Procedures for the Protection of Human Subjects
Department of Psychological Sciences
Purdue University
West Lafayette Campus

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Part I. Procedures for all Research Protocols

1. The Department has a Human Subjects Advisory Group (hereafter referred to as HSAG), which consists of faculty members with appointments in Psychological Sciences who are either tenured, tenure-track, or who have received permission from the Vice-President for Research to serve as principal investigators on protocols for research involving human subjects. Members are appointed to the group by the Head of the Department of Psychological Sciences. One member of the group, usually the Chair (and hereafter referred to as the Chair), is also a member of the Committee on the Use of Human Research Subjects (hereafter referred to as the IRB).

2. Investigators who have a faculty appointment in Psychological Sciences and who believe that their project is exempt from review submit a "Request for Research Exemption" (Form HS-95/4) first to the Department, which then forwards it to the IRB. If the IRB determines the project is exempt, then the project can proceed. If the IRB determines the project is not exempt, then investigators follow the procedure in (3) immediately below.

3. Investigators who have a faculty appointment in Psychological Sciences submit an "Application To Use Human Research Subjects" to the HSAG. Three members of this group are designated to review the entire protocol application and to judge whether the research qualifies for expedited review or requires full review.

4. The reports of the three HSAG members and the entire protocol application are given to the Head (or, more usually, a faculty member designated by the Head, hereafter referred to as the Head's designee), who then reviews the protocol taking into account comments made by the HSAG members. At this stage, two decisions are possible:

    1. If the protocol is judged to require full review, the protocol is forwarded to the IRB for full review.

    2. If the protocol is judged as qualifying for expedited review, it is forwarded to the Chair of the HSAG.

5. Protocols judged as qualifying for expedited review are sent, along with any comments from the three HSAG reviewers and the Head's designee, to the HSAG Chair.

This person then evaluates the protocol to determine whether it qualifies for expedited review or requires full review. At this stage, two decisions are possible:

1. If the protocol is judged to require full review, the protocol is forwarded to the IRB for full review.

2. If the protocol is judged as qualifying for expedited review, the Chair will so indicate on the approval form, and the protocol will be forwarded to the Chair of the IRB and then to the Assistant Vice President for Research Compliance.

6. Research projects can begin only after the following occurs:

1. For a protocol judged exempt by the IRB, research may begin after it is approved by the IRB.

2. For a protocol judged as qualifying for expedited review, research may begin after it is reviewed by the HSAG and approved by the Head's designee, then approved by the Chair of the HSAG, and then approved by the Chair of the IRB and then by the Assistant Vice President for Research Compliance.

3. For a protocol judged to require full review, research may begin after it is approved by the IRB after full review.

7. Procedures are in place for situations in which there may be a conflict of interest. Potential conflicts involving the Head's designee will be sent to the Head (or other appropriate faculty member so designated by the Head). Potential conflicts involving the Chair of the HSAG will be sent to the Chair of the IRB. In practice, conflicts involving the Head do not occur as the application is routinely considered by the Head's designee.

8. In all of the above, the definitions of research that is exempt or that qualifies for expedited review are those found in Title 45 Code of Federal Regulations part 46 (45 CFR 46), as most recently revised.

Part II: Additional Procedures for protocols that include students from PSY 120

1. In addition to the procedures outlined above, all research protocols that include PSY 120 students are subject to additional requirements, set forth below.

2. When the HSAG, the Head's designee, and the Chair of the HSAG review protocols that include students from PSY 120 as subjects, they additionally consider whether the protocol is suitable for the PSY 120 pool.

3. Protocols that involve more than minimal risk cannot use the pool. Protocols that have not been review by the HSAG, the Head's designee, and the Chair of the HSAG cannot use the pool.

4. Some students enrolled in PSY 120 are not yet 18 years old. They can choose either to participate as subjects in the department's on-going research projects or can choose to complete an alternate project to satisfy the course's research requirement. If they choose to participate in research, their data will be discarded. Investigators will ask each PSY 120 student his/her age and will discard all data from students who are not yet 18 years old.

5. Although all protocols that are given permission to use the PSY 120 pool will qualify for expedited review, being approved for expedited review does not guarantee approval for the use of PSY120 students.

6. If a protocol is judged as qualifying for expedited review and is judged suitable for PSY 120 students by the HSAG, the Head's designee, and the Chair of the HSAG, and the protocol has been approved by the Chair of the IRB and the Assistant Vice President for Research Compliance, the protocol is considered "approved" but the investigator does not yet have permission to begin conducting research using the PSY 120 pool.

