Institutional Review Board (IRB) Reference Guide

IRB Operations
The Princeton IRB is comprised of a group of individuals charged with reviewing proposed research involving human subjects. This group ensures the protection of those individuals in accordance with applicable laws, guidelines and policies including the Belmont Report, the Code of Federal Regulations [45 CFR 46], and Institutional policy. Princeton's IRB consists of faculty, staff, and representatives from the community. The IRB has the authority to review, approve, modify, disapprove, suspend, or terminate research protocols. The IRB and the Human Research Protection Program are committed to providing timely and high quality review, education, and monitoring of human research projects while facilitating excellence in research.

Submission
New protocols, amendments, and continuing reviews involving minimal risk to subjects may be reviewed using an expedited review procedure if research activities falls under one of nine expedited review categories. Some research can be considered for exempt status if the research activity falls under one of six exempt categories (see common research categories and examples of non-human research activity on pg. 2). These protocols are accepted daily and are reviewed on a rolling basis in the order received.

Full committee review may be required for protocols involving greater than minimal risk to human subjects. These studies should be submitted at the regularly scheduled meetings which are held once a month; with the exception of July and August.

Review Timeline
Initial and continuing review applications should be submitted at least two months in advance to avoid delays. Allow approximately one week review time for non-human research determinations, four weeks for exemptions, six weeks for expedited review and eight weeks for full board review. Review time includes initial submission triage, protocol review, required IRB requests for clarification or changes and final approval processing.

CITI Human Research Training Requirements
All research investigators who propose to work with human subjects in their studies must have human subjects training. Princeton has adopted the CITI program for this purpose. Through the Human Research Protection Education Program, we also offer targeted courses, seminars, workshops and department focused brown bag sessions. Additional information and CITI instructions are available on our website below.

http://www.princeton.edu/ria/human-research-protection/training/

Full Board Submission Deadlines and Meeting Dates

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Institutional Review Board
IRB@princeton.edu
(609)258-0865

IRB Contact
German Jimenez, Compliance Coordinator
Phone: (609) 258-1194
E-mail: gjimenez@princeton.edu

Gloria Gaines, Compliance Administrator
Phone: (609) 258-3077
E-mail: ggaines5@princeton.edu
When Does a Project Require IRB Review?

Whenever research is conducted with, on, or about human subjects, IRB review and approval is required. IRB review is required when the definitions of both "human subject" and "research" are satisfied. The regulatory definition of each is as follows: [45 CFR 46.102(f)]

"Research" is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

"Human subject" is a living individual about whom an investigator (whether professional or student) conducting research obtains

- data through intervention or interaction with the individual, or
- identifiable private information.

Key Terms to Note:

- **Develop or Contribute to Generalizable Knowledge** means that the research is designed to draw general conclusions, inform policy, develop theories, principals or relationships and interpretations that can be widely applied. If the intent of the research is to disseminate the results and conclusions beyond an individual or internal group, the research is generalizable. Common ways of disseminating results include publication, presentation, thesis or dissertation work. However, just because a project is not published or presented, does not mean it is not research.

- **Intervention** means 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** means communication or interpersonal contact between investigator and subject.

- **Private information** means 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, school records, or a private conversation).

- **Identifiable information** means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Examples of Non-Human Research Activity

- Research involving only one living individual is not generalizable beyond that individual. Therefore, this would not meet the definition of research requiring IRB review.

- Information—gathering interviews where questions focus on products, programs or policies rather than on people or their thoughts regarding themselves or others, such as interviewing librarians about inter-library loan policies, may not be human subject research.

- Research involving cadavers, autopsy material or specimens from deceased individuals is not human subjects research; however, some research in this category, such as genetic studies involving private information about living relatives, may meet the definition of human subjects research.

If you are unsure whether you are proposing human subjects research, please seek a determination from the IRB by submitting a Non-Human Research Determination form. Contact the IRB directly at (609)258- 0865 or irb@princeton.edu for further assistance.

Common Research Categories

If it has been determined that your research meets the federal definition of human subjects research, you will need to apply for IRB review. An IRB determination notice must be issued before you begin (IRB approvals are not issued retrospectively). While this list does not represent all categories of research conducted at Princeton, below are a few that are commonly IRB approved.

**Exempt Category 2** – Research involving educational tests, observation of public behavior, interview or survey procedures (non-sensitive material, anonymity guaranteed – only observation of children may occur).

**Exempt Category 4** – Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens

**Expedited Category 5** - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes

**Expedited Category 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 group, program evaluation, human factors evaluation, or quality assurance methodologies.

Only the IRB should determine the final research category. This requires an Exempt or Expedited/Full IRB application.

Investigator Responsibilities

Investigators play a crucial role in protecting the rights and welfare of human subjects and are responsible for carrying out sound ethical research consistent with research plans approved by the IRB. Additional responsibilities include, in summary:

- obtaining and documenting informed consent of subjects prior to their participation in the research, unless waived by the IRB,
- obtaining prior approval from the IRB for any modifications of previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects; and,
- ensuring that continuing review is conducted at least annually unless it is exempt
- providing to the IRB prompt reports of any unanticipated problems involving risks to subjects or others;
- providing to the IRB prompt reports of serious noncompliance with the regulations or the requirements or determinations of the IRB; and
- retaining certain research records as required by the HHS regulations for at least three years after completion of the study

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