**Example standardized language elements:**

**Non Biomedical Research Consent Form**

***THIS DOCUMENT****: is a companion document to the non-biomedical research* ***Consent Form Template****. It provides IRB-reviewed and approvable example standardized language that can be cut and pasted into the Consent Form Template. To download a copy of the Consent Form Template for developing a biomedical consent form, use this link* [***http://irb.med.nyu.edu/researchers/library/templates***](http://irb.med.nyu.edu/researchers/library/templates)*.*

***BLUE TEXT****: represents guidance language on the use of the standardized language text provided by this document.*

**BLACK TEXT***: represents example standardized language text. The standardized language text is presented under the applicable numbered consent section to make it easier to cut and past from this document into the Consent Form Template*

***RED TEXT:*** *Indicates sections where there is a requirement for the use of the specific standard language text – and is therefore already included in the Consent Form Template noted above. These required standard language elements have also been reviewed and approved by the Office of Legal Counsel and the Office of Compliance, Integrity, and Internal Audit.*

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

***[NOTE TO RESEARCHERS****:****]***

* *Reference is made to the NYU Langone Medical Center. For NYU researchers outside of the School of Medicine, make sure you replace School of Medicine text with the applicable NYU School or College and change the NYU logo above as appropriate.*
* *For various sections below that do not include standardized language text, see the companion document: Example Language for Non Biomedical Informed Consent Form*

1. **What is the purpose of the research study?**

The purpose of this research study is to *[Describe the* ***purpose******or research objectives from the protocol*** *in non-medical terms and at an 8th grade reading level].*

We are asking you to take part in this research study because you have a medical condition being studied and/or are scheduled to have test/procedure. *[Provide brief description of the medical condition being studied.]*

This research study is being done to collect your thoughts/reactions/opinions. We will do this through a Survey/Questionnaire/Focus Group/etc.

*[Use the following language for explanation of different types of study designs.]*

*[For healthy volunteers]*

You qualify for this study because you are a healthy volunteer.

*[For randomized study design]*

This study is a randomized study. This means, like flipping a coin, you will be assigned to one of the treatment groups and receive *[explain to subjects what they may receive]*. There are no special requirements or criteria to be in either group. You will have an *[explain to subject their chances of receiving either treatment].*

*[For comparison study design]*

This research study will compare *[fill in ]* to the standard of care. Standard of care is the first choice of treatment for your disease or condition.

1. How long will I be in the study? How many other people will be in the study?

This study will last about *[# of days, months, years]* and will involve about *[# of visits].*

About *[total (all sites) study subjects]* between the ages of *[XXX]* and *[YYY]* will be in this study.

*[If multicenter, state that fact, list the number of centers and the approximate total number of participants that will be participating here. Otherwise, delete this line.]*

This research study is happening at *NUMBER* other institutions as well.

*[Keep one of the following phrases; delete the rest (as appropriate).]*

This study will be an in-patient study. This means the study will happen only while you are in the hospital.

This study will be an out-patient study. Your study visits will be at *location*.

This study will be both an in-patient and an out-patient study. This means the study will happen while you are in the hospital. Other study visits will be at *location* as an outpatient.

1. What will I be asked to do in the study?

In this study you will be asked *[describe task, surveys, interviews or procedures].*

You will be assigned to an experimental/control group *[include this sentence only when applicable].*

Your participation in this study will last for *[insert # of hours, days, and months]* and will involve number of visits/sessions at *[insert the location].* We will schedule them at a time that is convenient for you.

*[If the study involves surveys or questionnaires, include:*

You are free to skip any questions that you prefer not to answer.

*[If consenting will occur prior to the initial study visit you can add the following:]*

As a participant in this study, you will be asked to come to [insert location].

*[If audio recording is optional, insert “I agree”… and “I do not agree…” options at the end of the form.]*

We will conduct this interview in a location of your choice and at a time of your choosing. We will audio record this interview and take detailed notes afterward. We will do so only with your permission. You have the right to review and edit the recording to delete any material you do not want recorded. You may also ask us to turn off the recorder at any point in the conversation.

*Or*

I will conduct the interview in your home, in an agreed-on location or over the telephone. I will audio record the interview so I can remember what you said. I will only do so with your permission. If you do not wish to be audio recorded it will not be possible for you to be in the study.

*[The “I agree...” “I do not agree...” options for recording are not needed if recording is required for participation and this is clearly stated on this form.]*

*[If audio recording is not optional, clear state that it is required for participation.]*

Audio and / or video recording are required for participation. If you do not wish to be recorded, you cannot participate in this study.

