Rensselaer Polytechnic Institute Review Board

Guidelines for Proposal Submission

• Send 15 copies to: Michael J. Kalsher, IRB Chairman, CA 305.
• No more than 5 pages; can be as short as one page.
• If the proposal is from a student, the proposal must include a cover memo from the research advisor which indicates that he/she has read and approved the proposal.
• Students can be used in classroom research as long as participation is voluntary, would not affect the student’s grade (+ or -) and anonymity is guaranteed. A statement to that effect should be included in the proposal. The students cannot be in the research professor’s class for research studies - in order to eliminate any indirect coercion.
• Informed consent form should be written at the 8th grade reading level and available in the participant’s native language.
• If you foresee any complications and would like help preparing this proposal for IRB review, contact Jean Bestle (x6472, bestlj@rpi.edu) and she will put you in touch with an IRB member.

Proposals should include the following:

1. Title of Proposal:
2. Researcher:
3. Address:
4. Phone:
5. Research Advisor (for students):
6. Department:
7. Objective:
8. Methods:
9. Effects on Subjects:
10. Measures to Minimize Risk:
11. Likelihood of Harm:
12. Documentation of Risks:
13. Benefits to Participants:
14. Alternate Method Not Using Human Subjects:
15. Qualifications of Researcher:
16. Recruiting of Subjects:
17. Confidentiality:
18. Specimen Consent Form:
Sample Informed Consent Form

I ____________________________, have been asked to participate in a research study which

A. Methods: (A brief description of the research methods.)

B. Risks or Discomfort:

C. Benefits:

D. Available Alternative Course of Treatment:

E. Termination: Participation is voluntary. There is no obligation. You are free to decide whether you
   are willing to participate or not, and may withdraw without penalty at any time during the experiment.
   (If the subject is being paid, a prorated payment should be described.)

F. Confidentiality: A description of the record keeping should be placed here, with emphasis on
   how confidentiality will be maintained.

G. Time Required:

*H. Medical Treatment:

*Note: In the event that you are harmed by participating in this study, and this harm cannot be
attributed to the fault and negligence of the investigator, compensation and/or medical treatment is not
available from Rensselaer Polytechnic Institute. However, compensation and/or medical cost might be
recovered by legal action.

*Include ONLY if it is determined that risk is involved.

Signature ______________________
Date ______________________

Contact Person Name:
Phone Number:

cc: participant
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All Human Subjects Research must be reviewed by the IRB. Not all research, however, is Human Subjects Research. Often, proposed research falls in a gray area. The Rensselaer IRB, must ultimately make the determination as to what it is required by law to review. To assure that it considers all arguments we strongly recommend that where a researcher believes that certain research is not Human Subjects Research, then the researcher provide to the IRB, along with the protocol, a written statement setting forth the basis for the researcher’s contention that the research is not Human Subjects Research.

In evaluating whether it must review any proposed research, the IRB is required to adhere to the following definitions and principals:

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

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

*Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulation of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contract between investigator and subject.

*Private information* includes 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). Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

An example of research that may not be Human Subjects Research is a survey of a car dealership sales managers conducted solely to determine the amount of sales of automobiles. A survey of those same managers as to the techniques they used to generate those sales, would most probably be Human Subjects Research.

**ALSO NOTE** not all Human Subjects Research must be fully reviewed. The following types of research activities may be reviewed through *expedited review* procedures:

Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects’ behavior and the research will not involve stress to subjects.

If you believe your protocol should be given expedited review, please submit together with the protocol, a statement showing how the protocol satisfies the above requirements for expedited review. The IRB will consider your contentions, and provide expedited review where appropriate.