NYU Langone Health

**Office of Science and Research**
**Institutional Review Board**
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# Guidance on Special Considerations for the Oversight of Research Protocols using an FDA-Regulated Product

Research Protocols using an FDA-regulated product, such as an investigational drug or investigational medical device, require special consideration from the Principal Investigator ("PI"). Please review the policy on Investigational Drugs & Devices in Research in the NYU Langone Health IRB Operation's Policies and Procedures (section 14) prior to reading this guidance. The policy applies to all research conducted at NYU Langone Health regardless of the reviewing IRB. This guidance is intended to guide researchers through additional considerations and responsibilities when using an FDA-regulated product in a research study.

## Investigational Drug Studies

Before beginning participation in an investigation, the Principal Investigator (PI) must commit to the sponsor that he/she will follow federal regulations governing investigational drugs and devices. The PI must agree to assume the regulations as described below:

### *PI Responsibilities: [21 CFR §312.53(c)(1)(vi)] [21 CFR §312.60]*

- Conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, the rights, or welfare of participants
- Comply with all requirements regarding the obligations of clinical PIs and all other pertinent requirements in this part
- Personally conduct or supervise the described investigation(s)
- Inform any potential participants that the drug(s) are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent and IRB review and approval are met.
- Report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with §312.64;
- Read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug
- Ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments
- Ensure that for an investigation subject to institutional review requirements under part 56, an IRB that complies with the requirements of that part will be responsible for initial and continuing review and approval of the clinical investigation and that the investigator will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others, and will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to the human subjects
- Maintain adequate records in accordance with §312.62 and to make those records available for inspection in accordance with §312.68
- Ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation
- Promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others
- Obtain IRB approval prior to making changes in the research, except when necessary to eliminate immediate hazards to human subjects
- Ensure that an investigation is conducted according to the signed statement, the investigational plan, and applicable regulations
- Protect the rights, safety, and welfare of participants under the PI's care.
- Control drugs under investigation.
- Obtain the informed consent of each human subject to whom the drug is administered, except as provided in §§50.23 or 50.24 of this chapter

### *Regulations specific to control of the investigational drug: [21 CFR §312.61]*

- The PI will administer the drug only to participants under the PI's personal supervision or under the supervision of a sub-investigator responsible to the PI
- The PI will not supply the investigational drug to any person not authorized under this part to receive it

### *Regulations for documentation of investigational drug research studies: [21 CFR §312.62]*

- The PI is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by participants
- If the investigation is terminated, suspended, discontinued, or completed, the PI must return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under §312.59
- A PI is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation
- Case histories include the case report forms and supporting data (e.g., example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes).The case history for each individual will document that informed consent was obtained prior to participation in the study
- PI must retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified

## Investigational Medical Device Studies

For medical device studies, each participating PI must sign an agreement with the sponsor that includes a statement of the PI's commitment to: [21 CFR §812.43(c)(4)]

- conduct the investigation in accordance with the agreement, the investigational plan, this part and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB or FDA
- supervise all testing of the device involving human participants
- ensure that the requirements for obtaining informed consent are met

### *PI Responsibilities: [21 CFR §812.100]*

- Ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations
- Protecting the rights, safety, and welfare of participants under the PI's care
- The control of devices under investigation
- Ensuring that informed consent is obtained

### *PI Must Maintain: [21 CFR §812.140]*

- Accurate, complete, and current records relating to the PI's participation in an investigation
- All correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including all required reports
- Records of receipt, use or disposition of a device that relate to:
    - The type and quantity of the device, the dates of its receipt, and the batch number or code mark.
    - The names of all persons who received, used, or disposed of each device
    - Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of
- Records of each participant's case history and exposure to the device. Case histories include the case report forms and supporting data (e.g., signed and dated consent forms and medical records, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes). Such records will include:
    - Documents evidencing informed consent and, for any use of a device by the PI without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual will document that informed consent was obtained prior to participation in the study
    - All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each participant upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests
    - A record of the exposure of each participant to the investigational device, including the date and time of each use, and any other therapy
    - The protocol, with documents showing the dates of and reasons for each deviation from the protocol
    - Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation