder.

The Principal Investigator must provide sufficient safety and efficacy data to the IRB in order for the IRB to determine whether the research interventions or procedures present only a minor increase over minimal risk. Such data is especially critical for research in which there is no prospect of direct benefit.

The IRB shall have discretion to determine whether such procedures are appropriately classified for a given research population, since the serious medical, neurological and psychiatric illnesses that give rise to impaired consent capacity may also place these individuals at an increased risk of harm and discomfort from research participation as compared to a healthy population.

The IRB will especially scrutinize any research protocols that are designed to provoke symptoms, to withdraw subjects rapidly from therapies (“wash-out”), or to use placebo controls.

**Additional Safeguards**

The IRB will assess the level of risk and likelihood of direct benefit that the research offers to the research subject to assess the amount and scope of any additional safeguards for the research population. The higher the risk or the less prospect of direct benefit, the more protections will be required.

Protective measures include, but are not limited to, independent consent monitors (“ICMs”) and medically responsible clinicians (“MRCs”).
• An ICM is an individual not affiliated with the research who is designated by the IRB to monitor the informed consent process. The IRB may determine the role and responsibilities of the ICM, from monitoring the informed consent process to advocating on behalf of potential and current research subjects.

• A MRC is a licensed medical doctor who is skilled and experiences in working with the research population and is not affiliated with the research, who acts as an active advocate for cognitively-impaired research subjects.

The IRB will require researchers employing surrogate consent to use ICMs and MRCs for (1) any study involving more than a minor increase over minimal risk or (2) any study involving a minor increase over minimal risk with no prospect of direct benefit. The IRB will usually require use of ICMs and MRCs for any study involving a minor increase over minimal risk with the prospect of direct benefit. In all other cases, the IRB shall consider whether the use of ICMs and MRCs is necessary or appropriate to safeguard the interests of the research population.

**IRB Composition**

An IRB that reviews research which is expected to enroll individuals who lack or who may lack capacity must include at least one individual who is an expert in the area of research and at least one individual who is knowledgeable about or experienced in working with the relevant population. The IRB may also consider consulting with a member of the relevant population, a family member of such persons, or a representative of an advocacy group for the research population.

**Required Submissions to IRB**

The Principal Investigator must describe in the submission to the IRB whether the research is expected to enroll individuals who lack or who may lack capacity to provide informed consent. If so, the Principal Investigator must specify:

• The research population and the justification for the use of these individuals as the least burdened population and for specific institutional settings, if any.

• The process by which capacity would be assessed and by whom. Such process may include involvement of ICMs, or a justification for why assessment may not be required for a given research population. See Determination of Decision-Making Capacity.

• The process by which legal authority of surrogates will be verified. See Legally Authorized Representatives.

• The process by which prospective subjects and, if necessary, the Legally Authorized Representative, will be informed about any capacity assessment, determination, consequence of such determination (including whether it will be documented in the individual’s medical record), the identity of a surrogate, the nature of the research, and the opportunity to assent, to the extent compatible with the subject’s understanding, prior to enrollment. See Notification and Assent of Subjects Who Lack Capacity.

• An appropriate monitoring plan that:
  o Describes how capacity will be monitored throughout the duration of the study, including a plan for obtaining re-consent by the subject (if any subject is reasonably expected to regain capacity) or by an Legally Authorized Representative (if any subject is reasonably expected to lose capacity), or why such processes may not be required for a given research population;
  o Minimizes risks and negative impact on the subject’s well-being, which may include involvement of MRC and must require regular communication with the Legally Authorized Representative; and
Requires that subjects who appear to be unduly distressed must be withdrawn from the research in a manner consistent with good clinical practice.

**Determination of Decision-Making Capacity**

The method used to assess capacity should be tailored to the research population, the level of study risk, and the likelihood that the study will involve subjects with impaired consent capacity, and should be in accordance with applicable law. In general, the IRB considers individuals who are unable to consent for their own clinical care to be unable to consent to participate in research.

For research conducted in New York State, the IRB will require investigators to consult with a licensed physician(s) who shall perform the capacity assessment in accordance with applicable law. In general, the individual performing the assessment should be a clinician familiar with the relevant population and qualified to assess and monitor capacity of such subjects on an ongoing basis. Ideally, the individual performing the assessment should not be otherwise involved in the research. The IRB will consider the qualifications of the proposed individual(s) and whether he or she is sufficiently independent of the research team. Where the reason for lack of capacity is mental illness, New York State law requires that a psychiatrist or licensed psychologist document this determination in the individual’s medical record in a signed and dated progress note [New York State Public Health Law 2994-C].

For research conducted outside of New York State, determination of capacity will be considered by the IRB in accordance with applicable local law.

For research in which recruitment of individuals with impaired consent capacity is not expected at the time of IRB submission, judgment that prospective subjects have the capacity to consent to the research can ordinarily be made informally during routine interactions with the individual during the consent process. An investigator who questions a prospective subject’s capacity to consent may not enroll the individual and should consult with the IRB.

**Legally Authorized Representatives**

Surrogate consent may only be provided by a subject’s “Legally Authorized Representative.” A Legally Authorized Representative is an individual or judicial or other body authorized under applicable local law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research.

In New York State, the following persons are considered Legally Authorized Representatives who may act as a surrogate under this Policy, in order of priority:

- A court-appointed Legally Authorized Representative/guardian or a guardian authorized to decide about health care pursuant to Article 81 of the Mental Hygiene Law.
- An individual who is designated as a representative/agent through a health care proxy signed by both the subject and the appointed representative/agent. For a health care proxy to be effective, it must have been signed at a time when the subject had decision-making capacity. In addition, the health care proxy must not specifically prohibit research.
- The spouse, if not legally separated from the subject, or domestic partner.
- A son or daughter 18 years of age or older.
- A parent.
- A sibling 18 years of age older.
- A step-child, step-sibling, step-parent, grandparent or grandchild 18 years of age or older who has maintained such regular contact with the subject as to be familiar with the subject’s activities, health or beliefs.

The IRB shall have discretion to limit the classes of persons who may act as the Legally Authorized Representative for a given study, given that each class of persons may have varying degrees of understanding of the wishes of the impaired individual regarding research participation. In general, the
riskier the research protocol and more remote the prospect of direct benefit, the closer (by kinship or intimacy level) the Legally Authorized Representative should be to an impaired individual in order to consent to the impaired individual’s participation in research.

The person highest on the priority list who is willing, competent and available shall be the surrogate, unless that person designates another person from the list and no one higher on the priority list than the newly-designated person objects.

The Principal Investigator shall describe how he or she will verify the legal authority of any surrogate.

The relationship of the surrogate to the individual must be documented on the signed informed consent form.

For research conducted outside of New York State, the categories of persons who may act as Legally Authorized Representatives will be considered by the IRB in accordance applicable state or local law.

**Notification and Assent of Subjects Who Lack Capacity**

The Principal Investigator must describe in the submission to the IRB the process by which prospective subjects and, if necessary, the Legally Authorized Representative, will be informed about any capacity assessment to be performed, the results of the assessment, and any consequences of a determination of incapacity. Such notice to the prospective subject shall include the identity of a surrogate should the assessment determine lack of capacity, the nature of the research, and the opportunity to assent. The IRB shall require assent to the extent and in a manner compatible with the prospective subject’s understanding.

If the prospective subject objects to the capacity determination, proposed surrogate, or decision to participate in research, such person may not be enrolled in the research unless otherwise required by law.

Once enrolled, no subject shall be required to continue to take part in research over his/her objection at any point, unless specifically authorized by a court of competent jurisdiction. Any early withdrawal of a subject shall be done in a manner consistent with good clinical practice.

**Additional Considerations**

**Subjects Whose Capacity May Change After Enrollment**

Individuals who lack capacity to consent should be included in the process of consent to the extent possible. The IRB shall require assent to the extent and in a manner compatible with the prospective subject’s understanding.

For some research populations, decision-making capacity may be reasonably expected to change during the course of the research study.

The Principal Investigator is always responsible for assessing the decision-making capacity of subjects enrolled in any research study.

If a subject unexpectedly loses capacity after enrollment, and the IRB has not prospectively approved a monitoring plan to address this circumstance, the Principal Investigator must notify the IRB. See **Required Reports to the IRB**. In most cases, the IRB will require re-consent by a Legally Authorized Representative in order for the subject to continue to participate in the research.

- For research involving subjects who have capacity to provide informed consent at the time of enrollment but who may be reasonably expected to lose such capacity during the course of the
For research involving subjects who may be reasonably expected to regain capacity during the course of the research study, the Principal Investigator must submit to IRB a plan that addresses how capacity will be monitored and establishes how re-consent by the subject will be sought if he or she regains capacity. A subject who regains capacity must re-consent in order to remain in the study. Such re-consent process must disclose all research procedures performed to date and all research procedures that remain to be performed, and allow the subject the opportunity to continue in or withdraw from the study. The subject must sign the informed consent document. If not, the subject must be withdrawn from the study in a manner consistent with good clinical practice.

Subjects with Decisional Impairment who are Determined to Have Sufficient Capacity to Consent

The NYU Langone Health IRBs recognize that decisional capacity varies along a continuum, and that the ability to provide voluntary and informed consent to participate in research may depend on factors that are specific to each protocol, such as protocol design, risks, anticipated benefits and safeguards. If appropriate, the IRB may require a Principal Investigator to include steps in the informed consent process in order to enable persons with some decisional impairment to make voluntary and informed decisions to consent to (or to refuse participation in) research, such as:

- Involvement of a trusted individual in the decision-making process.
- Allocation of additional time for the consent process.
- Waiting periods after initial discussion before enrollment.
- Repetitive teaching.
- Oral or written recall tests to assess subject understanding.
- Audiovisual presentations.
- Group sessions.
- Videotaping or audio-taping of consent interviews.
- Use of independent consent monitors to observe the consent process.

12. Complaints, Non-Compliance and Suspension or Termination of IRB Approval of Research

12.1. Complaints

As part of its commitment to protecting the rights and welfare of human subjects in research, the NYU Langone Health IRBs review all complaints and allegations of non-compliance and takes any necessary action to ensure the ethical conduct of research.

Complaints reported to the NYU Langone Health IRB will be evaluated as possible Unanticipated Problems involving risks to subjects or others under Unanticipated Problems.
A Chair of the IRB and the IRB Director will promptly handle (or delegate staff to handle), and, if necessary, investigate all complaints, concerns, and appeals received by the NYU Langone Health IRBs. This includes complaints, concerns, and appeals from investigators, research subjects and others.

All complaints, written or verbal (including telephone complaints), and regardless of point of origin, are recorded and forwarded to the IRB Chair and IRB Director.

Upon receipt of the complaint, the IRB Chair will ensure that the complaint is logged and make a preliminary assessment whether the complaint warrants immediate suspension of the research project. If a suspension is warranted, the procedures in Suspension will be followed.

If the complaint alleges non-compliance with any regulations and policies described in this Policy and/or failure to follow the IRB’s determinations, it will be considered an allegation of non-compliance according to Non-Compliance. If the complaint meets the definition of an Unanticipated Problem involving risk to subjects or others, it will be handled according to Unanticipated Problems.

Any external IRB that is duly authorized to review NYU Langone Health research must follow its own procedures for review and notification to NYU Langone Health of allegations of non-compliance, as well as the applicable terms of the IRB reliance agreement.

12.2. Non-Compliance

All members of the NYU Langone Health community who are involved in human subjects research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional and IRB policies governing the conduct of research involving human subjects.

Investigators and their study staff are required to report instances of possible non-compliance. The Principal Investigator is responsible for reporting any possible non-compliance by study personnel* to the IRB. Common reports to the IRB that are not serious or continuing are typically protocol violations. However, any individual or employee may report observed or apparent instances of non-compliance to the IRB. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality and cooperating with any IRB and/or institutional review of these reports.

If an individual, whether an investigator, study staff or other, is uncertain whether there is cause to report non-compliance, he or she may contact the IRB Chair directly to discuss the situation informally.

Reports of non-compliance must be submitted to the IRB Office within ten (10) working days of discovery of the alleged non-compliance. The report must include a complete description of the non-compliance, the personnel involved, and a description of the non-compliance.

Complainants may choose to remain anonymous.

*Study personnel include the Principal Investigator and any staff member directly involved with subjects or the informed consent process.

Definitions

Non-Compliance

means failure to comply with any of the regulations and policies described in this Policy manual and failure to follow the determinations of the IRB. Non-compliance may be minor or sporadic or it may be Serious or Continuing.
**Serious Non-Compliance**

means failure to follow any of the regulations and policies described in this Policy manual or failure to follow the determinations of the IRB and which, in the judgment of either the IRB Chair or the convened IRB, increases risks to subjects, decreases potential benefits, or compromises the integrity of the human research protection program. Examples of Serious Non-Compliance include: research being conducted without prior IRB approval; and participation of subjects in research activities without their prior consent (in studies where consent was not specifically waived by the IRB). A single instance of Non-Compliance may be determined to be Serious Non-Compliance.

**Continuing Non-Compliance**

means a pattern of Non-Compliance that, in the judgment of the IRB Chair or convened IRB, suggests a likelihood that instances of Non-Compliance will continue without intervention. Continuing Non-Compliance includes failure to respond to request to resolve an episode of Non-Compliance. Generally, Non-Compliance is not considered “continuing” upon initial reports or audits identifying Non-Compliance but is typically found only after repeated Non-Compliance findings.

** Allegation of Non-Compliance**

means an unproven assertion of Non-Compliance.

**Finding of Non-Compliance**

means an allegation of Non-Compliance that is proven true or a report of Non-Compliance that is clearly true. (For example, a finding on an audit of an unsigned consent document, or an admission of an investigator that the protocol was willfully not followed would represent reports of Non-Compliance that would require no further action to determine their truth, and would therefore represent findings of Non-Compliance.) Once a finding of Non-Compliance is proven, it must be categorized as Serious, non-serious, or Continuing.

**IRB Review of Allegations of Non-Compliance**

All allegations of Non-Compliance that are brought to the IRB will be reviewed by the IRB Chair and the IRB Director. They will review:

- all documents relevant to the allegation;
- the last approval letter from the IRB;
- the last approved IRB application and protocol;
- the last approved consent document;
- the last approved investigator’s brochure, if applicable;
- the associated grant (if applicable); and
- any other pertinent information (e.g., questionnaires, DSMB reports, etc.).

The IRB Chair and the IRB Director will review the allegation and make a determination as to the truthfulness of the allegation. They may request additional information or an audit of the research in question.

When, upon review of the information and/or results of an audit of the research in question, the IRB Chair and Director determine that Non-Compliance did not occur because the incident was within the limits of an approved protocol for the research involved, the determination is reported in writing to the Principal Investigator and, if applicable, the reporting party. The determination letter will be copied to the IO in cases where the IO and any other parties had been notified at the outset.

If, in the judgment of the IRB Chair and IRB Director, the reported allegation of Non-Compliance is not true, no further action will be taken. If, in the judgment of the IRB Chair and IRB Director, the reported allegation of Non-Compliance is true, the Non-Compliance will be processed according to [Review of Findings of Non-Compliance](#).
If, in the judgment of the IRB Chair and IRB Director, any allegation or findings of Non-Compliance warrants suspension of the research before completion of any review or investigation to ensure protection of the rights and welfare of subjects, the IRB Chair may suspend the research as described in below in Suspension or Termination with subsequent review by the IRB.

The IRB Chair may determine that additional expertise or assistance is required to make these determinations and may form an ad hoc committee to assist with the review and fact gathering process. When an ad hoc committee assists in the review process, the IRB Chair is responsible for assuring that minutes of the meeting are generated and kept to help support any determinations or findings made by the ad hoc committee.

**Review of Findings of Non-Compliance**

If, in the judgment of the IRB Chair and IRB Director, the reported finding of Non-Compliance is not Serious, not Continuing, and the proposed corrective action plan seems adequate, no further action is required and the IRB is informed at the next convened meeting. Otherwise, the matter will be presented to the IRB at a convened meeting with a recommendation that a formal inquiry (described below) will be held.

All findings of Non-Compliance referred to the IRB will be reviewed at a convened meeting. All IRB members will receive:

- all documents relevant to the allegation;
- the last approval letter from the IRB;
- the last approved IRB application; and
- the last approved consent document.

At this stage, the IRB may:

- find that there is no issue of Non-Compliance;
- find that there is Non-Compliance that is neither Serious nor Continuing and an adequate corrective action plan is in place;
- find that there may be Serious or Continuing Non-Compliance and direct that a formal inquiry (described below) be held; and/or
- request additional information.

**Inquiry Procedures**

A determination may be made by the IRB that an inquiry is necessary based on several issues that may include, but are not limited to:

- subjects' complaint(s) that rights were violated;
- report(s) that the Principal Investigator or other investigator is not following the protocol as approved by the IRB;
- unusual and/or unexplained adverse events in a study;
- FDA audit report of an investigator; or
- repeated failure of the Principal Investigator to report required information to the IRB.

A subcommittee is appointed consisting of IRB members, and non-members if appropriate, to ensure fairness and expertise. The subcommittee is given a charge by the IRB, which can include any or all of the following:

- review of protocol(s) in question;
- review of FDA or sponsor audit report of the investigator, if appropriate;
- review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files etc., as they relate to the investigator's
execution of her/his study involving human subjects;
- interview of appropriate personnel if necessary;
- preparation of either a written or oral report of the findings, which is presented to the full IRB at its next meeting; and/or
- recommend actions if appropriate.

