**Human Subjects Research Guide**

**Department of Psychological Sciences**

**Purdue University, West Lafayette Campus**

This is an overview for faculty and graduate students in the Department of Psychological Sciences, West Lafayette campus, about conducting research that involves human subjects. Researchers are encouraged to complete the “Nuts and Bolts” workshop provided by the IRB, which is available online at <https://www.irb.purdue.edu/irb-review-tutorial.php>.

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**What is the definition of research?**

 For an activity to be **research**, it must fall under the Department for Health and Human Services definition:

[a] systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Who is eligible to conduct research using human subjects?**

Tenured or tenure track Purdue faculty, including emeriti, who are certified by Purdue University as having received training in the conduct of research using human subjects are eligible to serve as principal investigators (PI) for Purdue projects involving human research subjects. Other faculty and staff members who fall into one of the following categories *may* be eligible to serve as PI with approval from the Vice Provost for Research (Institutional Official):

1. Non-tenure track faculty, and other senior academic staff whose appointments include responsibility for the direct, independent design and direction of research;

2. Clinical faculty;

3. Senior administrative staff with appointments as Director (or equivalent) and responsibility for the direct, independent design and management of projects; and,

4. Visiting faculty.

Graduate and undergraduate students shall not be permitted to serve as a PI for research protocols involving human research subjects. Purdue employees, who may otherwise be eligible under the above categories to be considered for PI status, cannot serve as a PI for a research protocol involving human subjects when they are conducting the research project as partial fulfillment of their graduate student obligations or training. When Purdue employees wish to conduct research involving human subjects as part of their graduate or undergraduate program, their faculty advisor must serve as the PI of record for the research protocol and application.

**What is the IRB?**

IRB stands for Institutional Review Board. The mission of Purdue's IRB is to protect the privacy, safety, welfare, and rights of human research subjects through a thorough evaluation of recruitment procedures, informed consent processes, and analyses of the risks to the subjects relative to the benefits of the research.

**What regulations govern human research?**

The "Common Rule" provides the basic regulations that govern human subject research. Formally, this is known as Title 45 of the Code of Federal Regulations, Part 46, which is usually abbreviated as [45 CFR 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). Depending on the exact nature of your research, other regulations may apply.

**Do I need any certification before conducting research?**

Short answer: Yes.

Long answer:

* Any faculty member, graduate student, or undergraduate student who will be working with human subjects will need to complete the CITI training at: <https://www.citiprogram.org/> prior to interacting with human subjects. You will need to register (this is free). You need to complete the basic course for behavioral and social researchers with 80% or higher in order to get your certificate.
* If you are someone other than an undergraduate or graduate student or faculty, but you are listed as *key personnel* on any protocol or grant, then you, too, need to complete the CITI training program at <https://www.citiprogram.org/>.

**Does my research project need reviewing?**

Most likely, if it involves humans or data from humans in any way, your research project needs to be reviewed *before* the project begins.

**What research is exempt from review?**

Research conducted in established or commonly accepted educational settings, involving normal education practices OR research involving **only** the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior is generally considered to be exempt. Specific criteria can be found at <https://www.irb.purdue.edu/forms.php>. Note that you must your research be *determined by the IRB* to be exempt. You cannot simply make that determination on your own and then forego submitting an exempt application to the IRB.

**What research qualifies for expedited review?**

The criteria for research that can qualify for expedited review can be found as part of application instructions at <https://www.irb.purdue.edu/forms.php>. Any research involving deception, or not revealing the full purpose of the research until the conclusion of the study, should be submitted as expedited (if not full) rather than as exempt. Research involving children or other potentially-at-risk populations, alcohol administration, procedures that are highly invasive and anything involving more than minimal risk should be submitted for full rather than expedited review. The term "expedited" is used to refer to the type of review process, not to the speed of the review process. You should allow 2-3 weeks during the Fall or Spring semesters, and longer during school holidays.

**What is full review?**

If a protocol does not qualify for exempt or expedited review, then it must undergo full review. In general, if your protocol involves the potential for more than minimal risk, or your protocol involves prisoners or groups who may have diminished capacity to provide consent or who may be at high risk, then it must undergo full review.