*[Describe how the post audio/visual recording options]*

After the interview, the recording will be transcribed and a written copy will be sent to you for review. You may delete anything you do not want included in the interview.

*Or*

We will contact you in six months to see if you feel differently after the passage of time about the event you described when your feelings were hurt.

*[Describe the procedures for discontinuation of a subject's participation, including the right to withdraw data already collected, if applicable.]*

At any time in the study, you may decide to withdraw from the study. If you withdraw no more information will be collected from you. When you indicate you wish to withdraw the investigator will ask if the information already collected from you can be used.

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study.

Each visit is listed separately and identified by visit number. Included in this visit list, will be the research procedures done to the subject, the amount of time the subject will be at the visit, and any other relevant information pertaining to that individual study visit. The list provided is a general list. This is to be tailored specifically to your individual protocol. Repeat each visit with a list of all procedures study related. You may use a table but the contents of that table must be relevant and in non-scientific terms.

Below is a list of each study visit that is part of the study. This list includes about how long each visit should take and a list of the research tests and procedures to be done at each visit and/or blood work to be taken. This section will help you understand what is expected of you at each visit.

**Visit 1: Your Screening Visit**

This visit takes about *[describe time interval]*. During this visit, we will do some tests and procedures to see if you meet the requirements to take part in the study. The study doctor will review the results of these tests and procedures. If you do not meet the requirements, the study doctor will tell you why.

At this visit, we will:

* Ask you about your medical history
* Ask you what medications you take – including over-the-counter and prescription medications, vitamins or herbal supplements.
* Give you a physical exam, including height, weight and “vital signs” (blood pressure, temperature, heart and breathing rates)
* Take a blood sample. We will insert a needle into your arm and take a small tube or vial of your blood (about *[x]* teaspoons). *[If Fasting Blood work include]* It is important that you DO NOT have anything to eat or drink (except water) for 8 hours before you come for this appointment. This includes candy and gum.
* Ask you for a urine sample. We will test your urine for:
  + certain drugs including illegal drugs. (See next section called Urine Drug Screen).
  + *[Include if applicable:]* Your blood will also be checked to see if you are pregnant. You may not take part in this study if you are pregnant.
* Perform an ECG (electrocardiogram) to check the electrical activity of your heart.
* Perform a chest x-ray
* Ask you to complete some forms about your *[select all that apply:]* general health and well-being, quality of life (if you are happy about your life), mental health, emotional health, mood and memory.

Urine Drug Screen

During the study, we will test your urine for drugs, including illegal drugs like *cocaine, marijuana, amphetamines and others (alter as appropriate).* If your urine shows you have taken any of these drugs, you cannot be in the study. The results of the urine test will NOT become part of your medical record. These test results WILL become part of your research record.

*Customize the Visit Section similar to the Screening Visit. All procedures are to be listed here and repeated for each study visit. Keep sentences short and use non-medical terminology. Use bullet points. Keep visits in chronological order. Include approximate time of each visit. Include amount of blood to be drawn at each visit using tsp. consistently throughout the consent. Be sure to include what is expected of the subject at the final study visit.*

*[****Blood sample****: Include the following for studies with blood sampling]*

**Blood Samples**

We will take blood samples every *[specify time interval]*. There will be about *[number]* blood samples taken all together. The total amount of blood drawn will be about *[number]* teaspoons during the entire study. A standard blood donation is about 96 tsps or about 2 cups.

After you complete the study, you will go back to your own doctor for your ongoing medical care. The study doctor will not be able to continue providing your medical care.

1. What are the possible risks or discomforts?

There may be some risk from being in this study *[Describe the risks-psychological, emotional, physical, legal, privacy issues, etc. Depending on the type of study, some risks may be better described as things that could make the subject “uncomfortable” –such a fatigue or embarrassment. There is no such thing as a “risk free” study. If there are no known risks, state that there are “no foreseeable risks” to participating]*

*Describe or list additional counseling or support services for studies that may engender strong emotions.*

*Example:*

You may experience frustration that is often experienced when completing surveys. Some questions may be of a sensitive nature, and you may therefore become upset as a result. However, such risks are not viewed as being in excess of “minimal risk”

If, however, you become upset by questions, you may stop at any time or choose not to answer a question. If you would like to talk to someone about your feelings about this study, you are encouraged to contact, *[if appropriate add in hotline numbers, agencies or another service if appropriate].*

*[Unforeseen Risks: In addition to anticipated/expected risks, certain studies may involve unforeseen reactions, hazards, discomforts, and inconveniences affecting the quality of life. If you anticipate unforeseen risks, a statement must be included that* "participation in the study may involve unforeseen risks". *Where possible, list such risks, indicate what will be done to avoid or minimize such unforeseen risks.]*

*If the research involves women of child bearing potential, and the risks of the interventions to the embryo or fetus are not well known [not needed if the interventions present no additional risk to a fetus or embryo]* add “If you become pregnant during the research, there may be unknown risks to the embryo or fetus, or risks to the embryo or fetus that we did not anticipate.”