**Final Review**

The results of the inquiry will be reviewed at a convened IRB meeting where the IRB will receive a report from the subcommittee. If the results of the inquiry substantiate the finding of Serious or Continuing Non-Compliance, the IRB’s possible actions could include, but are not limited to:

- request a corrective action plan from the Principal Investigator;
- verification that subject selection is appropriate and observation of the actual informed consent;
- an increase in data and safety monitoring of the research activity;
- request a directed audit of targeted areas of concern;
- request a status report after each subject receives intervention;
- modify the continuing review cycle;
- request additional Principal Investigator and staff education;
- notify current subjects, if the information about the Non-Compliance might affect their willingness to continue participation;
- require modification of the protocol;
- require modification of the information disclosed during the informed consent process;
- requiring current subjects to re-consent to participation;
- suspend the study (see below); and/or
- terminate the study (see below).

In cases where the IRB determines that the event of Non-Compliance also meets the definition of Unanticipated Problem involving risks to subjects or others, the Policy and Procedure for review of such events will also be followed.

The Principal Investigator is informed of the IRB determination and the basis for the determination in writing and is given a chance to respond. If the IRB determines that the Non-Compliance was Serious or Continuing, the results of the final review will be reported as described below in Reporting.

**Additional Actions**

A finding of Serious or Continuing Non-Compliance may also result in the following sanctions, among others:

- suspension or termination of IRB approval of specific research protocols or of all research involving human subjects in which the investigator participates;
- sponsor actions: in making decisions about supporting or approving applications or proposals covered by this Policy, the DHHS or sponsoring agency may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension as described above, and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the DHHS or agency, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects;
- OHRP and/or FDA action against the institution or individual(s). The OHRP and/or the FDA may:
  - withhold approval of all new studies by the IRB;
  - direct that no new subjects be added to any ongoing studies;
  - terminate all ongoing studies, except when doing so would endanger the subjects; and/or
  - notify relevant state, federal and other interested parties of the violations.
- individual disciplinary action of the Principal Investigator or other personnel involved in a study, up to and including dismissal, pursuant to institutional policies and procedures.
Failure to secure necessary NYU Langone Health IRB approval before commencing human subjects research must be reported to the appropriate Dean for Research for disciplinary action.

NYU Langone Health investigators should also be aware that, in general, they are indemnified under NYU Langone Health policies from liability for Adverse Events that may occur in NYU Langone Health studies approved by the NYU Langone Health IRB. Failure to follow approved procedures may compromise this indemnification and make the investigator personally liable in such cases.

12.3. **Suspension or Termination of a Study**

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects. Suspension of IRB approval is a directive of the convened IRB or IRB Chair or IRB Director either to temporarily stop all previously approved research activities short of permanently stopping all previously approved research activities. Suspended protocols remain open and require continuing review. The IRB Chair or IRB Director may suspend research to ensure protection of the rights and welfare of subjects. Suspension directives made by the IRB Chair or IRB Director must be reported to a meeting of the convened IRB.

Termination of IRB approval is a directive of the convened IRB to stop permanently all activities in a previously approved research protocol. Terminated protocols are considered closed and no longer require continuing review.

Research may only be terminated by the convened IRB. Terminations of protocols approved under expedited review must be made by the convened IRB.

The IRB shall notify the Principal Investigator in writing of such suspensions or terminations of IRB approval and shall include a statement of the reasons for the IRB’s actions and explicit terms and conditions of the suspension. The Principal Investigator will be provided with an opportunity to respond in person or in writing.

When study approval is suspended or terminated by the convened IRB or an authorized individual, in addition to directing the stop of all research activities, the convened IRB or individual ordering the suspension or termination will consider whether procedures for withdrawal of enrolled subjects are necessary to protect their rights and welfare of subjects, which may include any of the procedures listed in “Protection of Currently Enrolled Subjects” below.

If follow-up of subjects for safety reasons is permitted/required by the convened IRB or individual ordering the suspension or termination, the convened IRB or individual ordering the suspension or termination will require that the subjects should be so informed and that any Adverse Events/outcomes be reported to the IRB and the study sponsor.

In the case of study suspension, the Principal Investigator MUST continue to provide reports on Adverse Events and Unanticipated Problems to both the IRB and study sponsor just as if there had never been a suspension (i.e., all events that need to be reported during a study need to continue to be reported during the suspension period.)

*Note: Suspension or termination of protocols approved by the IRB can also be issued by the institution’s administrative officials acting outside of, and unrelated to, the IRB (i.e., not necessarily related to protecting the rights and welfare of study subjects). Such administrative actions may be made for any reason in furtherance of the institution’s interest. The Principal Investigator must report any suspension or termination of the conduct of research by the institution’s administrative officials.*
Investigator Hold

A Principal Investigator may request an administrative hold on a study protocol when the Principal Investigator wishes to temporarily stop some or all approved research activities. Administrative holds are not suspensions or terminations of IRB approvals; however, the IRB may decide to suspend or terminate an IRB approval regardless of whether a Principal Investigator has requested an administrative hold.

Procedures

Principal Investigator must make requests to the IRB for an administrative hold on his/her study in writing, which should include:

- a statement that they are voluntarily placing a study on administrative hold;
- a description of the research activities that will be stopped;
- proposed actions to be taken to protect current subjects; and
- actions that will be taken prior to IRB approval of proposed changes in order to eliminate apparent immediate harm.

Upon receipt of written notification from the Principal Investigator, the IRB Office staff will place the study on the IRB agenda for review.

The IRB Chair and/or Director, in consultation with the Principal Investigator, will determine whether any additional procedures need to be followed to protect the rights and welfare of current subjects as described in “Protection of Currently Enrolled Subjects” below. Suspensions of new enrollment pursuant to a Principal Investigator-initiated hold must be reported to the research sponsor(s).

The IRB Chair and/or Director, in consultation with the Principal Investigator, determine how and when currently enrolled subjects will be notified of the administrative hold.

A Principal Investigator may request a modification of the administrative hold by submitting a request for a modification to previously approved research.

Protection of Currently Enrolled Subjects

Before an administrative hold, termination, or suspension of a study is put into effect, the convened IRB or IRB designee considers whether any additional procedures need to be followed to protect the rights and welfare of current subjects. Such procedures might include:

- transferring subjects to another investigator participating in the study;
- making arrangements for clinical care outside the research;
- allowing continuation of some research activities under the supervision of an independent monitor;
- requiring or permitting follow-up of subjects for safety reasons;
- requiring Adverse Events or outcomes to be reported to the IRB and the study sponsor;
- notification of current subjects; or
- notification of former subjects.

12.4. Reporting

Serious or Continuing Non-Compliance, Unanticipated Problems posing risks to subjects or others and suspensions or terminations of IRB approvals must be reported to the appropriate regulatory agencies and institutional officials according to the procedures in Reporting to Regulatory Agencies and Institutional Officials.
13. Reporting to Regulatory Agencies and Institutional Officials

For applicable studies, federal regulations require prompt reporting to appropriate institutional officials, and government oversight agencies of (i) any Unanticipated Problems involving risks to subjects or others, (ii) any Serious or Continuing Non-Compliance or (iii) any suspension or termination of IRB approval. The NYU Langone Health IRB will comply with this requirement and the following procedures describe how these reports are handled.

The IRB Office will initiate these reporting procedures as soon as the IRB takes any of the following actions:

- determines that an event may be considered an Unanticipated Problem involving risks to subjects or others;
- determines that Non-Compliance was Serious or Continuing; and/or
- suspends or terminates IRB approval of research.

The IRB Office staff (manager, senior specialist, or specialist) will prepare a letter that contains the following information:

- the nature of the event (Unanticipated Problem involving risks to subjects or others, Serious or Continuing Non-Compliance, suspension or termination of IRB approval of research);
- name of the institution conducting the research;
- title of the research project and/or grant proposal in which the problem occurred;
- name of the Principal Investigator on the protocol;
- number/identifier of the research project assigned by the NYU Langone Health IRB and the number of any applicable federal award(s) (e.g., grant, contract, or cooperative agreement);
- a detailed description of the problem including the findings of the organization that conducted an audit/investigation of the alleged Non-Compliance and the reasons for the IRB’s decision;
- actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.); and
- plans, if any, to send a follow-up or final report by the earlier of a specific date when an investigation has been completed or a corrective action plan has been implemented.

The IRB Chair and the IRB Director will review the letter and modify the letter as needed.

The IRB Director will sign the letter and return it to the IRB Office staff, who sends a copy of the report to:

- the IRB by including the letter in the next agenda packet as an information item;
- the IO;
- OHRP, if the study is subject to DHHS regulations or subject to a DHHS federal wide assurance (FWA);
- the FDA, if the study is subject to FDA regulations;
- if the study is conducted or funded by any federal agency other than DHHS that is subject to the Common Rule, the report is sent to OHRP or the head of the agency as required by the agency;

  - Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization and the agency has been notified of the event by the Principal Investigator, study sponsor, another institution, or other mechanisms.
- the Principal Investigator;
The IRB Director ensures that all steps of this Policy are completed within ten (10) days of the initiating action whenever feasible. For more serious actions, the IRB Director will expedite reporting.

14. Investigational Drugs & Devices in Research

The following procedures describe the use of investigational drugs and devices in research conducted under the auspices of NYU Langone Health. Use of investigational drugs must be conducted according to FDA IND regulations, [21 CFR Part 312], other applicable FDA regulations, and institutional policies. Use of an investigational device in a Clinical Trial to obtain safety and effectiveness data must be conducted according to FDA's IDE regulations, [21 CFR Part 812], and other applicable FDA regulations. The IRB will provide written documentation of approval to the Principal Investigator with a determination of whether the investigational device presents a significant or non-significant risk as used in the research.

14.1. Definitions

Investigational Drug
means an investigational drug for clinical research use is one for which the Principal Investigator or a sponsor has filed an IND application [21 CFR Part 312], or an FDA-approved drug that is being studied for an unapproved or approved use in a controlled, randomized, or blinded Clinical Trial.

Investigational Device
means a medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. As further stated, a “medical device” is any healthcare product that does not achieve its principal intended purpose by chemical action or by being metabolized. The Investigational Device Exemption (IDE) regulations [21 CFR part 812] describes two types of device studies; “significant risk” (SR) and “non-significant risk” (NSR).

Investigational New Drug (IND)
means an Investigational New Drug application in accordance with [21 CFR Part 312].

Investigational Drug Exemption (IDE)
means an Investigational Device Exemption in accordance with [21 CFR 812].

Emergency Use
refers to the use of a Test Article with a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)].

Test Article
means any drug, biological product, or medical device for human use [21 CFR 56.102(1)].

Significant Risk (SR) Device
means [21 CFR 812.3(m)] a medical device that presents a potential for serious risk to health, safety, or welfare of a subject and
• is intended as an implant;
• is used in supporting or sustaining human life;
• is of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise prevents impairment of human health; and
• otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

**Non-Significant Risk (NSR) Device**

means an investigational medical device that does not meet the definition for a significant risk device.

**Humanitarian Use Device (HUD)**

means a device intended to benefit patients by treating or diagnosing a disease that affects fewer than 8,000 individuals in the United States per year.

### 14.2. FDA Exemptions

The following categories of clinical investigations are not regulated by DHHS or any other federal agency and are exempt from the requirements of FDA regulations for IRB review:

**Emergency Use of a Test Article**

Emergency use of a Test Article is exempt from prior IRB review and approval, provided that such emergency use is reported to the IRB within five (5) working days. Any subsequent use of the Test Article at the institution is subject to IRB review. [21 CFR §56.104(c)] Tracking of use of a Test Article at NYU Langone Health is a shared responsibility of the IRB Office and NYU Langone Health’s Research Regulatory Services (RRS) office.

**Taste and Food Quality Evaluations and Consumer Acceptance Studies**

If wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. [21 CFR §56.104(d)]

### 14.3. IND/IDE Requirements

When the principal intent of the investigational use of a Test Article is to develop information about the product’s safety or efficacy, an Investigational New Drug (IND) or Investigational Device Exemption (IDE) may be required.

Investigators will be asked through the IRB application to indicate whether the research involves drugs or devices. If so, they will be asked if there is an IND/IDE for the research. If there is, they will be asked for evidence of the IND/IDE, which could be in the form of:

• an industry sponsored protocol with IND/IDE;
• a letter from FDA;
• a letter from industry sponsor; and/or
• other document and/or communication verifying the IND/IDE.

Note: An IND goes into effect thirty (30) days after the FDA receives the IND, unless the sponsor receives earlier notice from the FDA.

If the research involves drugs or devices and there is no IND/IDE, the Principal Investigator must provide a rationale why it is not required. The rationale could be in the form of:

• a letter from FDA;
• protocol with justification for exemption from IND/IDE (as applicable); and/or
• a letter from an industry sponsor (or investigator-sponsor).
For studies involving drugs, an IND may not be necessary if all of the following conditions are met (21 CFR 312.2(b)(1)):

- The drug or drugs being studied in the research is lawfully marketed in the United States;
- The research is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use or to support any other significant change in the labeling for the drug;
- The research is not intended to support a significant change in the advertising for the product;
- The research does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
- The research is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50], respectively;
- The research is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]; and
- The research does not intend to invoke [21 CFR 50.24]: exception from informed consent requirements for emergency research.

For clinical investigations involving an in vitro diagnostic biological product (i.e., one or more of the following: (a) blood grouping serum, (b) reagent red blood cells, or (c) anti-human globulin), an IND is not necessary if:

(a) it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure; and
(b) it is shipped in compliance with 21 CFR 312.160.

If the research is a clinical investigation involving use of a placebo and does not otherwise require submission of an IND, an IND is not necessary.

For studies involving Medical Devices, an IDE may not be necessary if any of the following conditions are met:

- There is a claim that the device is a non-significant risk device (NSR);
- The research involves a device other than a transitional device, in commercial distribution immediately before May 28, 1976 when used or investigated in accordance with the indications in labeling in effect at that time;
- The research involves a device other than a transitional device, in commercial distribution immediately before May 28, 1976 that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of [21 CFR 807] in determining substantial equivalence;
- The research involves a diagnostic device, if the sponsor complies with applicable requirements in [21 CFR 809.10(c)] and if the testing:
  - is noninvasive;
  - does not require an invasive sampling procedure that presents significant risk;
  - does not by design or intention introduce energy into a subject; and
  - is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- The research involves a device undergoing consumer preference testing, testing of a modification, testing of a combination of two or more devices in commercial distribution, or if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk;
- The research involves a device intended solely for veterinary use;
- The research involves a device shipped solely for research on or with laboratory animals and labeled in accordance with [21 CFR 812.5(c)]; or
- The research involves a custom device as defined in [21 CFR 812.3(b)], unless the device is being used to determine safety or effectiveness for commercial distribution.
If a sponsor (or investigator-sponsor) has identified a study as a NSR device study, then the Principal Investigator must provide an explanation of the NSR determination, which could be in the form of:

- an industry protocol with NSR justification;
- a letter from the FDA; or
- a letter from the study’s industry sponsor, if applicable (or investigator-sponsor).

A study may be determined to be an NSR device study based on any of the following criteria:

- The device being studied is not intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject;
- The device being studied is not purported or represented to be for use in supporting or sustaining human life and does not present a potential for serious risk to the health, safety, or welfare of a subject;
- The device being studied is not for use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does not present a potential for serious risk to the health, safety, or welfare of a subject; or
- The device being studied does not otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

If the FDA has determined that the study is a NSR device study, documentation of that determination must be provided.

**Abbreviated IDE Requirements**

For Investigational Devices, NSR device studies follow abbreviated IDE requirements and are not required to have an IDE application approved by the FDA.

Under the abbreviated IDE requirements, the following categories of investigations are considered to have approved applications for IDE’s, unless the FDA has notified a sponsor under 21 CFR 812.20(a) that approval of an IDE application is required:

1. An investigation of a device other than a significant risk (SR) device, if the device is not a banned device and the sponsor (or sponsor-investigator):
   - (i) Labels the device in accordance with 21 CFR 812.5;
   - (ii) Obtains IRB approval of the investigation after presenting the reviewing IRB with an explanation of why the device is not a significant risk device, and maintains such approval;
   - (iii) Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent under 21 CFR Part 50 and documents such informed consent, unless documentation is waived by an IRB under 21 CFR 56.109(c);
   - (iv) Complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations of Investigational Devices;
   - (v) Maintains the records required under 21 CFR 812.140(b) (4) and (5) and makes the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10);
   - (vi) Ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 21 CFR 812.150(a) (1), (2), (5), and (7); and
   - (vii) Complies with the prohibitions in 812.7 against promotion and other practices.
If there is no submission to the FDA, the IRB Office staff will confirm that sufficient documentation is provided to demonstrate that the study meets NSR criteria or qualifies for one of the exemptions from IND/IDE requirements (as applicable).

The IRB will then review the IRB application and, based upon the documentation provided, determine: (a) that there is an approved IND/IDE in place, (b) that the FDA has determined that an IND is not required or that the study is exempt or is a NSR device study, or (c) if neither of the above, whether or not an IND/IDE is necessary, or that the device study is exempt or is a NSR device study, using the criteria above. In cases when the IRB determines a study does not meet the proposed IND/IDE exemption or NSR criteria, the IRB will require submission to the FDA. The FDA will make the determination and is the final arbiter. The IRB will not grant approval to the research until the IND/IDE status is determined, and, if necessary, an approved IND or IDE is in place.