Full review means that the proposal will be reviewed by the Full IRB Board at its monthly meeting. Deadlines and meeting dates are posted at <https://www.irb.purdue.edu/irb-home/social-sciences-irb.php>.

**What is the full review process like?**

The IRB members may have questions and/or comments. If so, you will receive these via email usually a couple of days before the meeting. This is your opportunity to address these concerns by revising your application. The full committee can then consider your revised application at the Tuesday meeting.

If there are many comments, you will be invited to attend the meeting. You should look at this as an opportunity to speed up the process. By answering questions at the meeting, your proposal might be approved then and there rather than giving you feedback and then waiting another month for the next meeting.

You will most likely receive an email within a couple of days after the meeting informing you of the decision. Official paper work will then follow.

**How do I submit a proposal?**

Go to COEUS-Lite and log in: <https://coeus.itap.purdue.edu/coeus/userAuthAction.do>

Follow the instructions for submission found in the user manuals (posted on the department’s Research Procedures website (<http://www.purdue.edu/hhs/psy/research/research_procedures.php>).

Note: Upload all appendix files separately. For example, upload consent form, materials, and debriefing form as separate files.

**How do I revise my protocol?**

If you want to make any substantive changes to an approved research protocol, submit an Amendment (see the relevant manual instructions on our department’s Research Procedures website, <http://www.purdue.edu/hhs/psy/research/research_procedures.php.>

**How long must I keep copies of the consent forms?**

You must keep the consent forms until three (3) years after the termination of your protocol. For example, if your protocol was approved in 2011 and the project is terminated in 2015, you must keep the consent forms from all subjects until 2018.

**What other information must I track?**

You must keep track of the number of participants you have tested in your protocol. The IRB will want to know (1) the number of subjects tested since the last continuing review form and (2) the total number of subjects tested.

**What do I need to know if I am using an online (e.g., MTurk) sample?**

The application process is generally the same as in other situations, except in the case of non-exempt applications, Section K of the Application needs to be completed (“Waiver of Informed Consent or Signed Consent”). You will request a waiver of signed consent and answer all of the items listed under point #2 in the application instructions. Also be aware that other aspects of your application may need to be tailored for the MTurk sample, such as noting how much they will be paid (note that you can specify the MAXIMUM amount, so that you have some wiggle room for changing payment without having to submit an amendment). Another example of tailoring may be related to Section F, Confidentiality of Data (e.g., are data to be collected and stored on a secure server? How do we know it is secure?).

**What do I do if my study involves deception?**

If your study involves deception (telling participants something that is not true), then you need two consent forms. The first consent form can look just like the templates. The second consent form will be administered after the debriefing. This form should describe the exact nature of the deception and the reasons why deception was necessary. This form will ask the subject for consent to use the data collected. The rationale is that in studies involving deception, subjects cannot give informed consent to allow the use of their data until they are informed of the nature of the deception. You will need to provide copies of both forms before you can access the PSY 120 subject pool. This applies to all studies.

A prototype is provided under “Protocol Preparation and Accessing the PSY 120 Subject Pool” at <http://www.purdue.edu/hhs/psy/research/research_procedures.php>.

**Can I use graduate students or PSY 390 students as subjects?**

The IRB requires full board review of all protocols that use participants, like PSY 390 students or graduate students, who are academically involved with the PI. The reason is the increased risk for coercion. Even though you aren't the sort of faculty member who would write a worse letter of recommendation for a student who declined to participate than if the student agreed to participate, the IRB is concerned with what the students themselves think. Do they really believe that they have a choice and that the choice will have no effect whatsoever on their grade or on (potential) letters of recommendations?

One method that has been used in the past is to have some neutral third party keep track of which students participate. You, as the faculty member, have no knowledge, and so your grading and the letters of recommendation that you write cannot be influenced by the students' decisions.

**What common mistakes delay approval?**

This list is not exhaustive, but does include the most common items.

* If you are using subjects from the PSY 120 subject pool, use the following for Section D (recruitment of subjects):

Subjects will be recruited from the Psychology 120 subject pool using the web-based SONA sign-up program.

