

<b>Policy Number:</b>	208	<b>Version Number:</b>	3.0
<b>Approval Date:</b>	February 14, 2020		
<b>Title:</b>	Collaborations with other researchers, institutions, and organizations		

### Purpose

This document describes the policy used to determine whether collaboration with other researchers, institutions, and organizations in human subjects research requires Princeton University IRB review.

### Scope

These procedures apply to all individuals at Princeton University, including the principal investigator, faculty, professional researchers, staff and students who are collaborating in human subjects research with other researchers, institutions, and organizations.

### Regulatory Background

When collaborating with other researchers, institutions, and organizations, the Princeton IRB must determine whether or not Princeton University is engaged in the research. Human subjects research that engages an institution must either obtain local IRB review (Princeton University IRB review) or the Princeton University IRB may rely on the review of another IRB. In general, an institution is considered *engaged* in human subjects research when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. Further details about the regulatory definition of engagement may be found at: <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

### Responsibilities

**Principal Investigator:** The individual who has ultimate responsibility for the overall conduct of the study. The principal investigator must meet the criteria listed in the "Principal Investigator Qualification Chart by Rank" established by the Princeton University Research Board. The Princeton PI must contact the Princeton University IRB for an engagement determination.

**Princeton IRB:** Makes the engagement determination. If a determination of engagement is made, the Princeton IRB recommends whether local IRB approval is required or whether the Princeton IRB will rely on an outside IRB for review and approval

## Policy

1. The Princeton PI must submit the following information to the Princeton IRB: the study funding; the purpose of the activity; the study procedures; and any study measurements.
2. The IRB will make an engagement determination based upon OHRP guidance
3. If the human subjects research engages Princeton University, the Princeton IRB will recommend that the PI must either obtain local IRB review (Princeton University IRB review) or the Princeton University IRB may rely on the review of another IRB.
4. If the Princeton PI seeks Princeton IRB review, the Princeton PI follows the submission process outlined in Princeton University SOP 202: [Initial Review of Research Involving Human Participants](#)
5. If the Princeton PI would like to rely on another IRB, the Princeton PI submits the following to the Princeton IRB via eRIA:
  - a. A new study application. The individual designated as PI must be eligible to serve as a PI at Princeton. PI eligibility criteria can be found [here](#).
  - b. Verification of human subjects training for the Princeton PI and all Princeton research personnel. This is a one-time training requirement. The training can be from any source if the training directly addresses human subjects research. For example, training in conflicts of interest, biosafety, animal research, or responsible conduct of research work will not be recognized. For more details, please see Princeton University SOP 202: [Initial Review of Research Involving Human Participants](#).
  - c. The protocol approved by the other IRB.
  - d. The IRB approval letter from the other IRB.
  - e. To ensure that the same human subjects regulations and ethical codes are applied to the research, the other institution must reside within the United States.
  - f. IRB Authorization Agreement (unless the study is exempt human subjects research). This Agreement can be obtained from the other institution. All IRB Authorization Agreements are executed at the discretion of the Dean for Research. If the study is exempt human subjects research, confirmation from the other IRB that it will serve as the IRB of record is required.

- g. IRB Authorization Agreements are executed at the discretion of senior officials at each institution. Consequently, some research collaborations may require separate IRB review (IRB review is secured at each institution).

**References**

45 CFR §46.103

OHRP Guidance on Engagement of Institutions in Human Subjects Research

**Version History**

Version Number	Revision Date	Revision Description
1.0	9/1/2016	Initiation
2.0	2/1/2018	Revised to reflect the use of eRIA
3.0	2/14/2020	Revised to reflect RIA policy template