14.4. Investigator-Sponsors

In reviewing research involving FDA-regulated Test Articles, the IRB will determine if the study will be conducted under an NYU Langone Health investigator-sponsor. If so, the IRB will inform the Principal Investigator that there are sponsor responsibilities applicable to IND or IDE studies, including reporting requirements to the FDA, (as well as the Principal Investigator responsibilities) and that all these requirements are his/her responsibility. The Principal Investigator is directed to the NYU Langone Health IRB Guidance for Special Considerations for the Oversight of Research Protocols in FDA-regulated Drug or Device Studies.

Staff from the NYU Langone Health Office of Research Regulatory Affairs – Research Regulatory Services will visit the investigator-sponsor before initiation of the research to determine compliance with these FDA regulatory requirements. If compliance has been demonstrated, the investigator-sponsor may begin the research. The Research Regulatory Services staff will evaluate whether the Principal Investigator is knowledgeable about the regulatory requirements of sponsors and will follow them. An internal audit of the study will take place after the enrollment of the first two (2) subjects in such study.

If the research involves drugs or devices and there is no IND/IDE, the investigator will be asked for a rationale as to why it is not required.

The NYU Langone Health IRB Office will conduct education programs for Principal Investigators holding an IND or IDE on the applicable regulations.

The IRB will review the IRB application and determine:

- whether there is an IND/IDE and if so, whether there is appropriate supporting documentation; and
- if there are drugs or devices involved, but no IND/IDE, whether the research meets the above criteria.

14.5. Responsibilities in Research of Investigational Drugs and Devices

Principal Investigator

The Principal Investigator is responsible for ensuring that the drug/device research is conducted according to all regulatory requirements, guidelines, and IRB and institutional policies and procedures, including obtaining approval from the IRB. For studies where the Principal Investigator files for and
conducts a study under an IND or IDE, the Principal Investigator is considered the sponsor-investigator and as such carries all of the FDA regulatory responsibilities and reporting obligations of both the Principal Investigator and the sponsor as described in the FDA regulations.

The Principal Investigator proposing the drug/device research will be required to provide a research plan that will be evaluated by the IRB, which should include the plan for:

- drug/device storage;
- maintaining security of the drug/device; and
- dispensation of the drug/device.

The Principal Investigator is responsible for the accountability of Investigational Drug/Device including receipt, storage, security, dispensation, administration, return, disposition, and keeping Investigational Drug/Device accountability records. The Principal Investigator may delegate the responsibility for drugs/device/biologic accountability to responsible staff of an investigational pharmacy.

If, because of special circumstances, an Investigational Drug is not stored in the designated investigational pharmacy, the Principal Investigator is responsible for the proper storage, security and dispensation of the Drug/Device. The Principal Investigator must complete and submit an investigational control sheet containing information on the plan for storage, security and dispensing of the drug or device to the IRB prior to its approval of the study. All Investigational Drugs and Devices received for use in a study must be stored in a secure, limited access area that is within an area of the Principal Investigator’s control. Drugs require additional security; the storage area must be locked. Proper instructions on the use of the Investigational Drug or Device must be provided to the study subjects. A log must be kept regarding the receipt, use and/or dispensing of the Investigational Drug and/or Device and the disposition of remaining supplies at the conclusion of the study.

The Principal Investigator is responsible for reporting all unexpected Adverse Events associated with the use of an Investigational Drug/Device to the FDA within fifteen (15) calendar days from initial receipt of the information if the Principal Investigator is the sponsor-investigator, and to the study sponsor, as applicable, in accordance with timelines proscribed by the sponsor in the study protocol. Unexpected fatal or life-threatening Adverse Events suspected to be related to use of the Investigational Drug/Device should be reported to the FDA as soon as possible but not later than seven (7) calendar days from initial receipt of the information. All Adverse Events that require prompt reporting to the IRB must be reported according to the IRB Policies and Procedures on Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events.

**Pharmacy Notification and Record-Keeping Requirements for Research Involving Investigational Drugs**

- The Principal Investigator is responsible for informing the applicable pharmacy that IRB approval has been obtained for a study involving Investigational Drugs. In addition, a signed copy of the IRB-approved consent form must be provided to the pharmacy to document each subject’s consent to participate in the study prior to Investigational Drug being dispensed to such subject.

- The Principal Investigator must inform the appropriate IRB and the applicable pharmacy when a study involving Investigational Drugs has been terminated.

- Where allowed, or required, the Principal Investigator may assign some or all duties for Investigational Drug accountability at the study sites to a qualified pharmacist or another appropriate individual who is under the supervision of the Principal Investigator.

The Principal Investigator or the pharmacist, or other designated individual must maintain records of the Investigational Drug’s delivery to the applicable study site, the Investigational Drug inventory at the study
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Receipt logs are maintained for all Investigational Drugs. Documentation of the following elements (as applicable) is required for each drug used:

- Name of drug
- Dosage and strength
- Lot and/or batch number
- Date received from supplier
- Shipment/packing slip number
- Expiration date of drug
- Number of boxes/kits received
- Condition of drug (intact/damaged)
- Recipient initials

Accountability logs are maintained for all Investigational Drugs. Documentation of the following elements (as applicable) is required for each drug used:

- Name of drug
- Dosage and strength
- Lot and/or batch number
- Research subject initials (for internal tracking purposes)
- Research subject study identification number
- Quantity dispensed and initials of the person who dispensed the drug
- Disposition. If drug is returned to the sponsor/supplier or destroyed, documentation of why, when and persons involved.
- Initials of all persons who used or disposed of each Investigational Drug

Notification, Maintenance and Record-Keeping Requirements for Research Involving Investigational Devices

For research involving Investigational Devices, the following notification and record-keeping requirements apply:

- If a device that the Principal Investigator or study sponsor considers to be NSR is determined by the IRB to be a significant risk (SR) device upon IRB review, the Principal Investigator is responsible for notifying the sponsor of the IRB’s determination upon receipt of written notice, as applicable. The Principal Investigator should provide the IRB with confirmation of this action.

- A copy of the protocol approval by the FDA and the IRB as well as a copy of the IRB-approved consent form must be provided to the designated pharmacist if the Investigational Device will be stored in an investigational pharmacy. A copy of the consent form signed by the applicable research subject must be provided to the pharmacist prior to the Investigational Device being released for use. If the Principal Investigator is self-storing the devices, a log must be maintained to indicate name of each subject, date the Investigational Device was dispensed, by whom it was dispensed, amount of Investigational Devices remaining, and who received the device (see below for detailed requirements related to management of research involving Investigational Devices).

- Following completion of the study, the termination procedure for Investigational Drug studies (informing the applicable IRB and pharmacy when the study has been terminated) must be applied if the Investigational Devices are under investigational pharmacy control. If the devices are kept by the Principal Investigator, the device accountability log must be completed regarding the receipt, use and/or dispensing of the Investigational Devices, and the disposition of remaining devices at the conclusion of the investigation.
The Principal Investigator is responsible for maintaining security of the Investigational Devices by ensuring that:

- all Investigational Devices used in conjunction with the protocol are kept in a locked and secured area, separate from materials used in standard clinical care;
- access to Investigational Devices is limited to personnel designated by the Principal Investigator; and
- receipt logs are maintained for all Investigational Devices. Documentation of the following elements (as applicable) is required for each device used:
  
  o Name of device
  o Model number
  o Serial number
  o Lot, batch, and/or serial number
  o Date received from supplier
  o Shipment/packing slip number
  o Expiration date of the device (if applicable)
  o Condition of the device (intact/damaged)
  o Recipient initials

- accountability logs are maintained for all Investigational Devices. Documentation of the following elements (as applicable) is required for each device used:
  
  o Name of device
  o Model number
  o Lot, batch and/or serial number
  o Research subject initials (for internal tracking purposes)
  o Research subject study identification number
  o Date implanted or used
  o Disposition. If device is returned to the sponsor/supplier or destroyed, documentation of why, when and persons involved.
  o Initials of all persons who received, used, or disposed of each Investigational Device.
  o Expiration date of the device.

The full names, title/positions, and signatures of all personnel responsible for maintaining or documenting information in the Investigational Device accountability logs must be indicated on a separate document or on the log itself.

Device accountability logs must be maintained in the study/research files or in the Principal Investigator’s study/research regulatory binder for the period of time required by the federal regulations or otherwise required by the relevant agreement/contract term, whichever is longer.

Prior to commencement of research at NYU Langone Health involving Investigational Devices, the applicable IRB Office staff will conduct a review to evaluate compliance with aforementioned in order to affirm compliance.

For studies involving Investigational Devices, the Principal Investigator is responsible for protecting the rights, safety and welfare of research subjects under the Principal Investigator’s care by ensuring that:

- the Investigational Device is not used on a research subject until FDA and/or IRB approval has been obtained and the research subject has signed an IRB-approved informed consent document;
- the research is conducted according to all regulatory requirements and guidelines;
- the Investigational Device is used only in accordance with the IRB-approved protocol;
- the Principal Investigator is thoroughly familiar with the appropriate use of the Investigational Device, as described in the protocol and product brochure, and in other informational sources provided by the sponsor/supplier;
all persons assisting in the study are adequately informed about the protocol and the Investigational Device; and

research subjects receive adequate instructions about the Investigational Device to assure their safe participation in the research study.

**IRB Responsibilities**

The IRB must review the Investigational Drug/Investigational Device research using the same criteria it would use in considering approval of any research involving an FDA-regulated product (21 CFR 56.111), and in compliance with these Policies and Procedures.

**Determination of Non-Significant Risk (NSR) vs. Significant Risk (SR) Device**

For research involving Investigational Devices where there is a claim that the device is a non-significant risk (NSR) device:

- The IRB is responsible for reviewing the protocol and determining whether it is adequate. If the IRB Chair determines that the IRB does not have the necessary expertise to evaluate the investigational plan, outside consultation will be sought as appropriate (e.g., from NYU Langone Health Biomedical Engineering).

- Unless the FDA has already made a risk determination for the study, the IRB will review NSR studies and determine if the Investigational Device represents significant or non-significant risk and report its findings to the Principal Investigator in writing.

- The IRB must consider the risks and benefits of the Investigational Device compared to the risks and benefits of alternative devices or procedures. NSR device studies do not require submission of an IDE application, but must be conducted in accordance with the abbreviated requirements of IDE regulations (see IND/IDE Requirements). If the study that has been submitted as a NSR device study but is subsequently determined to be a SR device study, the IRB must recommend that an IDE be obtained.


- The IRB must document in the IRB meeting minutes the rationale for the determination of the risk classification of a device (as NSR or SR).

- The IRB will provide written documentation of its approval of a study to the Principal Investigator with a determination of whether the Investigational Device involved presents a significant or non-significant risk.

If the FDA has already made the SR or NSR determination for a study, the FDA’s determination is final and the IRB does not need to make a risk determination.

14.6. **Emergency Use**

HHS regulations do not permit human subjects research activities to be started, even in an emergency, without prior IRB approval. When emergency medical care with any Test Article (including Investigational Drugs or Devices) is initiated without prior IRB review and approval, the patient may not be considered a research subject under [45 CFR Part 46]. However, nothing in the HHS regulations at [45 CFR Part 46] is intended to limit the authority of a physician to provide emergency medical care with any Test Article, Investigational Drug or Investigational Device, to the extent the physician is permitted to do so under applicable federal, state or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).
Emergency Exemption from Prospective IRB Approval

The FDA, in 21 CFR 56.102(d), defines “emergency use” as the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

If all conditions described in [21 CFR 56.102(d)] exist, then the emergency exemption from prospective IRB approval found at [21 CFR 56.104(c)] may be utilized. Informed consent is normally required and should be obtained and documented as per FDA regulations unless the conditions for exemption are met. See Emergency Waiver of Informed Consent.

The IRB must be notified within five (5) working days when an Investigational Drug, Investigational Device, or any other Test Article is used under the emergency exemption. Any subsequent use of the Test Article at the institution is subject to IRB review.

The IRB’s acceptance of the required notification to the IRB must not be construed as its approval for the emergency use. The IRB Director or designee will review the report to verify that circumstances of the emergency use conformed to FDA regulations.

If use of an Investigational Drug, Investigational Device, or other Test Article in a patient is initiated without prior IRB review approval, the data derived from such use may not be included in DHHS-regulated research in a prior or subsequent IRB-approved study.

If use is initiated without prior IRB review and approval, the FDA may require the data from emergency use to be included in the research results submitted to the FDA.

Emergency Waiver of Informed Consent

Under New York State law, the Principal Investigator is required to obtain informed consent from the patient or the patient’s Legally Authorized Representative unless an exception is met as follows.

An exception under FDA regulations at [21 CFR 50.23] permits the emergency use of an investigational drug, device, or biologic without informed consent where the Principal Investigator and an independent physician who is not otherwise participating in the clinical investigation certify in writing all four of the following specific conditions:

- The subject is confronted by a life-threatening situation necessitating the use of the test article.
- Informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject.
- There is insufficient time to obtain consent form the subject’s Legally Authorized Representative.
- No alternative method of an FDA-approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject’s life.

If there is not enough time to obtain the independent physician determination before use of the Test Article, the actions of the Principal Investigator must be reviewed and evaluated in writing by an independent physician within five to six (5-6) working days.

Expanded Access of Investigational Drugs

The term “compassionate use” is erroneously used to refer to the provision of investigational drugs outside of an ongoing clinical trial to a limited number of patients who are desperately ill and for whom no standard alternative therapies are available. The term “compassionate use” does not, however, appear in FDA or HHS regulations. 21 CFR Subpart I, Section 312.300 explains the regulations for “Expanded Access”, a mechanism for providing eligible subjects with Investigational Drugs or biologics (as early in the drug development process as possible) for the treatment of serious and life-threatening illnesses for which there are no satisfactory alternative treatments.
The FDA defines an “immediately life-threatening” disease as a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

The FDA defines a “serious disease or condition” as one associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity are usually insufficient, but the morbidity need not be irreversible, as long as it is persistent or recurrent. The determination of whether a disease is serious is based on clinical judgment when considering factors including survival, day-to-day functioning, or the likelihood that the disease, if left untreated, would progress from a less severe condition to a more serious one.

There are 3 requirements that must be met before Expanded Access to an Investigational Drug/biologic can be issued:

- The drug is intended to treat a serious or immediately life-threatening disease or condition and there is no comparable or satisfactory alternative treatment available;
- The potential benefit to the patient justifies the potential risks of the treatment use and those potential risks are not unreasonable in the context of the disease or condition to be treated; and
- Providing the Investigational Drug/biologic for the treatment use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use.

FDA regulations allow certain individuals who are not enrolled in clinical trials to obtain expanded access to Investigational Drugs, agents, or biologics through the following methods:

**Individual Patients, Including Emergency Use**

The FDA may approve use by a licensed physician of an Investigational Drug or biologic outside of a controlled clinical trial for individual patients, usually in a desperate situation, and if the patient is unresponsive to other therapies or is in a situation where no approved or generally recognized treatment is available. The drug or biologic may or may not be under development. There is usually little evidence that the proposed therapy is useful, but may be plausible on theoretical grounds or anecdotes of success. Access to Investigational Drugs/biologics for use by a single, identified patient may be gained either through the a drug manufacturer/sponsor’s existing IND under an Individual Patient Expanded Access Protocol, or through the FDA, by submitting a protocol for Individual Patient Expanded Access IND to the FDA requesting authorization to use the Investigational Drug/biologic for treatment use under a new IND and obtaining the drug from the drug manufacturer/sponsor. This type of submission is commonly referred to as a “Single Patient Protocol” or “Single Patient IND”. Along with meeting the criteria in 21 CFR 312.305(a), the sponsor must determine that the probable risk to the patient from the investigational drug/biologic is not greater than the probable risk from the disease or condition.

Unless the FDA authorizes treatment to begin sooner, there is a 30-day waiting period for the Individual Patient Expanded Access IND. However, there is no waiting period for the Individual Patient Expanded Access Protocol.

Prospective IRB review and approval is required prior to initiating treatment.

**Emergency IND (Individual patient access IND for emergency use) and Emergency Protocol (Individual patient expanded access protocol for emergency use):**

In emergency situations when a patient requires treatment before the FDA submission can be made in writing, the FDA may authorize the use of the Investigational Drug/biologic in the patient either by
Prospective IRB review and approval are required before treatment can be initiated unless the conditions for exemption are met [21 CFR 56.104(c) and 56.102(d)]. Informed consent is required unless the conditions for exemption are met (21 CFR 50.23).

A licensed physician or sponsor must submit the required documents for the Emergency IND or Protocol to the FDA within 15 business days of the FDA's telephone, facsimile, or other electronic authorization of the use of the Investigational Drug/biologic.

At the conclusion of the individual patient's treatment, the physician or sponsor must provide the FDA with a written summary of the results of the expanded access use, including adverse effects.

When a significant number of similar individual patient access/single patient IND requests have been submitted, the FDA may require the sponsor to submit an IND or protocol for intermediate-sized population or widespread expanded access.

**Intermediate-Size Patient Populations**

Access to an Investigational Drug or biologic for treatment can be granted to more than one patient, but fewer patients than are treated under a Treatment IND or Treatment Protocol for widespread use, either by submitting to the FDA a protocol under a new IND, subject to a 30-day waiting period (unless the FDA notifies the sponsor that treatment may begin sooner) or by submitting a protocol to an existing IND by the sponsor of the existing IND. In the latter example, there is no waiting period imposed by the FDA. However, prospective IRB review and approval are required before initiating treatment.