* List and assess all possible risks
* Use the most updated template for the consent form (found on the IRB website, <https://www.irb.purdue.edu/forms.php>)
* Write for an intelligent audience who may be unfamiliar with your specific topic and research methods
* Compensation (paying subjects) is *not* considered a benefit of participation, but rather is an inducement to participate
* If you have a multi-page consent form, leave room for the subject's initials and date on each page prior to the final page
* Include your recruitment ad (if applicable)
* Include copies of IRB approval from collaborating institutions (if applicable)
* Include copies of letters from school districts giving you permission to test students (if applicable)
* Include your debriefing sheet if the protocol involves PSY 120 students
* Include the text that will appear on the SONA web site (if applicable)
* Include both consent forms if your study involves deception.

**How do I get access to the PSY 120 subject pool?**

First, you must be either tenured or tenure-track faculty OR have approval from the Vice President for Research to conduct research using human subjects. Second, you must have a faculty appointment in the Department of Psychological Sciences at the West Lafayette Campus. Third, your protocol must have been approved (by either expedited review or full review) and your project's risk assessment must be "minimal."

First, obtain SONA numbers from Sue Phebus. Then, submit

* A "Request to use subjects from the psychology 120 subject pool"
* A copy of the consent form that will be used
* A copy of the second consent form if [deception](http://www1.psych.purdue.edu/hsag/#deception) is used
* A copy of the debriefing form that will be used
* A list of all people who will have contact with the subjects
* A copy of the experiment description that will be posted on the SONA web site

This information needs to be provided every semester. Please note: Not all projects that have "minimal risk" will qualify for access to the pool. Final judgment rests with the Head of Department (or more usually, the co-chair of the Human Subjects Advisory Group).

Once a semester, you will receive a form that solicits requests for credit hours. This form must be submitted on time. The form will list the deadline for that particular semester. If you miss the deadline, you will have to wait until the next semester.

**What common mistakes should I avoid when using the PSY 120 subject pool?**

The following are the most common areas where mistakes are made:

* Keep a copy of the signed consent form in a secured location
* Provide experiment credit in a timely fashion (within 24 hours after participation)
* Include in the estimated duration of the experiment time for the subject to ask any questions before, during, and after the experiment
* Make sure the room location is specified properly (e.g., PSYC 1111, not PSY 1111 or Psychology 1111)
* The PI (a faculty member) must keep a copy of all consent forms. You need to keep all consent forms until 3 years after the protocol has been terminated. If your protocol was approved in May 2012, and you terminate the proposal in May 2016, you need to keep all the consent forms until May 2019.

**What about PSY 120 students who are under 18 years old?**

According to Federal and Indiana State Law, students under 18 are not considered adults or emancipated minors. Therefore, they are not legally capable of providing informed consent. However, participation in experiments is one way that PSY 120 students can fulfill their research requirement. Therefore it is the obligation of each PI to determine the age of each PSY 120 student who volunteers to participate after testing. If the student is under 18 years old, then the PI must discard all data at the end of the session. PIs must test all PSY 120 students who sign up, even if they are less than 18 years old.

**Where is a copy of the Departmental Procedures?**

There are two documents, both available in PDF format. The [first document](http://www1.psych.purdue.edu/hsag/1-procedures.pdf) outlines the general operation of the review process within the department. The [second document](http://www1.psych.purdue.edu/hsag/2-procedures.pdf) outlines the rules that govern the PSY 120 subject pool.

**What are stamped consent forms and how do I get mine stamped?**

On September 1, 2003, the IRB began requiring that only stamped consent forms be used. The reason for the stamp is to comply with regulations demonstrating that each consent form has been read and approved by the IRB.

When you prepare your consent form (and second consent form), please make sure that it:

1. includes the research project number at the top left
2. does not include approval and expiration dates at the top
3. includes the relevant SONA number
4. leaves enough room for the stamp (approx. 1.5 x 2.3 inches), usually at upper right

If you are submitting an application to access the PSY 120 subject pool, please obtain SONA numbers from Sue Phebus *before* you submit your application and be sure to include them on your consent form(s) just before the title of your experiment.

**My question wasn't answered. What do I do?**

You can email Margo Monteith (mmonteit@purdue.edu), Chair of the Department's Human Subjects Advisory Group and Co-Chair of the University IRB.