

ROOSEVELT UNIVERSITY INSTITUTIONAL REVIEW BOARD ON HUMAN SUBJECTS (IRB) APPLICATION INSTRUCTIONS

Roosevelt University has a firm commitment to supporting research on human subjects that maintains strict participant safeguards as specified in these guidelines and the accompanying application. The Roosevelt University Institutional Review Board (IRB) must approve all studies that involve human participants and that are conducted under the auspices of Roosevelt University. This includes all studies conducted by Roosevelt students, faculty, and staff either on or off campus, as well as all research by outside investigators that involve Roosevelt students as participants.

All researchers (students, faculty, staff) and supervisors of student research must provide documentation of having received training in the responsible conduct of research with human subjects. That documentation is to be provided as part of the IRB application package. Links to several online tutorials are found on the IRB webpage (<http://www.roosevelt.edu/IRB/>).

To apply for IRB approval for proposed research, applicants are required to submit **four** hard copies of the completed application with original signatures as well as an electronic copy to Judith Gouwens, IRB Chair, **Gage Building 824**; jgouwens@roosevelt.edu.

The IRB meets each month during the fall and spring semesters; the schedule of meetings is posted on the IRB webpage (<http://www.roosevelt.edu/IRB/>). The IRB will review each application submitted by Thursday of the week prior to the board's monthly meeting. Applicants will be notified by email immediately following the IRB meeting of the disposition of their applications; applicants will also be notified if additional information or amendments to applications are requested by the IRB. Applicants will also receive a formal letter of approval when their applications have been approved.

A vote of the IRB and its subcommittees is final and may be reconsidered only by the Office of the Provost. The University Attorney may submit recommendations to the IRB but has no authority whatsoever to override a decision of the IRB.

Current members of the IRB are: LaVonne Downey, Susan Torres Harding, Martin Jason, Kathleen Kane-Willis, Kate Mahoney, Cami McBride, Josetta McLaughlin, Deborah Pavelka, Richard Ruby, Ali Thrower, and Judith Gouwens, Chair.

Read the application carefully and respond to each question or prompt. Applications with errors or omissions will be returned without review, delaying approval significantly. Applications must be submitted on the current form; those submitted on old forms will be returned without review.

Note to students: Both you and your instructor/supervisor *must* sign your IRB application before it is submitted. Both you and your instructor/supervisor will be notified of the disposition of your application when it is approved or when additional information or amendments are requested by the IRB.

The checklist below may help to ensure that you provide all necessary information as you complete the IRB application.

APPLICANT CHECKLIST

(Please do not submit with your application)

General Information

- Typed (hand completed forms will not be accepted) and signed IRB packet
- Provided documentation of completed online tutorials for the responsible conduct of research with human subjects
 - Supervisor documentation
 - Student documentation
 - All other faculty, staff, and/or researchers' documentation
- Provided four hard copies with original signatures and one electronic copy of your completed application to Judith Gouwens, IRB Chair
- Identified the monthly deadlines to submit your application
- Used the current IRB application form
- Responded to all items on the IRB application form, including your contact information
- Double checked for any errors or omissions

Identifying Information

- Provided all identifying information
 - Principal Investigator contact information
 - Supervisor contact information (for students)
 - All other key personnel and student investigators' contact information
 - Project title
 - Type of study
 - Application Date

Detailed Project Information

- Provided an abstract of your project in the space provided in the application
 - Purpose
 - Research design
 - Procedures
 - Expectations of participants
 - Estimated start date
 - Estimated completion date

Subjects/Participants and Consent

- Provided number of participants
- Identified any vulnerable populations
- Described how participants are recruited and informed
- Provided details for compensation (if any)
- Reviewed the guidance for determining the appropriate way to get consent and assent for your study
- Identified the form of consent that will be obtained
 - Included participants not legally competent (if any)
 - Provided copy of consent documents and forms
- Identified any ethnic groups or gender that will be excluded

- Provided translated consent forms and survey instruments (if participants are non- English speakers)
 - Translator credentials provided (if necessary)
- Indicated any participants located outside of the U.S.
- Described personal, educational, or business affiliation with any participant (if any)

Data Collection

- Indicated all methods to be used for data collection
 - Attached any survey instruments or questionnaires to be used
 - Included a list of interview questions and protocols
- Attached a reference list for any instrumentation from an outside source
- Included consent to use instrumentation developed by someone other than this study's investigator(s)
- Identified any type of recording of participants
- Indicated how participants will be identified and data will be protected
- Indicated how results of research will be disseminated
- Included waiver of authorization of review of PHI (if appropriate)

Drugs and Alcohol

- Reviewed the guidelines for use of drugs and alcohol
- Answered all questions regarding drugs and alcohol

Deception

- Explained the necessity of deception and debriefing procedures (if any)

Risk and Benefits

- Stated any potential risks and how they will be managed
- Stated potential benefits of study
- Described and explained procedures for any blood specimens

Funding Information

- Provided funding information from all outside sources
- Attached any collaborating agency's IRB approval
- Provided a list of all outside investigators

Conflict of Interest

- Answered all questions related to conflict of interest
 - Necessary explanations provided

Signatures

- Carefully read all investigator assurances
- Printed name, signed and dated each hard copy
 - All principal investigators
 - All faculty supervisors (if applicable)