This method of expanded access is appropriate for the following circumstances:

- Treatment of rare diseases or conditions when the drug or biologic is not being developed due to the inability to recruit a sufficient number of patients for a clinical trial.

- In cases when the investigational drug or biologic is being tested in a clinical trial, an intermediate-size population submission may be needed when the patients do not meet the eligibility criteria for the study, the trial is closed to enrollment, or enrollment is not feasible because the trial site is not geographically accessible to the patient.

- The FDA-approved drug or biologic or related product is otherwise unavailable to patients because the drug is no longer marketed for safety reasons or because it has failed to meet the conditions of its approved application, or due to a drug shortage.

- The regulations do not specify an upper-limit for the number of patients to be treated under an intermediate-size patient population IND or protocol. However, as the number of patients increases, the FDA may require the sponsor to submit an IND or protocol for treatment use under 21 CFR 312.320.

**Treatment IND or Treatment Protocol**

FDA regulations [21 CFR 312.320] address the widespread treatment use of an Investigational Drug or biologic (not approved for marketing, but under clinical investigation for a serious or immediately life-threatening disease condition) in patients for whom no comparable or satisfactory alternative drug or other therapy is available. Use of the Investigational Drug or biologic for this purpose must meet all criteria for Expanded Access Use (21 CFR 312.305(a) and the FDA must have determined that:

- The drug or biologic is already under investigation to support a marketing application for the expanded access use or clinical trials have been completed; and
- The trial sponsor is actively pursuing marketing approval for the drug; and
- There is sufficient clinical evidence of safety and effectiveness from Phase 3 data or compelling Phase 2 data to support the expanded access use OR
- Considering the available evidence as a whole, it is reasonable to conclude that the
Prospective IRB review and approval is required prior to this use.

**Informed Consent**

Informed consent is especially important in treatment use situations because the subjects are desperately ill and particularly vulnerable. They will be receiving medications which have not been proven either safe or effective in a clinical setting. Both the setting and their desperation may work against their ability to make an informed assessment of the risk involved. Therefore, the IRB should ensure that potential subjects are fully aware of the risks involved in participation.

**Charging for INDs under Expanded Access**

The FDA permits charging for the Investigational Drug, agent, or biologic when used in an Expanded Access IND or protocol. Therefore, the IRB Committee should pay particular attention to Expanded Access IND/protocols in which the subjects will be charged for the cost of the Investigational Drugs/products. If subjects will be charged for use of the Investigational Drug/agent/biologic, economically disadvantaged persons will likely be excluded from participation. Charging for participation may preclude economically disadvantaged persons as a class from receiving access to Investigational Drug/agent/biologic. The IRB should balance this interest against the possibility that unless the manufacturer/sponsor can charge for the Investigational Drug/agent/biologic, it will not be available for treatment use until it receives full FDA approval.

**Emergency Use IND and Emergency Waiver of IND**

The emergency use of an unapproved Investigational Drug, agent, or biologic requires an emergency IND. The FDA has established mechanisms and guidance for obtaining an emergency IND for the use of Investigational Drugs, agents, or biologics.

FDA regulations at [21 CFR 312.305(a)] address the need for an Investigational Drug to be used in an emergency situation that does not allow time for submission of an IND. The FDA may authorize shipment of the Investigational Drug for a specific use in such a circumstance in advance of submission of an IND. Prospective IRB review is required unless the conditions for exemption are met [21 CFR 56.104(c) and 56.102(d)]. Informed consent is required unless the conditions for exemption are met (21 CFR 50.23). All applicable regulations must be met including those at [21 CFR Parts 50 and 56], and [21 CFR 305(a)].

**Waiver of Informed Consent for Planned Emergency Research**

Planned emergency research that involves the waiver of informed consent is subject to specific review and requirements. [21 CFR §50.24] The research plan must be approved in advance by the FDA or DHHS and the IRB, and publicly disclosed to the community in which the research will be conducted. Such studies are not allowed under the regulations covering the emergency use of a test article in a life-threatening situation [21 CFR § 56.104(c)]. See Section 10.13 Waiver of Informed Consent for Planned Emergency Research.

Planned emergency research conducted by or at NYU Langone Health that involves the waiver of informed consent is subject to the additional requirements set forth in NYU Langone Health’s Policy on Planned Emergency Research.

**Expanded Access of Investigational Devices**

Individuals who are not enrolled in clinical trials may obtain access to Investigational Devices through
the following methods:

**Compassionate Use (Individual Patient/Small Group Access)**

The “compassionate use” mechanism allows access to Investigational Devices for patients who do not meet the requirements for inclusion in a clinical trial but for whom the treating physician believes the device may provide a benefit in treating and/or diagnosing or monitoring the patient's disease or condition and this potential benefit justifies the potential risks of the device. This provision is typically approved for individual patients but may be also approved to treat a small group. The patient’s disease must be a serious or life-threatening disease or condition with no alternative treatment available. FDA approval is needed before use of the Investigational Device under this provision.

If the Investigational Device already has an existing IDE, the IDE sponsor should submit an IDE supplement for Compassionate Use under 21 CFR 812.35(a) to treat the individual patient or small group. The IDE supplement is subject to a 30-day review cycle, although approval may be granted earlier in consideration of the need of the patient(s). After all patients have been treated, a follow-up report on the use of the Investigational Device must be submitted.

If the Investigational Device does not already have an IDE, the treating physician or device manufacturer needs to submit a compassionate use request for a single patient to the FDA. IRB review and approval are required prior to initiating use of the device. Following the compassionate use of a device, a follow-up report, including a summary of the patient outcome and any problems that occurred due to the use of the device, must be submitted by the IDE sponsor to the FDA within 45 days of using the Investigational Device. Additionally, this report must be submitted to the IRB as soon as possible.

**Treatment Use**

An approved IDE specifies the maximum number of clinical trial sites and the maximum number of human subjects that may be enrolled in the applicable study. During the course of the clinical trial, if the data suggests that the Investigational Device is effective, then the trial may be expanded to include additional subjects with life-threatening or serious diseases. The criteria for treatment use with an Investigational Device include:

- The device is intended to treat a life-threatening or serious disease.
- There is no comparable or satisfactory alternative treatment available.
- The device is already under investigation for the same use under an approved IDE or all controlled clinical trials have been completed.
- The clinical trial sponsor is actively pursuing marketing approval of the device.

**Continued Access**

The FDA may allow continued enrollment of subjects after a controlled clinical trial under an IDE has been completed in order to allow access to the Investigational Device while the marketing application is being prepared by the trial sponsor or is being reviewed by the FDA. There must a public health need or preliminary evidence that the device will be effective and there are no significant safety concerns.

**Emergency Use**

An Investigational Device may be used to treat a patient with a serious or life-threatening disease or condition when there is no available alternative and insufficient time to submit to the FDA. In order to use an unapproved device in an emergency situation, the treating physician must determine that the patient meets the above criteria and that there is potential benefit to the patient from the use of the unapproved device. The physician should obtain the following patient protection measures prior to initiating treatment:

- Informed consent from the patient or Legally Authorized Representative;
- Institutional clearance;
• IRB review and approval;
• An independent assessment from an uninvolved physician; and
• Authorization from the device manufacturer.

The FDA must be notified of the emergency use within 5 working days with a follow-up report that includes a summary of the conditions constituting the emergency, the patient protection measures followed, and the patient outcome. [21 CFR 812.35(a)(2)]

14.7. **Humanitarian Use Devices (HUD)**

In accordance with [21 CFR 814.124], treatment with a HUD is subject to IRB Full Board initial and continuing review by the IRB. At the time of review, the IRB will determine if written consent from subjects for use of the HUD is necessary. If a physician in an emergency situation determines that IRB approval cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior IRB approval. In this instance, approval must be obtained from the Chief of Staff (or designee) of the applicable NYU Langone Hospital, and the Principal Investigator is required to provide written notification of the use to the IRB within five (5) days after use of the device.

The IRB requires that such written notification includes identification (specification without identifiers) of the subject, the date on which the device was used, and the reason for the use. It is the responsibility of the Principal Investigator to notify the FDA if the IRB withdraws approval for use of a HUD. The FDA should be notified within five (5) working days of notification of the withdrawal of approval. Principal Investigators are reminded that Humanitarian Use Device Exemptions are for clinical use only and HUDs can be used only for purposes outlined in the approved IRB application. Required medical device reports submitted to the FDA must be copied to the IRB. Post-approval requirements are detailed in [21 CFR 814.126].

15. **Principal Investigator Responsibilities**

Principal Investigators are ultimately responsible for the conduct of research. Although they may delegate certain responsibilities in the research, the Principal Investigator must maintain oversight and retains ultimate responsibility for the conduct of those to whom they delegate responsibility.

In order to satisfy the requirements of this Policy, Principal Investigators who conduct research involving human subjects at or under the auspices of NYU Langone Health must:

• develop and conduct research that is in accordance with the ethical principals in the *Belmont Report*;
• develop a research plan that is scientifically sound and minimizes risk to the subjects;
• have sufficient resources necessary to protect the human subjects, including:
  o access to a population that would allow recruitment of the required number of subjects
  o sufficient time to conduct and complete the research
  o adequate numbers of qualified research staff
  o adequate facilities
  o a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions
  o availability of medical or psychological resources that subjects might require as a consequence of the research;
• ensure that all study-required procedures in a study are performed with the appropriate level of supervision and only by individuals who are licensed or otherwise qualified to perform such under the laws of the State of New York and the NYU Langone Health policies;
• ensure that all key study personnel are educated in the regulatory requirements regarding the conduct of research and the ethical principles upon which they are based;
• protect the rights and welfare of prospective subjects;
• ensure that risks to subjects are minimized by:
o using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
o whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

- recruit subjects in a fair and equitable manner;
- have plans in place to monitor the data collected for the safety of research subjects, as applicable;
- protect the privacy of subjects and maintain the confidentiality of data;
- when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, include additional safeguards in the study to protect the rights and welfare of these subjects;
- have a procedure to receive complaints or requests for additional information from subjects and respond appropriately;
- ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating co-investigators and research staff;
- obtain and document informed consent as required by the IRB and ensure that no human subject is involved in the research prior to obtaining their consent on an up-to-date IRB-approved consent form;
- ensure that all research involving human subjects receives IRB review and approval in writing before commencement of the research;
- comply with all IRB decisions, conditions, and requirements;
- ensure that protocols receive timely continuing IRB review and approval;
- report problems that require prompt reporting to the IRB (see: Required Reports to the IRB);
- obtain IRB review and approval in writing before changes (i.e. amendments) are made to approved protocols or consent forms; and
- seek IRB assistance when in doubt about whether proposed research requires IRB review.

15.1 Investigator Classifications: Who May Serve as Principal Investigator for NYU Langone Health Human Subjects Research

Principal Investigators
The NYU Langone Health IRB recognizes one Principal Investigator for each study. The Principal Investigator has oversight responsibility for the research activities covered under his/her research protocol.

At NYU Langone Health, only faculty or staff members with a NYUGSoM or NYU LISoM-paid appointment may serve as the Principal Investigator or as the faculty sponsor on a research project involving human subjects. Individuals whose primary appointment is as a non-compensated NYUGSoM or NYU LISoM faculty member cannot serve as Principal Investigator or faculty sponsor without the express approval of the applicable department chair.

Any investigator whose status is considered to be “in training” (i.e. students and medical residents) may not serve as Principal Investigator, but may serve as a co-Investigator (Co-I).

NYU Langone Health or NYU Meyers College of Nursing nurses holding doctorate-level degrees (e.g., DNP, PhD, DNS, DPH, EdD) may serve as a Principal Investigator.

All dental residents in NYU Langone Hospitals dental residency programs who are in training at locations outside of NYU Langone Health may serve as Principal Investigator for Minimal Risk studies, but only if an eligible, qualified mentor is listed as a co-investigator.

Protocols that require skills beyond those held by the Principal Investigator must be modified to meet the investigator's skills, or have one or more additional qualified faculty or staff listed as co-investigator.
**Student Investigators**

Other than as permitted above, students (including Fellows, Residents, medical students, dental students, nursing students, etc) may not serve as Principal Investigator. They must have a faculty sponsor who meets the Principal Investigator eligibility criteria and who will serve as Principal Investigator and faculty advisor on the study.

### 15.2 Protocol Development

The Principal Investigator is responsible for determining whether a protocol constitutes human subjects research which requires IRB review and approval, and if so, for ensuring that the study protocol and related information are submitted in accordance with the IRB’s policies and procedures, applicable regulations, and institutional policies. Although the Principal Investigator may designate others to write the protocol and submit information to the IRB, the Principal Investigator of the study is ultimately responsible for the accuracy, quality, and timeliness of the submissions.

**Determination of Human Subjects Research**

When developing a protocol, the Principal Investigator or a member of the protocol research team may contact the IRB Office for a determination whether the proposed study constitutes human subjects research, and if so, what level of review would be required. Contact with the IRB Office may be in the form of a phone call, by letter, or by email and must include a brief description of the proposed research. The IRB Office will respond to the Principal Investigator or member of the research team by phone, letter, or email.

**Pre-IRB Departmental Review**

In the event the Principal Investigator’s department (or department that is administering the proposed research) has a feasibility and/or scientific review process in place, the Principal Investigator is responsible for ensuring that the research protocol is reviewed by the approved department reviewer, if applicable. The Principal Investigator must make any changes to the protocol that are recommended by the department reviewer or committee. The intent of this Policy is to ensure that any issues that have been identified as needing to be addressed prior to review by the full IRB are fully addressed, thus avoiding delays in receiving IRB approval for the research study.

Following departmental review and sign-off by Department Chairs or other appropriate institutional official(s), the Principal Investigator must submit the required materials to the IRB Office.

**Submission Requirements**

Principal Investigators must provide complete answers to all questions on the IRB/Research Navigator application for new protocol review and ensure that information in the consent form is consistent with the research plan.

The proposed consent and/or assent form (if applicable) must include or address:

- the general principles and basic elements of informed consent;
- translated consent documents, as necessary, considering likely subject population(s);
- NYU Langone Health IRB-approved formats for consent forms and assent forms; and
- waiver of consent conditions.

The Principal Investigator must ensure that the protocol and attachments are submitted to other institutional regulatory committee offices (e.g., Institutional Biosafety Committee, Radiation Safety
If the research is DHHS-sponsored, the materials submitted to the IRB reviewer must include the entire sponsoring application. If there is a significant variation between the DHHS application and the IRB protocol, it is the Principal Investigator’s responsibility to identify and justify the discordance.

If the research is FDA-regulated and industry-sponsored, the IRB submission must include the complete sponsor’s protocol as well as, for drug studies, the investigator’s brochure [21 CFR 312.23(a)(5) and 312.55], and FDA form 1572.

15.3 Changes to IRB-Approved Research
Principal Investigators must seek IRB approval before making any changes in approved research, even if the changes are planned for the period for which IRB approval has already been given. The only exception to this is if the change is necessary to eliminate an immediate hazard to a subject, in which case the IRB must then be notified at once.

Minor protocol changes (i.e., changes that do not involve increased risk or discomfort to subjects) may be authorized by the IRB Chair or his/her designee. A completed Application for Approval of an Amendment with information specifying the changes requested, a revised consent form (if applicable), and a copy of the approved protocol with the proposed changes highlighted, should be sent directly to IRB Office according to the IRB Office procedures. The IRB Chair or IRB Director must sign and return a letter to indicate approval of the minor protocol changes. IRB-approved amendments to ongoing research do not serve to extend the term of the IRB approval/expiration date. For further information regarding amendments, see: Modification of an Approved Protocol.

15.4 Continuing Review after Protocol Approval
Ongoing research studies must be reviewed by the IRB at least annually, or more often, if the IRB finds that the degree of risk to subjects warrants more frequent review. This review must take place prior to the end of the approval period noted on the approved protocol; otherwise, subject recruitment/enrollment must be suspended and, if the research is DHHS-sponsored, the sponsoring agency must be notified.

It is the responsibility of the Principal Investigator to submit a timely continuing review application. The Principal Investigator should allow sufficient time for development and review of renewal submissions. Note: The "approval date" and the "approval expiration date" are listed on all IRB certifications. By federal regulation, no extension to that date can be granted.

Principal Investigators must provide complete answers to all questions on the IRB application for continuation (Request for Continuation form), the current consent document and newly proposed consent document. Note: Additional information may be required as specified in the original protocol review. For further information regarding continuing review, see Continuing Review of Active Protocols.

15.5 Required Reports to the IRB

Progress Reports
It is the responsibility of the Principal Investigator to report the progress of the research to the IRB in the manner and frequency prescribed by the IRB, but no less than once a year.

When an approved study is completed, the Principal Investigator must promptly notify the IRB and file with the IRB a final study progress report.

Once data collection has been completed and the study is closed at NYU Langone Health and/or other study sites, a final study closure submission must be made to the IRB. Once this final submission is complete, the Principal Investigator is not required to submit any further reports of the study to the IRB.
Unanticipated Problems
Principal Investigators must report Unanticipated Problems to the IRB Office in accordance with the IRB’s Section 8.8 Policies and Procedures, Unanticipated Problems.

Submission of Reports
Investigators must report possible Unanticipated Problems to the IRB promptly through IRB/Research Navigator in accordance with the IRB’s Section 8.8 Policies and Procedures, Unanticipated Problems.