*Do not use medical terminology to describe side effects – refer to IRB Glossary of Terms to assist you. All risks must be explained at an 8th grade level (or lower).*

### Side Effect of Having Blood Taken

* Fainting or feeling faint. Tell the study staff right away if you feel faint.
* Redness, pain, bruising, bleeding or infection at the needle site.

**X-ray Risks - standard**

During this study, you will have exposure to radiation from [*type of procedure can be specified or state - x-rays and other imaging tests*]. This radiation exposure is not necessary for your medical care and is for research purposes only. This means that you will be exposed to small doses or amounts of radiation. The risk from this amount of radiation is less than the risk from everyday exposure to the sun. The risks of receiving very small doses of radiation are thought to be low. These risks are not actually known.

Pregnant women cannot be exposed to radiation. Women must have a negative pregnancy test before they can have an X-ray.

***If the Effective Dose will be from 3 to 50 mSv USE THIS LANGUAGE:***

*During this study, you will have exposure to radiation from [type of procedure can be specified or state - x-rays and other imaging tests]. This radiation exposure is not necessary for your medical care and is for research purposes only.  The additional amount of radiation that you will receive as a result of participating in this study will be a maximum of approximately [insert amount] mSv, which is equivalent to [insert amount (times or percent of)] the yearly natural background of radiation in the US (3 mSv).  The use of radiation may involve a low risk of cancer and is required to obtain the desired research information.*

Pregnant women cannot be exposed to radiation. Women must have a negative pregnancy test before they can have an X-ray or *[insert other imaging test if applicable]*.

***If the Effective Dose will be from >50 mSv Use this Language:***

*During this study, you will have exposure to radiation from [type of procedure can be specified or state - x-rays and other imaging tests]. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be a maximum of approximately [insert amount] mSv, which is equivalent to [insert amount (times or percent of)] the yearly natural background of radiation in the US (3 mSv).  The use of radiation in this research study involves a low risk of cancer.  However, the NYULMC Radiation Safety Committee has reviewed the use of radiation in this research study and has found the use acceptable in relation to the potential benefits provided by the results of the study.*

Pregnant women cannot be exposed to radiation. Women must have a negative pregnancy test before they can have an X-ray *[or insert other imaging test if applicable]*.

*[Insert tests as required for your individual protocol.]*

### Electrocardiogram (ECG)

The ECG test is a recording of the electrical activity of your heart and an ECG harmless. The sticky pads (electrodes) that are placed on your chest can sometimes cause discomfort such as redness or itching. We may need to shave your chest before we attach these pads. Irritation from shaving also may occur.

### Magnetic Resonance Imaging (MRI)

MRI uses a strong magnetic field to create images of the body. Because of the strong magnetic field, there are risks. These risks are detailed in this section.

One possible risk is burns to the skin. There is an increased risk of burns from devices that conduct electrical energy. These devices can include metallic objects, pulse oximeters, EKG leads, or skin tattoos. These devices can be either in or on the patient in order for a skin burn to occur. The FDA has found that 70% of all reported injuries from MRIs were burns to the skin.

To reduce this risk, all patients who are scanned in this study must complete thorough screening to ensure that no conductive materials are present in or on the patient’s body. Additionally, the power limits of the magnet will adjusted as necessary.

Another possible risk is that a metal object could be pulled into the scanner and hit you. You could be physically injured as a result.

To reduce this risk, everyone near the magnet will remove all metal from their clothing or pockets when in the scanning environment. The door to the scan room will remain closed during the exam for your safety.

There are no known risks or adverse effects resulting directly from exposure to MRI. However, subjects who have a pacemaker or metal objects in their body such as shrapnel or metal in the eye should not have the scan performed. If you have any question about metal implants or metal fragments in the body, you should inform the technologist or investigators before entering the magnet room.

**Fear of Confined Spaces**: Some people may feel confined and experience anxiety in the MR scanner.  If you are unable to tolerate being in the scanner, we can stop the scan immediately at any time.

