

Guide to the IRB Approval Process

<https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/hrppirb-home-page>

- I. If your thesis research meets the following conditions:
 1. Data collection procedures present no more than minimal risk to the subjects.
 2. Vulnerable populations (i.e., children, prisoners, cognitively impaired) are not used.
 3. Data is collected in a manner such that the subjects are not identifiable or their confidentiality is protected.then you require IRB/HRPP notification, but **not** a protocol.
 - Submit an [Undergraduate Project Involving Human Subjects](#) form to the HRPP.
 - Provide [The Letter of Introduction for Undergraduate Work Involving Human Subjects](#) to all participants.

- II. If you're unsure about whether you meet these conditions fully, use the [Human Subject Determination Form](#), and/or double check below. You can also see if you qualify for exemptions or expedited review.
 - A. Is it **research**? **research** = a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
 - a) systematic investigations include:
 - *observational studies*
 - *interview or survey studies*
 - *group comparison studies*
 - *test development*
 - *interventional research*systematic investigations **do not** include:
 - *oral histories*
 - *journalism*
 - *case studies**
 - b) generalizable knowledge = intended to produce new data that will be relevant beyond the study population from which it was collected; may or may not include *quality improvement**

*gray areas — check website for more info

B. Does it involve **human subjects**? **human subject research** = research data obtained through interaction or intervention with individuals **or** identifiable private information about living individuals.

a) interaction or intervention with individuals — is the project focused on the person, or on policies/practices/procedures about which the person is knowledgeable? if it is the latter, this is not human subject research

(1) interactions include:

- *interviews*
- *questionnaires*
- *surveys*
- *observations*
- *manipulations of subject behavior*
- *diet, environment, physical measurements*
- *specimen collection*
- *administration of experimental drugs or devices*

(2) interventions include:

- *physical procedures*
- *manipulations of living individuals or their environments*

b) identifiable private information about living individuals = information that would typically not be made part of a public record and that is linked to identifies, such as name, address, phone number, SSN, or combination of data that, taken together, could make an individual identifiable

C. **Exemptions**** (if the **only** involvement of human subjects is through one or more of these categories)

- a) conducted in commonly accepted educational settings, involving normal educational practices
- b) use of educational tests, survey procedures, interview procedures, or observations of public behavior where subjects are unidentifiable and will not be put at risk of criminal or civil liability
- c) use of educational tests, survey procedures, interview procedures, or observations of public behavior where subjects are elected or appointed public officials or candidates, or where subjects' confidentiality will be federally protected
- d) publicly available or unidentifiable existing data, documents, records, pathological specimens, or diagnostic specimens
- e) conducted by, or subject to the approval of, department of agency heads, to examine public benefit or service programs

- f) taste and food quality evaluation and consumer acceptance studies if no additives or involved or food use levels are below those found safe by FDA, EPA, or USDA
- g) minimal-risk, non-federally-funded research activities that will not induce distress beyond that of daily life

******these exemptions exclude vulnerable populations, such as minors, prisoners, cognitively impaired individuals

D. Expedited

- a) Clinical studies of drugs and medical devices
- b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
- c) Prospective collection of biological specimens for research purposes by noninvasive means
- d) Collection of data through noninvasive procedures
- e) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes
- f) Collection of data from voice, video, digital, or image recordings made for research purposes
- g) Research on individual or group characteristics or behavior
- h) Continuing review of research previously approved by the convened IRB

E. Full Board Review

- a) greater than minimal risk
- b) children or other vulnerable populations
- c) experimental drugs or devices
- d) invasive procedures
- e) deception
- f) survey research that involves sensitive questions or information about sexual practices or illegal behavior
- g) any survey or interview that is likely to be stressful for the subject

III. If you require **IRB review**, your faculty advisor will act as your principal advisor.

Your submitted protocol should include:

1. Appropriate forms
 - [IRB Form #1](#) for full board or expedited review
 - [IRB Form #2](#) for exempted review
2. Appropriate appendices
 - appendices and other forms:

- [Consent Template for Adults \(18+\)](#)
 - [Additional Consent Language](#)
 - [Children as Subjects](#)
 - [Prisoners As Subjects](#)
 - [Use of Drugs](#)
 - [Use of Devices](#)
3. Lay summary describing the purpose of the study
 4. Description of the study population, criteria for including and excluding participants, the number of and the process of identifying subjects, and any other plans related to the selection of subjects
 5. Description of payment arrangements for participants, if applicable
 6. Description of the tasks that subjects will be asked to perform
 7. Full description of the anticipated risks and benefits of participating in the study
 8. Outline of strategies for minimizing risks
 9. Documentation of provisions to care for subjects in case of accident, injury, or risk of harm to self or others, when applicable
 10. Full description of procedures for maintaining confidentiality
 11. Description of the process by which informed consent will be obtained from the appropriate individuals (for example, subjects, parents, cooperating institutions)
 12. Documentation of any required approvals or applications for approval from other committees and from cooperating institutions
 13. All supporting materials and documents, including interview schedules, solicitation letters, advertisements, descriptions of any medications, and any survey instruments that will be used
 14. Original signatures, including an academic advisor's signature for student research

IV. While **CITI training certification** is not required by the time of submission of your protocol, it must be in place before the IRB can approve or grant exemption for your study. All principal investigators and student researchers must have active CITI certification.

1. Register for a new account at www.citiprogram.org
2. Answer Question #1 **only**, in “CITI Course Enrollment Questions”
3. Pick appropriate module: *Social-Behavioral-Educational Researchers*, *Biomedical Researchers*, *Biomedical Data or Specimens-Only Researchers*

V. Email (through single pdf file) or paper deliver/mail your submission to irb@brown.edu, campus mailbox **Box 1986**, or **2 Stimson Avenue 3rd floor**, by 5:00 PM on the day of the deadline.

A. Upcoming deadlines***:

- a) *October 31, 2017*
- b) *November 30, 2017*
- c) *January 2, 2018*
- d) *January 31, 2018*
- e) *February 28, 2018*

B. Average turnaround times

- a) Exempt review = 9 days
- b) Expedited or Full Board Review: 22 days

***New federal research regulations will be released in January, so for those starting research after February, it's recommended to submit protocol after January 19, 2018. For those starting before, submit ASAP before the review freeze starts on December 20, 2017

VI. Contact the HRPP (**401-863-3050** or irb@brown.edu) for more questions!