Complaints, Non-Compliance and Protocol Deviations
Each study’s Principal Investigator must report all complaints and concerns from the study’s subjects, non-compliance by research staff, and any protocol deviations to the IRB in accordance with The IRB’s Section 8.8 Policies and Procedures for reporting Unanticipated Problems for evaluation as possible Unanticipated Problems involving risks to subjects or others.

Principal Investigators must report all non-compliance by research staff to the IRB within ten (10) working days of discovery of the alleged non-compliance. See Section 12.2 Non-Compliance.

The following procedures further describe how protocol exceptions and deviations must be reported to the IRB.

15.6 Protocol Exceptions

Protocol exceptions are defined as circumstances in which the specific procedures called for in a protocol are not in the best interests of a specific patient/subject (Example: patient/subject is allergic to one of the medications provided as supportive care). Usually a protocol exception is a violation that is anticipated and happens with prior agreement from the study sponsor.

Protocol exceptions must be approved by the study sponsor and IRB before being implemented.

Protocol exceptions may not increase risk or decrease benefit, affect the subject’s rights, safety, welfare, or affects the integrity of the resultant data.

15.7 Protocol Deviations

A protocol deviation is defined as a violation that is unanticipated and happens without any prior agreement (Examples: protocol visit scheduled outside protocol window, blood work drawn outside protocol window, etc.). The IRB will review these reports for frequency and may audit any protocol in which frequent deviations occur. Repeated protocol deviations may be ruled by the IRB to constitute non-compliance resulting in suspension of IRB approval.

It is the responsibility of the Principal Investigator not to deviate from the protocol approved by the IRB, except to avoid an immediate hazard to the subject. The Principal Investigator must submit an amendment request to the IRB and receive written approval prior to implementation of any change to the protocol.

Deviations that increase risk have potential to recur or undertaken to eliminate an immediate hazard would be considered an Unanticipated Problem.
When a study sponsor requests that the IRB be notified of a protocol deviation, the Principal Investigator is responsible for ensuring that the completed Protocol Deviation/Exception form is forwarded to the IRB Chair or designee for review.

15.8 Protocol Exceptions and Deviations Reporting & Review

Unanticipated Event Reports must be completed for those events that qualify as a protocol deviation or exception. These reports should be filed with the IRB Office.

- The IRB Office will forward the report to the IRB Chair or designee for review and signature.
- A signed report will be sent back to the Principal Investigator for the study file.
- The IRB Chair may choose to place any protocol deviation or exception on the agenda of the next convened IRB meeting for discussion. The Principal Investigator may be asked to appear at that meeting to answer any questions or clarify issues for the IRB.

15.9 Principal Investigator-Required Record Keeping

Principal Investigators must retain copies of approved IRB documents, and implement a system to comply with approval expiration dates.

In addition to providing a copy of the signed and dated consent form to each subject, a copy of the signed consent form must be retained securely by the Principal Investigator in the research record for a minimum of five (5) years after completion of the research.

The Principal Investigator will further maintain the following in the research record, each as applicable:

1. current curriculum vitae (CV);
2. study protocol/investigational plan;
3. records of receipt and disposition of study drugs;
4. records of receipt and disposition of study devices;
5. list of any co-investigators with their curriculum vitae;
6. certification that all physicians, dentists, and/or nurses performing study procedures have appropriate valid licenses for the duration of the study;
7. records of animal study reports that relate to the proposed human subject research;
8. case histories with particular documentation on evidence of Investigational Drug and/or Investigational Device effects. Emphasis is on safety, toxicity and possible untoward happenings. All unexpected adverse drug or device effects are reportable; even if the Principal Investigator considers that the event is not related to the drug or device. All unexpected Adverse Events must be reported immediately to the IRB in the manner defined by the protocol;(8) IRB letters of approval and ethics committee approval letters (if applicable); and
9. documentation of Investigational Device training.

15.10 Training & Ongoing Education of Principal Investigator and Research Team

A component of a comprehensive human research protection program is an education program for all individuals involved with human research subjects. NYU Langone Health is committed to providing training and an on-going educational process for Principal Investigators and members of their research teams related to ethical concerns and regulatory and institutional requirements for the protection of human subjects. The Principal Investigator should ensure that he or she is trained, and ensure that members of his or her research team receive training and education necessary to correctly perform their delegated responsibilities.

O r i e n t a t i o n
All Principal Investigators and members of their Research Team (also known as “Key Personnel”) must review core training documents provided by NYU Langone Health, including the *NYU Langone Health IRB and Human Subjects Research Protection Program Policies & Procedures*, and the “Belmont Report: Ethical Principals and Guidelines for the Protection of Human Subjects of Research”.

**Initial Education**
The Principal Investigator and Key Personnel must complete the one of the basic courses offered through the CITI web-based program. While several basic course modules are available, Principal Investigators are responsible for completing the course relevant to the research activities being conducted and must ensure that each of their Key Personnel complete such courses prior to conducting human subjects research. Basic course options in CITI include: Biomedical, Social Behavioral, Research with Data or Laboratory—Specimens—Only, and Students Conducting No More Than Minimal Risk Research.

New research protocols and applications for continuing review will not be accepted from Principal Investigators who have not completed the initial education requirement.

While research protocols and applications for continuing review will be accepted and reviewed regardless of required training completion, neither the Principal Investigator nor any member of the Research Team can carry out research-related activities until the CITI training requirement has been satisfied.

**Waiver of Initial Education**
If Principal Investigators or members of their Research Team can verify that they have successfully completed human subjects research training equivalent to that required by the NYU Langone Health IRBs, they may request a waiver of the requirement for initial education. However, all Principal Investigators or members of their Research Team must complete the institutional requirements of continuing education.

**Continuing Education and Recertification**
All Principal Investigators and members of their Research Teams must complete CITI training every three (3) years after completion of their initial certification for as long as they are involved in human subjects research at NYU Langone Health. There is no exception to this requirement. This includes completion of appropriate refresher modules at the CITI web-based training site.

While research protocols and applications for continuing review will be accepted and reviewed regardless of required training completion, neither the Principal Investigator nor any member of the Research Team can carry out research-related activities until the CITI training requirement has been satisfied.

Investigators and members of Research Teams who also serve as IRB Chair, IRB committee members, or IRB Office staff must satisfy the training requirements for IRB committee members and IRB Office staff described in this Policy under Training & Ongoing Education of Chair and IRB Members in Regulations, Procedures.

**Additional Resources**
Human research protection information will be made available on the NYUGSoM and NYU Winthrop IRB websites on an ongoing basis to ensure that the NYU Langone Health research community is apprised of current regulatory and policy requirements and training opportunities.
15.11 Conflict of Interest

This Policy and procedures apply to both Financial Interests related to human subjects research and Non-Financial Conflicts of Interest (both defined below) and are guided by Code of Federal Regulations [Title 42 of the Code of Federal Regulations (CFR) Part 50 Subpart F] that promotes objectivity in research to ensure conflict of interests do not adversely affect the protection of subjects or the credibility of the NYU Langone Health Human Research Protection Program, including its NYU Langone Health IRBs. For clinical studies involving the use of new human drugs and biological products or medical devices, certifications and disclosure requirements are defined in FDA regulations, 21 CFR Part 54.

In the environment of research, openness and honesty are indicators of integrity and responsibility which are viewed as characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively disclosed and managed when they cannot be eliminated.

It is the policy of the NYU Langone Health IRB to preserve public trust in the integrity and quality of research at the organization by minimizing actual or perceived conflict of interest in the conduct of research. Under NYU Langone Health’s Policy on Conflicts of Interest in Research and Other Sponsored Programs (the “Conflicts of Interest in Research Policy”) and its Policy on Institutional Conflicts of Interest in Human Subjects Research (the “Institutional Conflicts Policy”), NYU Langone Health and all of its investigators including Research Team members participating in research at NYU Langone Health have a primary obligation to conduct the research free of the appearance of conflict. Participating in research that might be perceived to be compromised due to a personal or institutional interest is contrary to this commitment, unless the conflict of interest is managed or eliminated. Under certain circumstances, an investigator’s personal interest (or NYU Langone Health’s institutional interest) might be too significant to permit participation in the research. The Conflicts of Interest in Research Policy and the Institutional Conflicts Policy accommodate current federal regulations designed to protect the integrity of federally funded research and all other applicable laws and regulations and are consistent, to the extent appropriate for the NYU Langone Health community with the latest best practices recommendations of the Association of American Medical Colleges.

The Principal Investigator and Research Team members must comply with conflict of interest policies of their institution/organization. If the institution does not have a conflict of interest policy, the terms of an applicable agreement (such as an IRB reliance agreement) apply.

Definitions

Compelling Circumstances
means, for purposes of this Policy, facts that convince NYU Langone Health’s Executive Vice President and Vice Dean for Science, Chief Scientific Officer and/or the CIMU that an Investigator and/or NYU Langone Health may participate in a research study despite a Significant Financial Interest or Institutional Financial Interest, as applicable. Factors that may be evaluated to determine whether Compelling Circumstances exist are listed in NYU Langone Health’s Procedures on Research Conflict of Interest and Sponsored Programs.

Consulting Compensation
means, for purposes of this Policy, salary, consulting fees, honoraria, paid authorship, lecture fees, other emoluments, stocks, stock options, Royalty Income or “in-kind” compensation directly or indirectly received by an Investigator or the institution from an organization (or entitlement to the same), outside of the costs of conducting research, in the prior calendar year or are expected to be received in the current or next calendar year. Such items may be received in connection with a Management, Board, or Employment Position or for consulting, lecturing, or service on a scientific advisory board, data safety monitoring board, clinical trial steering committee or executive committee, or other committee for an
Conflict of Interest
A Conflict of Interest arises in a human subjects research study when NYU Langone Health’s designated officials reasonably determine that an Investigator’s or institution’s (NYU’s or NYU Langone Health’s) Financial Interest could affect, or appear to affect, the design, review, conduct, results or reporting of the research.

Financial Interest
for purposes of this Policy, is held when an Investigator participating in a research study or a member of his or her Immediate Family has a personal financial interest that reasonably appears to be related to the Investigator’s responsibilities to NYU Langone Health and includes all personal financial interests in the research funding sponsor or any other financially-interested company, or (ii) has intellectual property rights that cover a product or process being tested in the research. Examples are as described in the Policy on Conflicts of Interest in Research and include: Management, Board, or Employment positions, Ownership Interests, Consulting Compensation, paid/reimbursed travel, Royalty Income, and Intellectual Property Rights.

Immediate Family Member
refers to an individual’s spouse, domestic partner, person in a civil union, or similar relationship, parent, dependent child, or other family members residing in the individual’s household.

Institutional Financial Interest
for purposes of this Policy, is held when either (i) NYU or NYU Langone Health receives or might reasonably be expected to receive Royalty Income from the sale of a product covered by any patent (whether issued or pending), copyright, license, or other intellectual property right, held by NYU or NYU Langone Health and proposed to be used in a human subjects research project; and/or (ii) NYU or NYU Langone Health holds or proposes to hold, directly or indirectly, any equity interests in any amount (or entitlement to the same) in the research sponsor through NYU’s or NYU Langone Health’s technology licensing activities or investments related to such activities with the research sponsor.

Intellectual Property Right
consistent with its definition in the Policy on Conflicts of Interest in Research, means an issued or pending patent, license, or copyright covering products or processes being used in a research project, and includes: the right to income from NYU in connection with a patent, license, or copyright held by or to be held by NYU.

Investigator
For the purpose of this Policy and consistent with the definition in NYU Langone Health’s Conflicts of Interest in Research policy, means “any person in the NYU Langone Community, regardless of title or position, who is any of the following in connection with a” human subjects research study “at or under the auspices of NYU Langone Health” who is

- responsible for the design, conduct or reporting of the research;
- proposes to be the Principal Investigator/program director or key personnel in a grant application for the research that is submitted by NYU Langone Health;
- serving as the Principal Investigator/program director, co-investigator, sub-investigator, or key personnel on the research; or
- listed as an investigator or coordinator on the IRB application for the research.

“NYU Langone Community”
means NYU Langone Health faculty (including adjunct, clinical, voluntary, and visiting faculty);
researchers, who may include persons participating in research at or under the auspices of NYU Langone Health; employees; professional staff, including medical, dental and nursing staff; volunteers; fellows; trainees and post-doctoral appointees; students; and consultants, vendors and contractors.

Under the Conflicts of Interest in Research policy, “Investigator” also includes outside persons (e.g., sub-grantees, contractors, collaborators or consultants of NYU Langone Health) who are determined by NYU Langone Health, in consultation with the Principal Investigator/program director of the [study] to be responsible for the design, conduct, or reporting of the [study] conducted at or under the auspices of NYU Langone Health.”

Non-Financial Conflict of Interest
may exist when an individual serves dual roles, such as health care provider and study investigator. Other interests such as publication, promotion or tenure, can also become conflicts of interest that may affect an individual's judgment. Membership in oversight committees such as the IRB as well as positions of authority may pose potential conflicts of interest. Any position that includes responsibilities for the review and approval of research projects or contracts other than his/her own may potentially affect the design of, decisions made and/or action taken surrounding a specific study.

Ownership Interest
means any equity interest, including stock and stock options in any amount in either a publicly-traded or non-publicly-traded entity. except those held in mutual funds, provided that the Investigator or any of his/her Immediate Family members do not have 15% or greater interest in the fund and do not have a Management, Board, or Employment position in the fund.

Royalty Income
means payment linked to product sales, or the written contractual right to receive future royalty payments, directly or indirectly, under an issued or pending patent, license, or copyright, that has been received in the prior calendar year or is expected to be received in the current or next calendar year.

Significant Financial Interest
means, for the purpose of this Policy:
a Financial Interest that is

(a) any Management, Board or Employment Position (including as a director, trustee, partner, senior executive, officer or employee), regardless of compensation;

(b) Ownership Interests (including stocks, options, and warrants) related to the research, greater than $10,000 when aggregated for the Immediate Family;

(c) Ownership Interests of any amount in a privately-held company;

(d) Consulting Compensation, including salary, consulting income, and honoraria), paid/reimbursed Travel for personal benefit as determined by the CIMU (e.g., a gift or a trip whose primary purpose is pleasure or celebration), and Royalty Income, when aggregated, of more than $25,000 in any relevant year; or

(e) any Intellectual Property Right being tested, developed, or validated in the research.

Individual Conflicts of Interest

An individual Conflict of Interest may exist whenever an Investigator has a Financial Interest related to research in which he/she participates, including any interest in entities sponsoring or otherwise affected
by the research and any interests in products being used in the research. The *Conflicts of Interest in Research Policy* identifies requirements for disclosure, and procedures for evaluation and either management or elimination of potential Conflicts of Interest in research. Under the *Conflicts of Interest in Research Policy*, Investigators participating in research and other sponsored programs must disclose all Financial Interests that reasonably appear to be related to the Investigator’s responsibilities at NYU Langone Health and the specific research project. NYU Langone Health, through its Conflicts of Interest Management Unit (“CIMU”), a division of its Office of Internal Audit, Compliance and Enterprise Risk Management (“IACERM”), will then review and evaluate such disclosures, determine whether the Financial Interest could give rise to a Conflict of Interest in the research, and determine whether the Conflict of Interest can be managed or must be eliminated in order for the individual to engage in the research project.

- If the CIMU determines that the disclosed Financial Interest is not a Significant Financial Interest, the CIMU will determine if a Conflict of Interest exists. If so, the disclosing Investigator’s participation in the research will normally be permitted, subject to the terms of a CIMU-issued conflict of management plan.

- If an Investigator discloses a Significant Financial Interest that could give rise to a Conflict of Interest, the CIMU will first (1) determine whether or not Compelling Circumstances exist to justify the Investigator’s participation in the research, notwithstanding the Significant Financial Interest, and (2) if the matter gives rise to a significant potential Conflict of Interest, the CIMU will, with consultation from the Office of General Counsel and/or NYU Langone Health’s Executive Vice President and Vice Dean for Science, Chief Scientific Officer, use diligent efforts to eliminate or manage the conflict. If the CIMU is not able to eliminate or manage the conflict, or if so recommended by the Executive Vice President and Vice Dean for Science, Chief Scientific Officer, the CIMU may refer the matter to NYU Langone Health’s Business Conflict of Interest Committee (“BCOIC”).

  If the CIMU determines Compelling Circumstances exist for the Investigator’s participation in the research, the CIMU will approve a conflict management plan. In order for the Investigator to participate in the research, the conflict management plan must be agreed to by both the project’s Principal Investigator and the Investigator (if different). If Compelling Circumstances are not found or the conflict management plan is not agreed-to, the Investigator may carry out the research only if the Conflict of Interest is eliminated.

To assure that all potential Conflicts of Interest are identified, the *Conflicts of Interest in Research Policy* requires all that Investigators participating in a research project (including Principal Investigator, co-investigators and other Research Team Members) submit, at the time the project is first submitted to the IRB to SPA or the IRB, protocol-specific disclosures of personal Financial Interests of the individual and his/her Immediate Family. In addition, all such individuals will be required to complete and return a disclosure form on an annual basis under which they disclose any Financial Interests related to their responsibilities at NYU Langone Health and its affiliates. The IRB or SPA will forward to the CIMU any project-specific disclosure in which an Investigator has indicated a Financial Interest for further review, evaluation, and determination of whether the Financial Interest could give rise to a Conflict of Interest in the research in accord with the *Conflicts of Interest in Research Policy*.