7. To obtain permission to use the PSY 120 subject pool, the principal investigator, who must have a faculty appointment in Psychological Sciences, must provide the following information to the Head's designee:

1. The investigator must submit a "Request to use subjects from the Psychology 120 subject pool" that provides information about the approved protocol, the risk level, the principal investigator, and the names and roles of all people who will have contact with the subjects (e.g., a secretary as a receptionist, a graduate student as an assistant, etc.).

2. The investigator must submit a copy of the experiment description that will be posted on the Experimetrix web program. This is a web-based program that provides a list of approved experiments in which students may participate to fulfill their research requirement. The URL is: https://experimetrix2.com/Purdue/

3. The investigator must submit 3 copies of the specific written informed consent form to be used.

4. The investigator must submit a copy of the specific debriefing form to be used. The debriefing form must answer six specific questions, including ones about the purpose, the design, and where further information about the topic can be obtained.

8. This information is requested every semester. Approval ends at the end of each semester. The investigator must apply every semester, even if the protocol does not change. The Head's designee reviews this application, with special attention that the consent form and debriefing form contribute to the educational nature of participation.

9. Part of protecting human subjects involves information presented as part of the PSY 120 course itself. This information informs students of their rights and obligations.

    1. The course catalog description for PSY 120 states that "Students also will be obliged to fulfill a research requirement through participation in experiments or writing reports." Students are thus aware of the research requirement prior to enrolling in PSY 120.

    2. Each instructor sets aside class time at the beginning of the semester for a videotape presentation about the research requirement and handing out relevant materials. The videotape ensures uniform presentation of information.

    3. Each student receives a course syllabus that includes information about research participation and the alternative to participating in experiments. The alternative is designed to provide a similar educational experience and to take the same amount of time.

    4. The course syllabus also includes information about using the Experimetrix system that helps in coordinating students' experiment participation (see below).

    5. The course syllabus also indicates that any student who missed the class in which the videotape presentation was made and materials distributed should contact Connie Stump, the experiment coordinator. The contact information includes an office location, a phone number, and an email address. Connie Stump then gives those students the information they missed.

10. PSY 120 subjects are recruited in the following way:

    1. The course syllabus provides detailed information for accessing the Experimetrix program. This is a web-based program that provides a list of approved experiments in which the students may participate to fulfill their research requirement. The URL is: https://experimetrix2.com/Purdue/.

    2. The web connection is via a secure server, the same type of security used when making purchases via the web.

    3. A list of all approved experiments is provided by the Experimetrix program. In addition to a descriptive title, a short paragraph provides further details about the experiment so that students can decide whether they would like to participate.

    4. When arriving at the experiment session, the students are given an informed consent document. This includes a statement about the voluntary nature of the research and a statement that indicates that they can withdraw at any time

without penalty. The consent form also includes a description of the specific procedures.

5. If the student decides to participate, s/he signs two copies of the form, which is countersigned by the experimenter. The student keeps one copy of the consent form, and the other copy is kept on file by the Department. (Revised June 1, 2002) The Principal Investigator will keep copies of all informed consent forms completed on or after June 1, 2002 until 3 years after the termination of the protocol. However, the Department will continue to keep all consent forms completed prior to June 1, 2002.

11. When the student leaves, s/he is debriefed. All experiments include time for the student to ask any questions about the experiment or research, or to comment on the research. Thus, an experiment that is said to last 1 hour will include as part of that hour time for the subject to ask questions or make comments.

12. (Adopted following the May 28, 2002, meeting of the Committee on the Use of Human Research Subjects) All studies that involve deception (i.e., telling subjects something that is not true) must provide the subjects with an opportunity to sign a second consent form after the debriefing. This form will explicitly grant or deny the investigator permission to use the collected data, and it will also describe the exact nature of the deception and the reasons why deception was necessary.

13. (Adopted following the September 23, 2003, meeting of the committee on the Use of Human Research Subjects) Beginning September 1, 2003, the IRB requires the use of an "approved" consent form indicated by an approval stamp. The IRB will allow both the Head's designee and the Chair of the HSAG to stamp consent forms for previously-approved active protocols that use the PSY 120 pool and include only procedures already approved in the parent protocol. The original stamped consent form will be forwarded to the IRB office for post-review. PIs will be permitted to use the stamped forms immediately, but may be required to modify the forms and/or stop research as a result of any post-review in the IRB office.