**Noise Levels**: The MR scanner produces tapping sounds during operation, which may reach very loud levels.  To minimize any discomfort from this noise, you will be given disposable earplugs to reduce the noise levels but will still allow voice communication with the scanner operator.

**MRI system failure (quench)**: In extremely rare cases, a magnet can lose its magnetism, in which case cooling fluids may be released noisily through escape valves and may collect in gas form in the scan room.  The gas is not harmful in itself as long as fresh air is available.  In this very remote event, you will immediately be brought out of the magnet room.

**Neurostimulation and heating**: Some subjects may experience muscle twitches or tingling sensations and/or a slight increase in body temperature during some types of scan activity. These are very unlikely under current MR guidelines.

ADDITIONAL LANGUAGE:

**FOR STUDIES REQUIRING EXTERNAL LEAD PLACEMENT (e.g., Cardiac MRI):**

Wires placed on the body during a scan can result in warming and in some cases the potential for burns. If cardiac monitoring wires are required during the scan, the operator is trained to inspect and arrange them to minimize this risk.

**FOR STUDIES REQUIRING GADOLINIUM CONTRAST MATERIAL**:

The FDA approves the imaging agent gadolinium for use in MRI. Some subjects, (less than 3%) may experience minor discomforts that include nausea and /or headache after injection. These side effects usually pass quickly without medical treatment.

**Risk of NSF**: In a small number of cases, a condition known as NSF or nephrogenic systemic fibrosis has been linked to gadolinium in subjects with a history of moderate to severe kidney disease. Subjects with a history of moderate to severe kidney disease will be required to undergo a blood test prior to receiving gadolinium to verify adequate kidney function.

**Pregnant patients**: Gadolinium-DTPA should not be administered to pregnant patients. If there is a possibility that you could be pregnant, you will be asked to undergo a pregnancy test before being allowed to participate in this study.

Risks to the intravenous injection of gadolinium include bleeding or bruising around the injection site, and rarely, infection.

*Receiving Contrast Material*

In order to better see internal structures of your body during the imaging study, there is the injection of contrast media (“dye”). Infrequently, needle (catheter) may slip of out the vein. The injected contrast media goes into the tissues and causes local pain. This is usually treated with appropriate compresses.

Some systemic reaction may occur, such as a metallic taste, nausea, vomiting, and hives. This is usually limited. Very infrequently, there is difficulty in breathing, low blood pressure and dizziness that requires appropriate treatment. Severe reactions are extremely rare where death has occurred. If you have allergies, the possibility of reaction is higher than patient a without allergies. If applicable, in consultation with your doctor, it maybe needed to have pre medication to decrease the possibility of these complications.

Patients who have bad kidney function are at risk for worsening their kidney function. A simple blood test will identify the patient at risk for kidney damage. Alternative imaging studies maybe indicated. If you are a diabetic on oral medication, it is recommended that you stop taking the medication for the two days after the contrast injection.

### FDG-PET/CT Scan

A small amount of radioactive sugar will be injected (shot) into your blood through a vein in your arm about 1 hour before the scan. You should not feel any effects from the sugar as it is a small, safe amount of radioactive material. There is a small risk of allergic reaction to the radioactive material and there is always a slight risk from being exposed to any radiation. You may have swelling, soreness, or infection at the injection site. The radioactive material is passed out of the body through the urine (pee) within 24 hours after the test is completed.

You will need to lie still for up to 1 hour in the PET/CT scanner. You will have a brief CT scan that takes about a minute followed by the PET imaging that takes between 25 and 45 minutes. If you know that closed spaces make you anxious, speak to the study staff before the PET/CT scan. You may be able to take medication to help you relax. You will be exposed to some radiation during the scan. Each PET/CT gives off about as much radiation as you would be exposed to from the earth and the sun in 4 – 5 years. There is always a slight risk from being exposed to any radiation. If you become anxious or uncomfortable during the PET/CT, tell the study staff or technologist and they will stop the PET/CT right away.

### Bone Scan

A dose of radioactive material will be injected (shot) into a vein in your arm. You should not feel any effects from the injection, as it is a small, safe amount of radioactive material. You may develop swelling, soreness or infection at the injection site. After 2 – 3 hours, you will be asked to lie down on a flat table and a special camera will pass over your body. The scan will take about 45 – 60 minutes once you are on the table. If you know that closed spaces make you anxious, speak to the study staff before the test starts. You may be able to take medication to help you relax. There is a small risk of allergic reaction to the radioactive material and there is always a slight risk from being exposed to any radiation. Each bone scan gives off about as much radiation as you would be exposed to from the earth and sun in 6 months. If you become anxious or uncomfortable during the Bone Scan, tell the study staff or technologist and they will stop the Bone Scan right away.