For any study where an Investigator or other Research Team member discloses a Financial Interest, the IRB will not issue its final initial approval of the study until the NYU Langone Health CIMU and/or the BCOIC has completed its review and evaluation of the potential conflict as required under the *Conflicts of Interest in Research Policy*. The reviewing IRB may not approve research protocols referred to the CIMU and/or the BCOIC that have not been approved by the CIMU and/or the BCOIC or approve monitoring procedures or other conditions that are less restrictive than those imposed by the CIMU and/or the BCOIC. Upon completion of its review and evaluation, the CIMU will notify the IRB of the final
determination of the Conflict of Interest review and, if applicable, will submit to the IRB the conflict management plan issued by the CIMU or the BCOIC and approved by the applicable Investigator(s). Upon receipt, the IRB Chair (or designee) will review the conflict management plan and report the results of the evaluation and management plan to the convened IRB or the reviewer using the expedited procedure before issuing the IRB’s final initial approval of the study. The IRB may modify the plan to impose more stringent restrictions than those imposed by the CIMU or the BCOIC in order to protect research subjects. The IRB Office must document completion of the review required under the Conflicts of Interest in Research in the applicable IRB protocol/study file, which will include retaining a copy of the final, approved conflict management plan.

If an Investigator’s Financial Interests in a research project change during the course of the study, the Investigator is required to submit a revised Investigator Financial Interest Disclosure Form to the IRB prior to acquiring such new Financial Interests. If there are material changes from the prior disclosures, the CIMU and the BCOIC will review the change to determine if the conflict management plan on file is adequate and appropriate for the changed circumstances.

In addition, every Investigator listed on the IRB protocol is required to submit a new disclosure form at the time of each annual continuing review of a research project. The IRB will review material changes to the disclosures as part of its continuing review process. Approvals of continuing review for the research will not be held in the event of a change to an Investigator’s financial interest disclosure. However, if there is a modification to add new study personnel and the new study personnel discloses a Financial Interest, the IRB will hold its continuing review approval until the NYU Langone Health CIMU and/or the BCOIC has completed its review and evaluation of the potential conflict.

Institutional Conflicts of Interest

The Institutional Conflicts Policy sets forth procedures for reporting, evaluation, and either management or elimination of potential institutional Conflict of Interests (“ICOIs”) in research. Under the Institutional Conflicts Policy, all potential ICOIs require disclosure, evaluation and either management or elimination in order for the research to be conducted at or by NYU Langone Health. Under the Institutional Conflicts Policy, an ICOI “arises in human subjects research when a financial interest of NYU or NYU Langone Health may affect or appear to affect the design, conduct, reporting, review, or oversight of the human subjects research.” ICOIs are of significant concern when an Institutional Financial Interest creates the potential for inappropriate influence over the research, particularly to the integrity of the research and the safety and care of patients enrolled in the research.

NYU Langone Health’s policy is that it will not participate in a human subjects research project that involves a significant ICOI due to Institutional Financial Interests. Examples of situations that may give rise to a significant ICOI include:

- A clinical trial or other human subjects research that is greater than minimal risk, that involves testing, validating, or developing a product covered by an NYU or NYU Langone Health Intellectual Property Right; or
- A clinical trial sponsored by a for-profit company in which NYU or NYU Langone Health holds or proposes to hold an equity interest.

If the CIMU determines that a significant ICOI may exist, the CIMU, in consultation with the Office of General Counsel and NYU Langone Health’s Executive Vice President and Vice Dean for Science, Chief Scientific Officer, will determine whether Compelling Circumstances exist to merit an exception and whether diligent efforts to eliminate the ICOI have not succeeded. If the CIMU determines Compelling Circumstances exist for NYU Langone Health’s participation despite the Institutional Financial Interest, a conflict management plan will be issued and must be approved by the study’s Principal Investigator.
before being adopted. The conflict management plan can include restrictions similar to those contemplated for individual conflict management plans, and additional restrictions on NYU Langone Health’s institutional participation in the research.

For any human subjects research study where an ICOI exists, the IRB will not issue its final initial approval of the study before the CIMU has completed its review and evaluation of the ICOI as required under the Institutional Conflicts Policy. The IRB may not approve research protocols referred to the CIMU that have not been approved by the CIMU or approve monitoring procedures or other conditions that are less restrictive than those imposed by the CIMU.

Upon completion of its review and evaluation, the CIMU will notify the IRB of its final determination of the ICOI review and, if applicable, will submit to the IRB the approved conflict management plan. Upon receipt of the agreed-upon conflict management plan, the IRB Chair (or designee) will review the conflict management plan prior to issuing the IRB’s final initial approval of the project. The IRB may modify the plan to impose more stringent restrictions than those imposed by the CIMU in order to protect research subjects. The IRB Office must document completion of the review required under the Institutional Conflicts of Interest Policy in the applicable IRB protocol/study file, which will include retaining a copy of the final, approved conflict management plan.

15.12 Subject Recruitment
Investigators are responsible for recruiting research subjects in a manner that is fair, ethical and equitable. IRB approval is required for all study recruitment procedures and materials. Recruitment materials must be consistent with the IRB-approved protocol, accurate, and not coercive. If recruitment procedures contemplate concurrent enrollment of subjects in multiple ongoing studies, such procedures must be explicitly described in the relevant protocol(s). For specific information regarding recruitment materials, review and creation guidance, please see the Informational Sheet regarding Advertisements and Recruitment Materials. For specific information regarding recruitment materials, review and creation guidance, please see the Informational Sheet regarding Advertisements and Recruitment Materials.

Recruitment Incentives
Payment arrangements among sponsors, organizations, investigators, and those referring research subjects may place subjects at risk of coercion or undue influence or cause inequitable selection. Payment in exchange for referrals of prospective subjects from researchers/physicians (referred to as “finder’s fees”) is not permitted. Similarly, payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (referred to as “bonus payments”) are also not permitted.

Payment to Subjects
Payment to research subjects may be an incentive for participation or a way to reimburse a subject for travel and other expenses incurred due to participation. However, payment for participation is not considered a research benefit. Regardless of the form of remuneration, investigators must take care to avoid coercion of subjects. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation in the study. The amount of compensation must be proportional to the risks and inconveniences posed by participation in the study. Subjects in a study should not be paid unless the IRB first reviews and approves the relevant research protocol, the associated informed consent form, and the terms of payment to the subjects.

Justification for Payment
Principal Investigators who wish to compensate research subjects must indicate in their IRB application the justification for such payment. Such justification should:

- substantiate that proposed payments are reasonable and commensurate with the expected
contributions of the subject;

- state the terms of the subject participation and the amount of payment which should be incorporated in the informed consent form; and

- substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure on the patient to volunteer for the research study.

**IRB Review**
The IRB must review both the amount of payment and the proposed method of disbursement to assure that neither entails problems of coercion or undue influence.

Credit for payment should accrue and not be contingent upon the subject completing the entire study. Any amount paid as bonus for completion of the entire study should not be so great that it becomes coercive.

The NYU Langone Health IRBs prohibit:

- the entire payment to be contingent upon completion of the entire study; and

- compensation for participation in a trial in the form of a coupon offered by the sponsor that is good for a discount on the purchase price of the product being investigated once it has been approved for marketing.

The IRB consent form must describe the terms of payment and the conditions under which subjects would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed).

**Procedures for Disbursement**
Unless the study is confidential/ of a sensitive nature, the NYU Langone Health Office of Business and Financial Services requires personal identifying information in order to issue checks payable through NYU Langone Health’s Accounts Payable procedures, bank cards, or gift cards to subjects. The study’s consent form must inform subjects that they will be asked to provide their social security number and verification of U.S citizenship or permanent resident status to receive payment. For confidential studies/studies of a sensitive nature, only the subject’s name and address are required, but the Principal Investigator must keep an identity key in a secure place.

NYU Langone Health investigators should refer to NYU Langone Health’s *Policy on Human Subjects Payments (Policy #SP-17)* for additional and current guidance on acceptable payment methods and procedures.

**15.13 Investigator Concerns**
Investigators who have concerns or suggestions regarding NYU Langone Health’s human research protection program should convey them to the Institutional Official or other responsible parties (e.g., Department Chair, NYU Langone Health’s Chief Scientific Officer, Office of Research Compliance, Office of General Counsel) regarding the issue, when appropriate. The Institutional Official will research the issue, and when deemed necessary, convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted. In addition, the IRB Chair or the IRB Director will be available to address investigators’ questions, concerns and suggestions.

**15.14 Updating CVs for NYU Langone Health Employees**
CVs for the Principal Investigator and each member of the research team for a study are required for each
new study submission, and are included in the relevant Research Navigator study record. An up to date CV is required for IRB review and must be uploaded for any NYU Langone Health employee in his/her Research Navigator person profile.

**Effective February, 2019**, any NYU Langone Health personnel who does not have a CV uploaded in a Research Navigator person profile associated with that individual will not be approved to be added to a study until the individual’s person profile is updated. CVs should be updated every three (3) years in the Research Navigator person profile or whenever updates are made to the CV, whichever is sooner. Investigators may assign a designee to upload and manage his/her CV in person profile.

16. **Health Insurance Portability and Accountability Act (HIPAA)**

The *Health Insurance Portability and Accountability Act of 1996* (“HIPAA”) is an expansive federal law, only part of which is intended to protect the privacy of health care information. HIPAA required Congress to enact a health information privacy law by August 1999 and stated that if it did not act by then, which it did not, the U.S. DHHS must develop privacy regulations. HIPAA required the creation of a Privacy Rule for identifiable health information. The resulting Privacy Rule, finalized in August 2002, set a compliance date of April 14, 2003. While the main impact of the Privacy Rule will be on the routine provision of and billing for health care, the Privacy Rule also affects the conduct and oversight of research. Investigators, researcher team members, IRB Office staff, and IRB members as well as research administrators must be aware of HIPAA and the Privacy Rule.

The objective of the Privacy Rule is to protect the privacy of an individual’s health care information. It creates a federal “floor” of protection so that every person in the U.S. has at least the same basic rights and protections, though some may have additional rights depending on state law. Protected Health Information (“PHI”) collected and maintained by NYU Langone Health may not be used internally or disclosed to any outside person or organization for research purposes without prior approval of the IRB. NYU Langone Health researchers must also abide by all institutional/corporate policies regarding HIPAA privacy and security.

The following describes the procedures for conducting research at NYU Langone Health in accordance with HIPAA and the Privacy Rule.

16.1 **Definitions**

**Access**
means, for purposes of this Policy, the mechanism of obtaining or using information electronically, on paper, or other medium for the purpose of performing an official function.

**Authorization**
means, for purposes of this Policy, a detailed document that gives Covered Entities permission to (a) use PHI for specified purposes, which are generally for purposes other than treatment, payment, or health care operations, or (b) to disclose PHI to a third party specified by the individual whose PHI is to be disclosed.

**Covered Entity**
is the term applied to institutions that must comply with the Privacy Rule. These include:

- health plans (such as health insurance companies, health management organizations (HMOs), and government programs that pay for health care, e.g., Medicare and Medicaid);
- health care clearinghouses (including entities that process non-standard health information they may receive from another entity into a standard format, i.e., standard electronic format or data
Common Rule
is the federal policy on human subject protection that provides for the primary source of regulation of human subject research.

De-Identified Information
means health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. If information is de-identified, it no longer is subject to the Privacy Rule and exempt from HIPAA.

Deletion
means the removal, erasing, or expunging information or data from a record.

Disclosure
means the release, transfer, provision of access to, or divulging in any other manner, information outside of the Covered Entity.

Health Information
means any information created or received by a health care provider or health plan that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or payment for the provision of health care to an individual.

Identifiable Health Information
is a subset of Health Information including demographic information collected from an individual and that (a) identifies the individual or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Limited Data Set
is PHI that excludes specific direct identifiers of the individual or of relatives, employees or household members of an individual. A Limited Data Set can only be used for the purposes of research, public health, or healthcare operations, and disclosed for the purpose of research.

Minimum Necessary
refers to the principle that any access should be limited to the minimum amount of information needed to accomplish the intended purpose of the use or disclosure.

Privacy Board
is the term used to describe a board comprised of members of varying backgrounds and appropriate professional competencies, as necessary, to review individuals’ privacy rights. It is only an alternative to an IRB for privacy issues. A Privacy Board cannot replace the IRB for Common Rule purposes.

Privacy Act
is a law that provides for the confidentiality of individually identified and retrieved information about living individuals that is maintained in a system of records and permits the disclosure of records only when specifically authorized by the statute. The Act provides that the collection of information about individuals is limited to that which is legally authorized, relevant, and necessary.

Privacy Rule
enacted under HIPAA provides guidance on the use of PHI in the conduct of research. It imposes
requirements on those involved in research, both individuals and institutions. “Privacy” refers to a person’s desire to control the access of others to themselves. The evaluation of privacy involves consideration of how the Principal Investigator will access information from or about research subjects. The IRB members should know strategies to protect privacy interests relating to contact with potential subjects, and access to private information.

**Protected Health Information (“PHI”)**
is individually identifiable health information transmitted or maintained electronically or in any other form or medium, except for education records or employment records, as excluded in the HIPAA Privacy Rule.

**Waiver of Authorization**
is a means of requesting approval from an IRB or Privacy Board rather than asking each research subject for an authorization to access subjects' PHI.

### 16.2 Impact of HIPAA on Research

The final Privacy Rule published on August 14, 2002 included a number of changes in how the Rule applies to research. See the [NIH HIPAA Privacy Rule Booklet for Research](https://www.hhs.gov/hipaa/for-professionals/protection-of-individuals/protection-of-individuals.html) and the [NIH fact sheet on Institutional Review Boards and HIPAA](https://www.hhs.gov/hipaa/for-professionals/protection-of-individuals/protection-of-individuals.html) for more information on how HIPAA applies to research. See also [Influence of the Privacy Rule on Academic Research](https://www.hhs.gov/hipaa/for-professionals/protection-of-individuals/protection-of-individuals.html), a white paper published by the American Council on Education.

NYU Langone Health is a Covered Entity under HIPAA. NYU Langone Health researchers who are working with PHI will be required to comply with the rules on HIPAA. The NYU Langone Health IRBs each act as the institution’s Privacy Board.

The Privacy Rule permits Covered Entities to use or disclose PHI for research purposes when the individual who is the subject of the information authorizes the use or disclosure. For clinical research, Authorization must be sought in addition to informed consent. Authorization must also be sought for other research uses or disclosures of PHI that do not qualify for an IRB Waiver of Authorization (discussed below).

The Privacy Rule has several special provisions that apply to Authorizations for uses and disclosures of PHI for research purposes. These provisions are as follows:

- An Authorization for use or disclosure of PHI for a research purpose may state that the Authorization does not expire, that there is no expiration date or event, or that the Authorization continues until the end of the research study;

- An Authorization for the use or disclosure of PHI for research may be combined with a consent to participate in the research, or with any other legal permission related to the research study, with the exception of research involving the use or disclosure of psychotherapy notes, which must be authorized separately; and

- Research Authorization forms must be filled out completely and accurately by the Principal Investigator, to ensure that all parties who require access to PHI for the research (including sponsors, contract research organizations, DSMBs, IRBs, etc.) are identified in the Authorization form and may receive the PHI. The combined Authorization/consent form should be completed by the Principal Investigator and submitted to the applicable NYU Langone Health IRB, for review and approval.

### 16.3 Applicability of HIPAA on Research

HIPAA defines “research” as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." This definition is identical
Waiver of Authorization for Use or Disclosure of Protected Health Information in Research

Under the Privacy Rule, Covered Entities are permitted to use and disclose PHI for research with an individual’s Authorization, or without individual’s Authorization under limited circumstances. A Covered Entity may use or disclose PHI for research when presented with documentation that an IRB has granted a Waiver of Authorization request [see 45 CFR 164.512(i)(1)(i)]. This provision of the Privacy Rule might be used, for example, to conduct records research, epidemiological studies, or other research where de-identified data is unavailable or not suited to the research purpose.

Required Waiver Documentation

The waiver documentation presented to the Covered Entity must include the following:

- Identification of the IRB or Privacy Board and the date on which the alteration or Waiver of Authorization was approved;
- A statement that the IRB or Privacy Board has determined that the alteration or Waiver of Authorization, in whole or in part, satisfies the three criteria in the Privacy Rule;
- A brief description of the PHI for which use or access has been determined to be necessary by the IRB or Privacy Board;
- A statement that the alteration or Waiver of Authorization request has been reviewed and approved under either normal or expedited review procedures; and
- The signature of the IRB Chair or other member, as designated by the IRB Chair, or the Chair of the Privacy Board, as applicable.

Criteria for IRB Approval of Waiver of Authorization

All of the following three criteria must be satisfied for the IRB to approve a Waiver of Authorization under the Privacy Rule.

1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
   - an adequate plan to protect the identifiers from improper use and disclosure;
   - an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
   - adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this subpart.

