All researchers who use human subjects in their research must have their research protocol approved by the Institute Review Board. Most of the necessary information for the preparation of such a protocol is contained in the Institute Guide for Sponsored Research. The definitive guide for the Protection of Human Subjects is contained in the Code of Federal Regulations 45 CFR 46. If you wish a copy of this code, please contact Michael Kalsher, Department of Cognitive Science, at x8267 or email kalshm@rpi.edu. A sample proposal outline and consent form is enclosed.

The policy of the Institute Review Board is that all proposals are to be submitted by the date listed under “Proposals Due” starting in September. The IRB will review these proposals on the date indicated of the following month. The schedule is as follows:

<table>
<thead>
<tr>
<th>Proposals Due</th>
<th>Proposals Reviewed</th>
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<tbody>
<tr>
<td>Monday, September 16</td>
<td>Friday, October 18</td>
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<tr>
<td>Monday, November 4</td>
<td>Friday, November 29</td>
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<tr>
<td>Monday, January 6</td>
<td>Friday, February 7</td>
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<tr>
<td>Monday, February 24</td>
<td>Friday, March 21</td>
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<tr>
<td>Monday, April 7</td>
<td>Friday, May 2</td>
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</table>

All proposals which miss a due deadline will be processed as if received on the next due deadline. Fifteen copies of all protocols which involve human subjects should be sent to:

Michael J. Kalsher, Ph.D.
IRB Chairman
Carnegie Building, Room 305

according to the above schedule.

Enclosed: sample outline and consent form,
Guidlines for Proposal Submission

- Send 15 copies to: Michael 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 can not 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 Michael Kalsher (x8267, kalshm@rpi.edu) and he 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
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.