### Echocardiogram

The sticky pads (electrodes) that are placed on your chest may cause discomfort such as redness or itching. If we need to shave your chest before we attach the pads, irritation from shaving may also occur. You may feel slight pressure from the transducer or probe that the technician rubs across your chest. You may be asked to breathe, hold your breath or to lie in a position that may be uncomfortable during the test.

1. What are the possible benefits of the study?

**Note**: The standard language scenarios for this section are already included in the Consent Form Template for biomedical research; to access that template click: <http://irb.med.nyu.edu/researchers/library/templates>

You *[may not/will not]* benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because *[describe why others might benefit in the future in terms of the knowledge that will be gained].*

*[Compensation/extra credit is not a benefit and should not be listed as a benefit.]*

1. What other choices do I have if I do not participate?

*[Open this section with the following statement]*

You may choose to not participate in this research study.

*[and, if applicable, list any and all currently available alternative procedure(s).]*

*[If there is no alternative to participation, the opening statement is sufficient.]*

*[For studies awarding course credit for participation, describe the IRB-approved alternative(s) to research participation, for which equal credit will be awarded]*

If you do not wish to participate in this study, the following alternatives are available:

**Note**: For the sections noted below, the standard language scenarios for this section are already included in the Consent Form Template for social-behavioral research; to access that template click: <http://irb.med.nyu.edu/researchers/library/templates>

1. Will I be paid for being in this study?

You will be paid to take part in this study. We will pay you by *[method of payment].*

*[If payment is by check:]*

In order for you to receive a check, you need to give the study staff either your Social Security number or your Alien Registration number.

If you do not have either of these numbers, you may be in the study but will not receive any payment.

You will be paid per completed *[visit, procedure, etc.]* If you choose to leave or are withdrawn from the study for any reason before finishing the entire study*,* you will be paid for each completed *[visit, procedure, etc.]* You will receive payment within *[number of days, weeks]* after your last study visit.

If you complete all the study visits, you will receive *[$0.00]* for being in this study.

*Or*

You will not be paid for being in this study.

*[Insert if applicable:]*

We will pay you back for travel costs to and from the study site and any hotel costs related to the study. In order to be paid, you must have given the receipts to the study staff. You can expect to receive a refund check in about *[XXX]* weeks.

1. Will I have to pay for anything?

*[Choose one:]*

There will be no cost to you for being in this research study.

*Or*

There will be costs to you for being in this study.

*[May include:]*

You or your insurance will be billed for some study costs.

*[Either:]*

Your insurance may not pay for all of the costs that we bill them for. You are responsible for any costs that your insurance does not pay. These costs may include co-payments, deductibles, insurance denials and/or balances due because of limited insurance.

*[And/or]*

This study involves procedures that are the *standard of care*. This means that these procedures are a usual part of treatment for *[name of condition]* and you would have been given these procedures even if you were not in the study. You or your insurance will be billed for these procedures.

*[Name of Sponsor]* is providing financial support to *[NYU School of Medicine or Name of Your Institution]* to conduct this study.

1. What happens if I am injured from being in the study?

**Note**: The standard language scenarios for this section are already included in the Consent Form Template for biomedical research; to access that template click: <http://irb.med.nyu.edu/researchers/library/templates>

1. When is the study over? Can I leave the study before it ends?

It is your choice to be in this study. No one can force you to be in the study. No one can force you to stay in the study. You can leave the study at any time. Leaving the study will not affect the care you receive. You will still receive the same high level of expert care you were receiving at NYU School of Medicine before you became part of the study.

The study doctor, the sponsor of the study or government monitors like the FDA or NYU School of Medicine IRB can take you out of the study without your permission at any time for the following reasons:

* you do not follow the study doctor’s instructions
* the study staff finds out you do not meet the requirements of the study
* the study is stopped
* taking part in the study becomes harmful to your health

If you choose to leave the study or if you are taken out of the study, you may be asked to come for a final visit to have some end of study evaluations or tests. These are for your safety and protection. Please note all the data that has been collected on you to the point that you leave the study will remain part of the study.

1. How will my information be protected?

Federal law requires NYU School of Medicine to protect the privacy of any health information that identifies you. This law is called the Health Insurance Portability and Accountability Act, also known as HIPAA. We must keep all of your personal health information private unless you give us permission to share some of it.