2. The research could not practicably be conducted without the Waiver of Authorization or alteration; and

3. The research could not practicably be conducted without access to and use of the PHI.

PHI Review Preparatory to Research

The Privacy Rule permits a Covered Entity to use or disclose PHI to a researcher without Authorization or Waiver of Authorization for the limited purpose of a “review preparatory to research.” Such reviews may be used to prepare a research protocol, or to determine whether a research site has a sufficient population of potential research subjects. Prior to permitting the researcher to access the PHI, the
Covered Entity must obtain representations from the researcher that (a) the use or disclosure of the PHI is solely to prepare a research protocol or for similar purposes preparatory to research, (b) the researcher will not remove any PHI from the Covered Entity, and (c) PHI for which access is sought is necessary for the research purpose. Researchers should consult the Covered Entity regarding any forms or applications necessary to conduct a review preparatory to research.

Researchers conducting a review preparatory to research may not record information in identifiable form, nor may they use PHI that they receive to contact potential subjects, unless the investigator is also the subject’s treating physician. Because the Privacy Rule permits a Covered Entity to disclose PHI to the individual who is the subject of the information, covered health care providers and patients may continue to discuss the option of enrolling in a clinical research study without patient authorization.

Even when permitted by the Privacy Rule, however, any use of patient information for recruitment must comply with IRB policies relating to subject recruitment, as noted below.

- All human subjects research requires IRB review to determine either (a) Exempt status or (b) need for further review.

- Reviews preparatory to research that are permitted under HIPAA may or may not be human subjects research depending on the investigation being conducted. IRB review is not required only in the case where the proposed activity is review of a database by an individual who is entitled to access it, which database is intended to enumerate an available data set without reviewing PHI and where no PHI is recorded. For example: medical records may be queried for information such as: In the year XXXX how many patients had a discharge diagnosis of [indicate disease/diagnosis]. IRB Privacy Board review is required for all other uses of PHI as indicated. If the research involves a de-identified data set, defined as a data set where all of the identifiers (as listed below) are removed, then a de-identified data set certification form must be completed, submitted for administrative review, and certified prior to accessing the data set. This activity also requires an IRB-determined exemption from review:
  1. Names (full name or last name and initial(s))
  2. Postal address information (geographical subdivisions smaller than a state including street, address, city, county, precinct, zip code, equivalent geocodes)
  3. All elements of dates directly related to an individual, other than years
  4. Telephone numbers
  5. Fax numbers
  6. E-mail addresses
  7. Social Security numbers
  8. Medical Record numbers
  9. Health plan beneficiary numbers
 10. Account numbers
 11. Certificate/License numbers
 12. Vehicle identifiers (including serial numbers, license plate numbers)
 13. Device identifiers, serial numbers
 14. Web URLs
 15. IP address numbers
 16. Biometric identifiers (e.g., fingerprints, retinal or voice prints)
 17. Full face photo images and any comparable photo images
 18. Any other unique identifying numbers, characteristics, or codes other than the unique code assigned by the investigator to code the data (e.g., prescription numbers)

IRB and Privacy Board review and approval is required prior to initiating research. Investigators are not authorized to contact potential research subjects identified in reviews preparatory to research unless they are directly responsible for care of the potential subject and entitled to PHI as a result of that duty. Principal Investigators who have previously obtained full consent and Authorization to contact a research subject as a result of a previously IRB-approved research project may contact his or her former research subjects.
provided that the subject agreed to be contacted for information on future research conducted by the same Principal Investigator or co-investigator(s).

Research on Protected Health Information of Decedents

The protections of the Common Rule apply only to living human beings. By contrast, the Privacy Rule also protects the identifiable health information of deceased persons ("Decedents"). The Privacy Rule contains an exception to the Authorization requirement for research that involves the PHI of Decedents.

A Covered Entity may use or disclose Decedents’ PHI for research if the Covered Entity obtains representations from the researcher (a) that the use or disclosure being sought is solely for research on the PHI of Decedents, and (b) that the PHI being sought is necessary for the research.

If requested by the Covered Entity, documentation of the death of the individuals about whom PHI is being sought must be obtained and provided.

IRB approval is required for research involving Decedents’ PHI. The Principal Investigator should submit the applicable IRB form for IRB approval when they intend to conduct research involving Decedents’ PHI.

Limited Data Sets with a Data Use Agreement

When a researcher does not need direct identifiers of individuals for a study but does require certain identifiable data elements that are normally not permitted in de-identified data, the Privacy Rule permits a Covered Entity to disclose a “Limited Data Set” to the researcher without Authorization or Waiver of Authorization, provided that a data use agreement has been signed between the researcher and Covered Entity. The Limited Data Set as defined by HIPAA is still considered to be PHI and is therefore still subject to the requirements of the Privacy regulations as it can include identifiable patient information, but it must exclude specified direct identifiers of the individual whose information is to be used, or of the individual's relatives, employers, or household members.

Specifically, all of the following 16 identifiers must be removed in order for the health information to be a Limited Data Set:

1. Names
2. Street addresses (other than town, city, state and zip code)
3. Telephone numbers
4. Fax numbers
5. Email addresses
6. Social Security numbers
7. Medical Record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers (including serial numbers, license plate numbers)
12. Device identifiers, serial numbers
13. Web URLs
14. IP address numbers
15. Biometric identifiers (e.g., finger prints, retinal or voice prints)
16. Full face photo images and any comparable images

Health information that may remain in a Limited Data Set includes:

- Dates such as admission, discharge, service, date of birth, date of death;
- City, state, five digit or more zip code; and
- Ages in years, months or days or hours.
The Privacy Rule requires that the data use agreement used in conjunction with the Limited Data Set contain provisions that:

- establish the permitted uses and disclosures of the Limited Data Set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Privacy Rule if done by the Covered Entity;
- limit who can use or receive the data;
- require the recipient to agree to the following:
  - not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;
  - use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;
  - report to the Covered Entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware. The recipient must agree to ensure that any of its agents, including a subcontractor to whom the recipient provides the Limited Data Set, agrees to the same restrictions and conditions that apply to the recipient with respect to the Limited Data Set; and
  - not to identify the information or contact the individual.
- requires that researchers who will be receiving Limited Data Sets under the data use agreement submit a signed copy of the Covered Entity’s data use agreement to the applicable NYU Langone Health IRB for approval, prior to initiating the research.

**Transition Provisions**

The Privacy Rule contains certain grandfathering provisions that permit a Covered Entity to use and disclose PHI for research after the Privacy Rule’s compliance date of April 14, 2003, if the researcher obtained any one of the following prior to the compliance date:

- An Authorization or other express legal permission from an individual to use or disclose his/her PHI for the research;
- The informed consent of the individual to participate in the research; or
- A waiver of informed consent granted by the IRB for the research.

Even if informed consent or other express legal permission was obtained prior to the compliance date, if new subjects are enrolled or existing subjects are re-consented after the compliance date, the Covered Entity must obtain the individual’s Authorization. For example, if there was a temporary waiver of informed consent for emergency research under the FDA’s human subject protection regulations, and informed consent was later sought after the compliance date, individual Authorization must be sought at the same time.

The transition provisions apply to both uses and disclosures of PHI for specific research protocols and uses or disclosures to databases or repositories maintained for future research.

**16.4 HIPAA and Document Requirements**

HIPAA documents include an Authorization form, a Waiver of Authorization form, Limited Data Set form, and a de-identification form. One of these documents must be used whenever PHI is utilized in the research.

**16.5 Patient Rights and Research**

Under HIPAA, patients have certain rights. Those that may affect research include the right to receive a Notice of Privacy Practices, the right to access, inspect, and receive a copy of one’s own PHI, the right to request an amendment to one’s own PHI, and the right to an accounting of certain disclosures of PHI that occur outside the scope of treatment, payment and health care operations that have not been
16.6 HIPAA and Existing Studies
Any research subject enrolled in a study that uses PHI from a Covered Entity must sign a HIPAA-compliant Authorization form. This form is in addition to the existing Informed Consent document, and is federally required.

17. Special Topics
17.1 Certificate of Confidentiality

Statutory Basis for Protection
The Public Health Service Act §301(d), 42 U.S.C.§241(d) provides for protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research:

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

Certificates of Confidentiality (“CoCs”) constitute an important tool to protect the privacy of research study subjects. CoCs are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the Principal Investigator and others who have access to research records to refuse to disclose identifying information of research subjects in connection with any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

CoCs may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, CoCs help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects.

CoCs are granted sparingly. The study's funding source, if any, is not relevant to the decision.

The CoC goes beyond the consent form in ensuring confidentiality and anonymity. Without the CoC, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects).

Any Principal Investigator engaged in research in which sensitive information is gathered from human subjects (or any person who intends to engage in such research) may apply for a CoC. Research can be considered "sensitive" if it involves the collection of:

- information about sexual attitudes, orientation, practices;
- information about personal use of alcohol, drugs, or other addictive products;
- information about illegal conduct;
- information that could damage an individual's financial standing, employability, or reputation.
within the community;
• information in a subject’s medical record that could lead to social stigmatization or discrimination; or
• information about a subject’s psychological well-being or mental health.

This list is not exhaustive. Researchers contemplating research on a topic that might qualify as sensitive should contact the IRB Office for help in applying for a certificate.

The IRB may require Principal Investigators to apply for a CoC.

**Limitations**

The protection offered by a CoC is not absolute. A CoC protects research subjects only from legally compelled disclosure of their identity. It does not restrict voluntary disclosures.

For example, a CoC does not prevent researchers from voluntarily disclosing to appropriate authorities such matters as child abuse, a subject’s threatened violence to self or others, or from reporting a communicable disease. However, if researchers intend to make such disclosures, this should be clearly stated in the informed consent form which research subjects are asked to sign.

In addition, a CoC does not authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research subject if:

• the subject (or, if he or she is legally incompetent, his or her legal guardian) consents, in writing, to the disclosure of such information;
• authorized personnel of the DHHS request such information for audit or program evaluation, or for investigation of DHHS grantees or contractors and their employees; or
• release of such information is required by the Federal Food, Drug, and Cosmetic Act or regulations implementing that Act.

**Application Procedures**

Any person engaged in research collecting sensitive information from human research subjects may apply for a CoC. For most research, CoCs are obtained from the NIH. If the NIH funds the research project, the Principal Investigator may apply through the funding institute. However, even if the research is not supported with NIH funding, the Principal Investigator may apply for a CoC through the NIH Institute or Center (IC) funding research in a scientific area similar to the project.

**Note: Effective October 1, 2017**, CoCs will be automatically issued as a term and condition of the award for any NIH-funded project that uses identifiable, sensitive subject information that was ongoing on or after December 13, 2016.

If the research is conducting a sensitive research project that is covered by the Agency for Healthcare Research and Quality (AHRQ) confidentiality statute [42 U.S.C. section299a-1(c)] entitled “limitation on use of certain information” or the Department of Justice confidentiality statute [42USC section 3789g], then a CoC is not required.

If there is an Investigational New Drug Application (IND) or an Investigational Drug Exemption (IDE), the study sponsor can request a CoC from the FDA.

For more information, see the NIH Certificates of Confidentiality Kiosk (https://humansubjects.nih.gov/coc/index.)
17.2 Mandated Reporting

This Policy addresses mandated reporter obligations in relation to human subjects research.

While any person may make a report if they have reasonable cause to believe that a child or elderly person has been or is being abused or neglected, New York State law mandates that certain persons must report suspected child abuse or maltreatment, when, in their professional capacity, they are presented with reasonable cause to suspect child abuse or maltreatment. “Reasonable cause” to suspect child abuse or neglect means that based on one’s observations of the evidence, professional training and experience, one believes that the parent or legal guardian has harmed or placed a child in danger of being harmed. When elder abuse in residential facilities is suspected, certain persons are required under New York State Law to report such cases to authorities as well.

NYU Langone Health policy requires that informed consent be obtained from all adult research subjects and assent from children involved as research subjects, in addition to the consent of their respective parents/legal guardians. In situations where conditions of abuse or neglect might be revealed, mandated reporters under New York State law should make themselves and their obligations known to parents of children under age 18, to subjects who are children, and to subjects who are potential victims of elder abuse or neglect.

New York Social Services Law § 413 states, in part:

Sec. 1. (a) The following persons and officials are required to report or cause a report to be made in accordance with this title when they have reasonable cause to suspect that a child coming before them in their professional or official capacity is an abused or maltreated child, or when they have reasonable cause to suspect that a child is an abused or maltreated child where the parent, guardian, custodian or other person legally responsible for such child comes before them in their professional or official capacity and states from personal knowledge facts, conditions or circumstances which, if correct, would render the child an abused or maltreated child: any physician; registered physician assistant; surgeon; medical examiner; coroner; dentist; dental hygienist; osteopath; optometrist; chiropractor; podiatrist; resident; intern; psychologist; registered nurse; social worker; emergency medical technician; licensed creative arts therapist; licensed marriage and family therapist; licensed mental health counselor; licensed psychoanalyst; licensed behavior analyst; certified behavior analyst assistant; hospital personnel engaged in the admission, examination, care or treatment of persons; a Christian Science practitioner; school official, which includes but is not limited to school teacher, school guidance counselor, school psychologist, school social worker, school nurse, school administrator or other school personnel required to hold a teaching or administrative license or certificate; social services worker; director of a children's overnight camp, summer day camp or traveling summer day camp, as such camps are defined in section thirteen hundred ninety-two of the public health law; day care center worker; school-age child care worker; provider of family or group family day care; or any other child care or foster care worker; mental health professional; substance abuse counselor; alcoholism counselor; all persons credentialed by the office of alcoholism and substance abuse services; peace officer; police officer; district attorney or assistant district attorney; investigator employed in the office of a district attorney; or other law enforcement official.

Additional guidance should be obtained from the child protection coordinators at the social work department of each NYU Langone Hospitals site. Reports must be made as soon as abuse or maltreatment is suspected, and are be reported by telephone to the New York Statewide Central Register of Child Abuse and Maltreatment (SCR). For more information about how to report, see the
New York State Public Health Law §2803-d requires certain persons (i.e., physicians and their assistants or associates, nurses, social workers, physical and occupational therapists, psychologists) to report suspected instances of abuse, neglect or mistreatment of a person residing in a nursing home when there is reasonable cause to believe that a person in the facility, other than another patient, is the cause of such physical abuse, neglect or mistreatment. Any other person may, but is not obligated by law, to report. Reports must be made immediately by telephone and within 48 hours of discovery in writing. Reports must be made to the Department of Health, Office of Health Systems Management.

Principal Investigators should consult these sources to determine if potential subjects should be advised of mandatory reporting requirements during the informed consent process.

17.3 NYUGSoM/NYU LISoM Students and NYU Langone Health Employees as Subjects

When NYUGSoM or NYU LISoM students and/or NYU Langone Health employees are being recruited as potential research subjects, researchers must ensure that there are additional safeguards for these subjects. The voluntary nature of their participation must be paramount and without undue influence on their decision. Researchers must emphasize to subjects that neither their academic status or grades, or their employment, will be affected by their decision whether or not to participate. A record of the participation of an NYUGSoM or NYU LISoM student cannot be linked to an academic record. The IRB should also ensure when necessary a certificate of confidentiality (CoC) is sought in sensitive research topics such as mental health, drug/alcohol abuse, sexual behavior, or others that fall into this category.

The Principal Investigator is also responsible for seeking the approval from the NYU Langone Health Human Resources department, before approval of any project focused on recruitment of NYU Langone Health employees.

To minimize coercion, Principal Investigators should avoid, whenever possible, the use of their students and employees in procedures which are neither therapeutic nor diagnostic. In these latter situations, investigators should solicit subjects through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes other than their own. When entering a classroom to recruit students and conduct research, e.g. administer a survey, investigators must do so at the end of the class period to allow non-participating students the option of leaving the classroom, thereby alleviating pressure to participate.

17.4 Oral History Activities

The following Policy is based on guidance received from the OHRP:

A decision whether oral history or other activities solely consisting of open ended qualitative type interviews are subject to the policies and regulations outlined in an institution’s FWA and HHS regulations for the protection of human research subjects (45 CFR 46) is based on the prospective intent of the investigator and the definition of "research" under HHS regulations at 45 CFR 46.102(d): "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
Specifically, for the purposes of this Policy, the evaluation of such activities hinges upon whether:

- The activity involves a prospective research plan which incorporates data collection, including qualitative data, and data analysis to answer a research question; and
- The activity is designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

In order to be subject to NYU Langone Health’s human research protections policies, the proposed activity must meet both of the above standards.

General Principles for evaluating Oral History type activities:

- Oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without intent to draw conclusions or generalize findings would not constitute "research" as defined by HHS regulations 45 CFR part 46.

  Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the videotape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.

- Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) would constitute "research" as defined by HHS regulations at 45 CFR part 46.

  Example: An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.

- Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR part 46, the creation of such an archive would constitute research under 45 CFR part 46.

  Example: Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research.

Principal Investigators are advised to consult with the IRB Office regarding whether their oral history project requires IRB review.

17.5 Genetic Studies

Since human genes are the sequence instructions to make all human proteins, genetic studies can lead to a molecular description of normal physiological function. Likewise, defects (mutations) in individual genes can lead to pathology. This is a major current area of health research, although the potential power of genetic research is also the inherent risk. In particular, patients and family members can learn of ominous mutations prior to disease symptoms. Thus, genetic information, not specifically solicited by the subject, could be the first warning sign of a troubled future. Furthermore, such mutations can be carried through subsequent generations, affecting as yet unborn descendants; and potential illness can be predicted even for family members, un-enrolled and unaffiliated with the research protocol. Although of high predictive value when proven, un-validated results of genetic experiments can still cause actual
Privacy and Confidentiality

In human subjects research using genetic testing, the actual physical interventions involved are usually minor, and would ordinarily be reviewed under the Minimal Risk categories of the federal regulations as just a blood draw. However, the IRB Board, when reviewing any studies with genetic testing, must also consider the various psychosocial and financial risks. This includes examining the procedures in place to preserve confidentiality of study information, and subject identity. It also includes assessing the potential consequences of inadvertent disclosure.

