

APPLICATION TO USE HUMAN RESEARCH SUBJECTS
Purdue University
Institutional Review Board

1. Project Title: _____
2. Full Review Expedited Review
3. Anticipated Funding Source: _____

4. Principal Investigator [*See [Policy on Eligibility to serve as a Principal Investigator for Research Involving Human Subjects](#)*]:

Name and Title

Department, Building, Phone, FAX, E-mail address

5. Co-investigators and key personnel [*See [Education Policy for Conducting Human Subjects Research](#)*]:

Name and Title

Department, Building, Phone, FAX, E-mail address

6. Non-key personnel [*See [Education Policy for Conducting Human Subjects Research](#)*]:

Name and Title

Department, Building, Phone, FAX, E-mail address

7. Consultants [*See [Education Policy for Conducting Human Subjects Research](#)*]:

Name and Title

Department, Building, Phone, FAX, E-mail address

8. The principal investigator agrees to carry out the proposed project as stated in the application and to promptly report to the Human Subjects Committee any proposed changes and/or unanticipated problems involving risks to subjects or others participating in approved project in accordance with the Purdue Research Foundation-Purdue University Statement of Principles and the Confidentiality Statement. The principal investigator has received a copy of the [Federal-Wide Assurance](#) (FWA) and has access to copies of [45 CFR 46](#) and the [Belmont Report](#). The principal investigator agrees to inform the Human Subjects Committee and complete all necessary reports should the principal investigator terminate University association.

Principal Investigator Signature_____
Date

9. The Department Head (or authorized agent) has read and approved the application. S/he affirms that the use of human subjects in this project is relevant to answer the research question being asked and has scientific or scholarly merit. Additionally s/he agrees to maintain research records in accordance with the IRB's research records retention requirement should the principal investigator terminate association with the University.

Department Head (*printed*)_____
Department Name_____
Department Head Signature_____
Date

APPLICATION NARRATIVE

A. PROPOSED RESEARCH RATIONALE

- Describe why you are conducting the study. Identify the research question being asked.

B. SPECIFIC PROCEDURES TO BE FOLLOWED

- Describe in a step-by-step manner what you will require subjects to do in this study.
- Identify all data you will collect.

C. SUBJECTS TO BE INCLUDED

Describe:

- The inclusion criteria for the subject populations including gender, age ranges, ethnic background, health status and any other applicable information. Provide a rationale for targeting those populations.
- The exclusion criteria for subjects.
- Explain the rationale for the involvement of any special populations including prisoners
- Provide the maximum number of subjects you seek approval to enroll from all of the subject populations you intend to use and justify the sample size. You will not be approved to enroll a number greater than this. If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.
- **For NIH funded protocols:** If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

D. RECRUITMENT OF SUBJECTS AND OBTAINING INFORMED CONSENT

- Describe your recruitment process in a step-by-step manner. The IRB needs to know all the steps you will take to recruit subjects in order to ensure subjects are properly informed and are participating in a voluntary manner. An incomplete description will cause a delay in the approval of your protocol application.

E. PROCEDURES FOR PAYMENT OF SUBJECTS

- Describe any compensation that subjects will receive. Please note that Purdue University Business Services policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

F. CONFIDENTIALITY

- Describe what steps you will take to maintain the confidentiality of subjects.
- Describe how research records, data, specimens, etc. will be stored and for how long. The IRB generally recommends locked storage, such as a cabinet, for identifiable information. Please note, consent forms signed by subjects, parents and/or legally authorized representatives ARE considered research records.
- Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes.

G. POTENTIAL RISKS TO SUBJECTS

- There are always risks associated with research. If the research is minimal risk, which is no greater than every day activities, then please describe this fact.
- Describe the risks to participants and steps that will be taken to minimize those risks. Risks can be physical, psychological, economic, social, legal, etc.

- Where appropriate, describe alternative procedures or treatments that might be advantageous to the participants.
- Describe provisions for ensuring necessary medical or professional intervention in the event of adverse effects to participants or additional resources for participants.

H. BENEFITS TO BE GAINED BY THE INDIVIDUAL AND/OR SOCIETY

- Describe the possible direct benefits to the subjects. If there are no direct benefits, please state this fact.
- Describe the possible benefits to society.

I. INVESTIGATOR'S EVALUATION OF THE RISK-BENEFIT RATIO

J. WRITTEN INFORMED CONSENT FORM *(to be attached to the Application Narrative)*

- Submit a copy of the informed consent document in the form that it will be disseminated to subjects. The approved consent form will be stamped with the IRB's approval and returned to you for use.
- If recruiting subjects who do not speak English, submit both an English version as well as a version translated into the appropriate foreign language.

K. WAIVER OF INFORMED CONSENT OR SIGNED CONSENT

If requesting either a waiver of consent or a waiver of signed consent, please address the following:

1. For a Waiver of Consent Request, address the following:
 - a. Does the research pose greater than minimal risk to subjects (greater than everyday activities)?
 - b. Will the waiver adversely affect subjects' rights and welfare? Please justify?
 - c. Why would the research be impracticable without the waiver?
 - d. How will pertinent information be reported to subjects, if appropriate, at a later date?
2. For a Waiver of Signed Consent, address the following:
 - a. Does the research pose greater than minimal risk to subjects (greater than everyday activities)?
 - b. Does a breach of confidentiality constitute the principal risk to subjects?
 - c. Would the signed consent form be the only record linking the subject and the research?
 - d. Does the research include any activities that would require signed consent in a non-research context?
 - e. Will you provide the subjects with a written statement about the research (an information sheet that contains all the elements of the consent form but without the signature lines)?

L. SUPPORTING DOCUMENTS *(to be attached to the Application Narrative)*

- Recruitment advertisements, flyers and letters.
- Survey instruments, questionnaires, tests, debriefing information, etc.
- If the research is a collaboration with another institution, the institution's IRB or ethical board approval for the research.
- If the research accesses the PSYC 120 Subject pool include the description to be posted on the web-based recruitment program (formerly *Experimetrix*).
- If the research will be conducted in schools, businesses or organizations, include a letter from an appropriate administrator or official permitting the conduct of the research.