If you decide to consent to be in this research study, you are giving us permission for your health information to be used within NYU School of Medicine and to be shared with others outside NYU School of Medicine as described below. By signing this form, you are giving the research team permission to use your private health information for this study. If you do not want to allow this, you cannot be in this study. This is your choice.

The study staff collects health information about you during the study. This information goes into your study chart.

The documents in your study chart may include:

* Your medical records
* Reports and results of your physical exams
* Your personal information including your address, social security number, date of birth
* Any/all of your laboratory results
* Your research record including your consent form, lab results and study notes
* Your HIV-related information (if applicable)

Members of the study staff will be able to review your study chart. Other people who monitor research activities at NYU School of Medicine may have access to your study chart. They include members of the:

* Institutional Office for Research Oversight
* Data Safety and Monitoring Board
* Institutional Review Board Members and Staff

Organizations and offices outside NYU School of Medicine may need to see the study information collected for the study. They include: *[delete those that are not applicable]*

* Federal offices that are responsible for protecting people including the Department of Health and Human Services and the FDA
* Federal safety governing agencies
* Data Safety and Monitoring Board
* Sponsor: *[insert name if applicable]*
* Contract Research Organization: *[insert name, if applicable]*
* Laboratories that perform research related study procedures

Some people or groups who get your health information might not have to follow the same privacy rules that we follow at NYU School of Medicine. We share your health information only when we have to. We ask anyone who receives this information from us to protect your privacy. Once your information is shared outside NYU School of Medicine, we cannot promise that it will remain private. You need to know that if your information is given to a person or organization that is not covered by the HIPAA Privacy Rule, the information is no longer protected. The information may then be shared with others.

### Your Privacy Rights

* You have the right not to sign this form allowing us to use and share your health information for research. If you do not sign this form, you cannot take part in this research study. This is because we need to use the health information of everyone who takes part in this research study.
* If you sign this form and allow us to use and share your health information for research, you have the right to withdraw your permission at any time. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.
* If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality.
* In this research study, you may be able to get the results of the study after the research is finished.

NYU School of Medicine keeps your research records private according to state and federal laws. If your study information is given to others outside NYU School of Medicine, the information that can identify you will be removed. This will protect your confidential health information. Your research record has a code that we use to identify you. This code will not be given to anyone unless required by law.

Your research records will be stored in a way that they are not available to anyone but the study staff. The research records can only be reviewed by outside agencies such as the ones listed above under the supervision of the study team unless required by law. All paper records are stored in an area with 2 locked doors and/or drawers. Only the study staff can open the locks. All computerized records are password protected. Only the study team knows the password. Your research records can be transmitted to the sponsor agency using electronic data transfer. This is a computerized transfer of information. The federal government regulates this type of transfer. The information that can identify you will be removed.

Your research record will be kept for at least six years after the study is over or as long as the sponsor requires them to be kept. They will be stored in a place that will not allow anyone to see them without permission. Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. Your name or other identifying information will not be used for these purposes unless you sign a special consent form saying we can do so.

*The following section is required on ALL consent forms in this format [delete this statement when preparing your form]*

15. Optional permission for future use

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. Such health information may include biological samples from the study. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

|  |  |  |
| --- | --- | --- |
| Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. | |  | | --- | |  |   Subject Initials |

1. The Institutional Review Board (IRB) and how it protects you

#### What is the Institutional Review Board (IRB) and how does it protect me?

The IRB reviews all human research studies – like the one you are considering. The IRB protects the rights and welfare of the people taking part in the research studies. The IRB follows rules and guidelines from the Federal Government and reviews each research study using these guidelines. The IRB also reviews research to make sure the risks for all studies are as small as possible.

The NYU School of Medicine’s IRB is made up of:

* Doctors
* Nurses
* Non-scientists
* People from the Community

You may contact the IRB if you have any questions about your rights as a subject, if you think you are not treated fairly or if you have any questions about this research study. The NYU IRB Office number is (212) 263-4110.

1. Who can I call with questions, or if I’m concerned about my rights as a research subject

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4140.

[Add this paragraphs for studies requiring registration with ClinicalTrial.gov:]

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov/), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website site at any time.

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| **When you sign this form**, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. |

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|  |  |  |  |  |
| Name of Subject (Print) |  | Signature of Subject |  | Date |
|  |  |  |  |  |
| Name of Person Obtaining Consent (Print) |  | Signature of Person Obtaining Consent |  | Date |