The procedures that could be used to preserve confidentiality include: keeping the test results in the research records and out of the clinical patient charts, and doing the testing in research laboratories where results could not be relied on for clinical decision making or provided to insurance companies as validated health records.

Encoding data such that individual identity is separate from medical/genetic information (de-identification) is a key element in dealing with all research data that could suggest, among other things, that:

- a subject may eventually suffer a serious loss of abilities related to his/her career;
- the subject might incur higher than usual health care costs;
- the subject has a statistically lower life expectancy; or
- the subject’s ability to procreate and perform socially may become impaired.

Diagnostic Status and Types of Tests

In assessing these risks, aside from considering the predictive confidence of the information and its health implications, one should also consider the current diagnostic status of the subject. For example, genetic test studies that are confirmatory of an established diagnosis (testing the test), have much lower risk than when they are predictive in the absence of any symptoms. Also, gene expression studies that are mechanistic in nature may not directly relate to a genetic mutation that could be inherited.

Pharmacogenomic studies, for example, could help chose the most effective therapy, or inform the subject that the available therapies would or would not be effective—thus conferring a range of risks and benefits that must be considered.

Federal vs. State Law

Thus, federal human subjects regulations treat genetic testing to the extent that risks associated with breach of confidentiality, financial harm and psychosocial consequence must all be analyzed along with the potential benefits of the study. However, New York State (NYS) law includes some specific provisions which must be applied whenever human subjects participate in a genetic testing trial located in NYS, where NYS law defines a “genetic test”.

The definition of “genetic test” is less important in the context of federal laws on genetic testing because there is no “genetic testing article”. Both sets of laws apply to all subjects in NYU Langone Health clinical research.
In Section 79-L.1.(a) of the NYS Civil Rights Law:

“Genetic test” shall mean any laboratory test of human DNA, chromosomes, genes, or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or the individual’s offspring; such term shall also include DNA profile analysis. “Genetic test” shall not be deemed to include any test of blood or other medically prescribed test in routine use that has been or may be hereafter found to be associated with a genetic variation, unless conducted purposely to identify such genetic variation.

While “gene product” could be implied to refer to either proteins or RNA, expression studies often are not designed to “diagnose the presence of a genetic variation linked to a predisposition to a "genetic disease". In any case, there are specific requirements that need to be incorporated in the informed consent form if the study is determined to be a genetic test study, and these apply in addition to the elements of consent for general human subjects research defined under federal law in the Code of Federal Regulations (45 CFR 46.116). These additional requirements include (Section 79-L.2.(b). of the NYS Civil Rights Law):

1) a general description of the test
2) a statement of the purpose of the test; … {including}… a statement indicating that the individual may wish to obtain professional genetic counseling prior to signing the informed consent.
3) a statement that a positive test result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may wish to consider further independent testing, consult their physician or pursue genetic counseling;
4) a general description of each specific disease or condition tested for;
5) the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease - If no level of certainty has been established, this subparagraph may be disregarded;
6) the name of the person or categories of persons or organizations to whom the test results may be disclosed;
7) a statement that no tests other than those authorized shall be performed on the biological sample and that the sample shall be destroyed at the end of the testing process or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent; and
8) the signature of the individual subject of the test or, if that individual lacks the capacity to consent, the signature of the person authorized to consent for such individual.

Furthermore in Section 79-L.2.(f), NYS law indicates that to keep a genetic sample for more than sixty (60) days, the approval of an IRB is required. It acknowledges further that genetic research often cannot provide the information in (3), (4) and (5) above, and that this is acceptable.

The presence of these affirmative requirements for informing the subjects of the purpose and procedures of the genetic tests do not preclude more open ended use of de-identified genetic material at a later time, provided that certain provisions are followed and that the subject did not specifically disallow this:
9. Notwithstanding the provisions of subdivisions two and ten of this section, samples may be used for tests other than those for which specific consent has been obtained, for purposes of research conducted in accordance with applicable law and regulation and pursuant to a research protocol approved by an institutional review board, provided the individuals who provided the samples have given prior written informed consent for the use of their sample for general research purposes and did not specify time limits or other factors that would restrict use of the sample for the test, and
   (1) the samples have been permanently stripped of identifying information; or
   (2) a coding system has been established to protect the identity of the individuals who provided the samples, and an institutional review board has reviewed and approved the procedures for the coding system.

Thus, in terms of the written law, there are more stringent requirements for IRB Full Board review for genetic studies under NYS in contrast to federal law.

Furthermore, the DHHS, in an advisory publication, has listed a variety of specific issues which must be dealt with in the consent form (and the review process), including:

- what data (including its reliability and significance) will be provided to the subject and when;
- that subjects may obtain information about themselves or family members which may make them uncomfortable, and likewise family members may be privy to the same information;
- that actions taken may compromise their privacy, insurability and result in financial loss;
- a list of assurances about safeguards to prevent loss of privacy;
- the rights subjects retain over tissue samples and medical information, including the consequences of withdrawing from the study; and
- any potential costs associated with participation.

Other state laws may have different requirements which must be applied for genetic testing studies conducted in those jurisdictions.

**Recruitment for Individual or Pedigree Analysis Studies**

A “pedigree analysis study” refers to the study of an inherited trait or disease in a group of related individuals to assess patterns and characteristics of the trait/disease, and to determine if there is a potential genetic basis for the trait/disease.

In genetic studies, confidentiality (the obligation of institutions to appropriately use restricted information once disclosed to them) and respect for privacy (the right to be left alone) begins with the recruitment process.

Contacting an individual to solicit participation in a genetic study can produce stress in the individual and should be done by the physician treating the patient for their related illness. However, this is often not possible for pedigree analysis studies, where it is desired to recruit family members. In such cases, the current subject under treatment or enrolled in the study (proband) should be used to contact the family members and assess their interest in being contacted.
There is additional legal basis for protecting the privacy of third parties in NYS law, which acts decisively in this regard. NYS Civil Rights Law, Section 79-L, 3(b) states:

No person who lawfully possesses information derived from a genetic test on a biological sample from an individual shall incorporate such information into the records of a non-consenting individual who may be genetically related to the tested individual; nor shall any inferences be drawn, used, or communicated regarding the possible genetic status of the non-consenting individual.

Nonetheless instances may develop where unsolicited disclosure to a proband’s family member of results from genetic testing is necessary, and the need to violate confidentiality must be considered. The conditions under which this is acceptable require all of the following:

- The subjects are at risk of serious harm;
- The harm can be ameliorated; and
- Only information necessary for amelioration is communicated.

**Summary**

The following questions are useful in when reviewing genetic studies. In studies involving genetic testing, several questions need to be addressed, including:

- Will test results be given?
- Will disease risk be quantified, including the limits on certainty of the testing?
- Will a change in a family relationship be disclosed, such as mistaken paternity?

- Does the subject or family member have the option not to know the results? How will this decision be recorded?
- Could other clinically relevant information be uncovered by the study? How will disclosure of this added information occur?
- Do any practical limitations exist on the subject’s right to withdraw from the research, withdraw data, and/or withdraw DNA?
- Is the subject permitted to participate in the study while refusing to have genetic testing (such as in a treatment study with a genetic testing component)?

For DNA banking studies, several questions need to be addressed, including:

- Will DNA be stored or shared? If shared, will the subject’s identity be known by the new recipient investigator?
- Will the subject be contacted in the future by the investigator to obtain updated clinical information?
- How can the subject opt out of any distribution or subsequent use of his/her genetic material?

**Research Involving Coded Private Information or Biological Specimens**

This Policy is based on the Office of Human Research Protection (“OHRP”) guidance document entitled *Coded Private Information or Specimens Use in Research, Guidance* (October 16, 2008 [https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html)). This OHRP document:

- Provides guidance as to when research involving coded private information or specimens is or is not research involving human subjects, as defined under Health and Human Services (“HHS”) regulations for the protection of human research subjects [45 CFR part 46],
- Reaffirms OHRP policy that, under certain limited conditions, research involving only coded private information or specimens is not human subjects research.
- Provides guidance on who should determine whether human subjects are involved in research.
For purposes of this Policy, *coded* means that:

- identifying information (such as name or Social Security number) that would enable investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
- a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Under the definition of “human subject” in this IRB Policies and Procedures document, obtaining identifiable private information or identifiable specimens for research purposes constitutes human subjects research.

For purposes of this Policy, “obtaining” means receiving or accessing identifiable private information or identifiable specimens for research purposes. This includes an investigator’s use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.

In general, private information or specimens are considered to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. Private information or specimens are not considered to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Research involving only coded private information or specimens does not constitute involve human subjects research under this Policy if the following conditions are both met:

1. The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
2. The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
   - the key to decipher the code is destroyed before the research begins;
   - the investigators and the holder of the key enter into an agreement (data use agreement) prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (Note: the HHS regulations do not require the IRB to review and approve this agreement);
   - there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
   - there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

In some cases, an investigator who obtains coded private information or specimens about living individuals under one of the conditions cited in 2(a)-(d) above may:

- unexpectedly learn the identity of one or more living individuals, or
- for previously unforeseen reasons now believe that it is important to identify the individual(s).

If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information or specimens pertain, then the research activity then would be deemed to be human subjects research. Unless this human subjects research is determined by the IRB to be exempt (See Exempt Research), IRB review of the research would be required. The investigator would also be required to obtain informed consent of the subjects also would be required unless the IRB approves a waiver of informed consent (See Waiver of Informed Consent).
The Principal Investigator in consultation with the IRB Chair or IRB Director will determine if the research involving coded information or specimens is human subjects research and requires IRB review. If the request for consultation is verbal (by phone or in person) or by email, it is the Principal Investigator’s responsibility to maintain documentation of such a decision. If the Principal Investigator submits a formal request for determination in writing, the request must include sufficient documentation of the activity to support the determination. The formal submissions will be responded to in writing and a copy of the submitted materials and determination letter/email will be kept on file by the IRB Office.

17.6 Case Reports Requiring IRB Review

A “single case report” refers to the external reporting (e.g., publication or poster/verbal presentation) of an interesting clinical situation or medical condition of a single patient. Case reports normally contain detailed information about an individual patient and may include demographic information and information on diagnosis, treatment, response to treatment, follow-up after treatment, as well as a discussion of existing relevant literature. The patient information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience.

A “case series” refers to the external reporting (e.g., in a publication or poster/verbal presentation) of an interesting clinical situation or medical condition in a series of patients (i.e., more than one patient). A case series usually contains detailed information about each patient and may include demographic information and information on diagnosis, treatment, response to treatment, follow-up after treatment, as well as a discussion of existing relevant literature. The information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience.

In general, anecdotal reports on a single patient or series of patients seen in one’s own practice and a comparison of these patients to existing reports in the literature is not research and does not require IRB approval. Going beyond one’s own practice to seek out and report cases seen by other clinicians, however, creates the appearance of a systematic investigation with the intent to contribute to generalizable knowledge. Therefore, the latter activity should be considered research and requires IRB approval.

17.7 International Research

The IRB will review all NYU Langone Health research utilizing human subjects that is conducted internationally to assure adequate provisions are in place to protect the rights and welfare of the subjects.

Approval of research is permitted if “the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in [45 CFR 46].”

All policies and procedures that are applied to research conducted domestically should be applied to research conducted in other countries, as appropriate.

The IRB must receive and review the foreign institution or site’s IRB review and approval of each study prior to the commencement of the research at the foreign institution or site.

For federally funded research, approval of research for foreign institutions or sites “engaged” (as defined in Section 3, Definitions) in research is only permitted if the foreign institution or site holds an Assurance with OHRP and local IRB review and approval is obtained.

Approval of research for foreign institutions or sites “not engaged” in research is only permitted if one or more of the following circumstances exist:
• When the foreign institution or site has its own established IRB or independent ethics committee (“IEC”), the NYU Langone Health Principal Investigator must obtain approval to conduct the research at the “not engaged” site from the site’s IRB/IEC or provide documentation that the site’s IRB/IEC has determined that approval is not necessary for the Principal Investigator to conduct the proposed research at the foreign site.

• When the foreign institution or site does not have an established IRB/IEC, a letter of cooperation must be obtained demonstrating that the appropriate institutional or oversight officials are permitting the research to be conducted at the foreign site.

IRB approval for the NYU Langone Health Principal Investigator to conduct research at the foreign institution or site is contingent upon the IRB receiving documentation of the foreign site’s IRB/IEC determination, or letter of cooperation, as applicable.

It is the responsibility of the NYU Langone Health Principal Investigator and the foreign institution or site to assure that the institution/site’s resources and facilities are appropriate for the nature of the research activities.

It is the responsibility of the NYU Langone Health Principal Investigator and the foreign institution or site to confirm the qualifications of the researchers and research staff for conducting the research activities in that country(ies).

It is the responsibility of the NYU Langone Health Principal Investigator and the foreign institution or site to ensure that the following activities will occur:

- Initial review, continuing review, and review of modifications by the appropriate IRB/IEC or other institutional or oversight officials;
- Post-approval monitoring of the foreign institution or site; and
- Handling of complaints, non-compliance and Unanticipated Problems involving risk to subjects or others.

The IRB will not rely on a local ethics committee that does not have documented policies and procedures for the activities listed above.

It is the responsibility of the NYU Langone Health Principal Investigator and the foreign institution or site to notify the IRB promptly if a change in research activities alters the foreign site’s engagement in the research (e.g., performance site “not engaged” begins consenting research subjects, etc.).

The IRB will consider local research context when reviewing international studies to assure that protections are in place that are appropriate to the setting in which the research will be conducted, including knowledge of local laws and cultural context.

In the case where there is no local IRB review, the IRB may require an expert consultant, either from the local country where the research is conducted or from an international organization, with the expertise or knowledge required to adequately evaluate the research in light of local context.

The informed consent documents must be in a language understandable to the proposed subjects. Therefore, the IRB will review the document and a back translation of the exact content contained in the foreign language informed consent document that must be provided by the foreign site’s principal investigator, with the credentials of the translator detailed in the IRB application or amendment form. Verification of the back translation should be made available for the IRB file.

**Monitoring of Approved International Research**

The IRB is responsible for the ongoing review of international research conducted under its jurisdiction through the continuing review process in accordance with all applicable federal regulations. When the IRB and a local ethics committee will both be involved in the review of research, there is a plan for coordination and communication with the local ethics committees.
The IRB will require documentation of regular correspondence between the NYU Langone Health Principal Investigator and the foreign institution or site and may require verification from sources other than the NYU Langone Health Principal Investigator that there have been no substantial changes in the research since its last review.

17.8 Embryonic Stem Cell Research

Under NYU Langone Health’s Policy on Human Stem Cell Research (NYU Langone Health Policy #ESCRO-1), NYU Langone Health regulates the use of human embryonic stem cells and other human stem cells in research, and the derivation for research, to assure compliance with all applicable laws, rules and regulations and to ensure that all such research is performed ethically. Certain activities relating to human stem cells, such as human reproductive cloning and research requiring the breeding of animals into which human embryonic stem cells have been introduced, are expressly prohibited.

All other research using human stem cells at NYU Langone Health is subject to the oversight and approval of NYU Langone Health’s Embryonic Stem Cell Research Oversight (“ESCRO”) Committee. The ESCRO Committee is also charged with maintaining a registry to document the source of any human embryonic stem cell lines being used in research at NYU Langone Health.

The composition, duties and responsibilities of the ESCRO Committee are distinct and separate from the IRB. Review and approval of the NYU Langone Health ESCRO Committee is therefore required in addition to the IRB’s approval prior to commencement of applicable research at NYU Langone Health. The Policy on Human Stem Cell Research provides that, to the extent practicable, the subject matter of the ESCRO Committee’s review should not overlap with the subject matter of the IRB’s review.

17.9 Community Based Research

Where research is being conducted by or under the auspices of NYU Langone Health in communities, NYU Langone Health Principal Investigators are encouraged to involve members of the community in the research process, including the design and implementation of the research and the dissemination of results when appropriate. NYU Langone Health’s Community Engagement and Population Health Research (CEPHR) program at the Clinical and Translational Sciences Institute (“CTSI”) works with community members, health and social service providers, community-based organizations, research investigators, and policymakers to develop, adapt, and advance evidence-based health interventions in real-world healthcare and community settings. As part of the CTSI, CEPHR provides training and education necessary for research faculty members, post-doctoral researchers, health professionals, community providers, community members, and students to engage in translational research and to strengthen the relationships among these stakeholder groups.

CEPHR convenes the CTSI’s Community Advisory Board (CAB). This group represents a diverse cross-section of New York City’s ethnic communities, government, healthcare community, social services, and neighborhoods and boroughs. CAB’s mission is to create healthier communities and multidirectional, equal, and reciprocal partnerships among the communities of New York City, NYU Langone Health, and NYC Health + Hospitals through participatory and sustainable methods of research, education, and advocacy.

The document “Guidance: Conducting Community-Engaged Research” provides further guidance on community based research.

When reviewing community-based research, the IRB will use the questions in the above-mentioned document as part of its evaluation of the research. The IRB will work in close collaboration with CEPHR to provide guidance on the issues related to the protection of human subjects in community based research.