

<b>IRB Policy Number: 207</b>	<b>Version Number: 3.0</b>
<b>Effective Date: October 17, 2016</b>	
<b>Title: Obligations of the Principal Investigator for Human Subjects Research</b>	

**Purpose**

This document outlines the obligations of the principal investigator of a study involving human subjects research approved by the Princeton University IRB.

**Regulatory Background**

The IRB must ensure that a human subjects research study has the resources necessary to protect subjects. These resources include a principal investigator who is aware of his/her obligations.

**Scope**

This policy applies to all principal investigators at Princeton University conducting research involving human research participants.

**Responsibilities**

**Principal Investigators:** Principal Investigators (“PIs”) are responsible for the obligations outlined in this policy. The PI has the ultimate responsibility for the overall conduct of the study. When research is initiated by a student, a faculty advisor must act in the capacity of PI for the study. Federal regulations and the Princeton IRB recognize only one individual as the PI of a study.

**Policy**

Principal investigators have the following obligations when conducting human subjects research:

1. Principal investigators must not commence research until the PI has the IRB approval letter and obtained all other required approvals, such as approvals of departments or divisions that require approval of the use of their resources. If a PI is collaborating on a human subjects research study that is approved by another IRB, the PI's actions may engage Princeton University in the human subjects research. If Princeton University is engaged in the human subjects research, local IRB review (Princeton IRB review) is required or an IRB Authorization Agreement or Reliance Agreement must be fully executed before the PI begins collaboration in the human subjects research. Please see Princeton University IRB SOP 208 for details.
2. If the PI has any questions about whether s/he is conducting research involving human subjects, including collaboration in human subjects research that engages Princeton University, the PI must contact the IRB before commencing the study
3. PIs must conduct the research in accordance with the most recent protocol approved by the IRB.

4. PI must protect the rights, safety, and welfare of subjects involved in the research.
5. The PI must comply with all requirements and determinations of the IRB.
6. The PI must use sound study design in accordance with the standards of his/her discipline and design studies in a manner that minimizes risks to subjects.
7. The PI must ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
8. PIs are required to provide verification of human subjects training. This requirement is described in greater detail in SOP 202.
9. The PI must ensure that research staff are qualified including, but not limited to, appropriate human subjects training, education, expertise, credentials, protocol requirements and privileges, to perform procedures and duties assigned to them during the study.
10. PIs must submit proposed modifications to the IRB prior to a modification's implementation.
11. PIs must not make modifications to the research without prior IRB review and approval, unless necessary to eliminate apparent immediate hazards to subjects.
12. The PI must report the information items listed in "SOP 206: Reporting Requirements for Investigators" to the IRB within 5 business days of learning of the information.
13. PIs must submit continuing reviews to avoid a lapse in approval of their study. If approval of the research expires, the PI must stop all research activities immediately and contact the IRB.
14. PIs must close the research (end the IRB's oversight) when all the following criteria are met:
  - a. The protocol is permanently closed to enrollment and
  - b. All subjects have completed all protocol-related interventions and interactions and
  - c. No additional identifiable private information about the subjects is being obtained and
  - d. The PI's analysis of private identifiable information is completed.
15. Unless the IRB approved a protocol to include the following populations, the PI must not enroll the following subjects in the study:
  - a. Adults unable to consent
  - b. Children

- c. Neonates of uncertain viability
  - d. Nonviable neonates
  - e. Pregnant women
  - f. Prisoners
  - g. Individuals unable to speak English
16. When consent, permission, or assent are required by the IRB, the PI must ensure that it is obtained and documented in accordance with the most recent approved protocol.
17. The PI must retain research records (including signed consent documents) for three years after completion of the research. “Completion of the research” means when the definition of human subjects research is no longer met: the protocol is permanently closed to enrollment; and all subjects have completed all protocol-related interventions and interactions; and no additional identifiable private information about the subjects is being obtained; and analysis of private identifiable information is completed. Completion of the research is typically evidenced by the PI submitting a closure form or the study’s lapse (expiration) of approval.
18. If the PI is a lead investigator of a multi-site study, the PI must ensure there is a plan to manage information that is relevant to the protection of subjects, such as Unanticipated Problems Involving Risks to Subjects or Others, interim study results, and protocol modifications, and include that Plan in the protocol.
19. For studies regulated by a federal department or agency, the PI must follow the additional obligations of that federal department. These agencies include, but are not limited to, the Department of Defense; Department of Energy; Department of Justice; Environmental Protection Agency; Education Department; and the Federal Drug Administration.
20. For studies where the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use-Good Clinical Practice (ICH-GCP) compliance is required, the PI must follow the ICH-GCP.

**References**

- 21 CFR §50, §56
- 45 CFR §46

**Version History**

	Version Number	Revision Date	Revisions
Add	1.0	March 2016	New policy
	2.0	April 2016	Revised training requirement
	3.0	October 2016	Clarified engagement process