

Shippensburg University
RESEARCHPROJECTS INVOLVING HUMAN SUBJECTS AND PARTICIPANTS

Pursuant to action taken by the Board of Trustees on June 23, 1981, all members of the Shippensburg University faculty, staff. And student body (full or part time) who are conduction research or related activities with human beings as subjects, must conform with procedures prescribed in the regulations issued by the Department of Health and Human Services. The completion and filing of *the APPLICATION to USE HUMAN SUBJECTS in RESEARCH* is part of these procedures. This form **MUST** be completed for each project **BEFORE** any research (including data collection) is conducted and before support (e.g., grant funding) for this research is solicited from any source.¹

For research projects lasting longer than 12 months, continuing approval is required on or before the anniversary date of the initial approval. The same above-mentioned form is utilized for this continuation process as well.

The person filing an application must be the principal investigator. All applications will be sent to Dr. Steven J. Haase, Chairperson of the Committee on Research on Human Subjects. The committee is appointed by the President of the University and is comprised to meet the criteria or membership established at 45 CFR. Part 46.107. If the application satisfies the criteria for an *expedited* review as established at 45 CFR. Part 46.110, the Chair or his appointee will conduct the review. The full committee or a subset of that committee will consider those applications that do **NOT** meet the criteria (stated below) for expedited review. The criteria to be used by the full committee for review of application of research involving human subjects/participants are established at 45 CFR Part 46.111.

These criteria are:

1. Risks are minimized.
2. Risks to the subjects are reasonable in relation to anticipated benefits to subjects and the importance of the knowledge that may reasonable be expected to result.
3. The selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject/participant or the subject's legally authorized representative.
5. Informed consent will be appropriately documented.
6. Provision is made for monitoring the data collected to ensure the safety of the subject/participants.
7. Adequate provisions are made to protect the privacy of subjects/participants and to maintain the confidentiality of data.
8. Where subjects/participants are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards are included to protect their rights and welfare.

ITEMS to INCLUDE with Application:

1. A photocopy of the research or thesis proposal. This will be a concise and clear document outlining the proposed project, including but not limited to subject/participant selection, recruitment, research design and methodology, relevant literature that supports the project. One may think of this as an Executive Summary. Be cautious to explain the proposed research in a way that reviewers **NOT** from your profession or field of inquiry are able to understand.

¹ This does **NOT** impose limitations where student researchers seek pre-approval from field/internship sites for the conduct of eventual research once approved.

2. A copy of the subject/participant INFORMED CONSENT form. This form must clearly explain ALL possible risks and will assure the subjects/participants that they are free to withdraw from the study/experiment/project at any time without penalty.
3. Written informed consent is required of parent or legal guardian of all subjects/participants who are less than eighteen years of age, whether or not the minor will be exposed to risk. If minor subjects/participants are in the fifth grade or higher, the Board recommends that “assent” be signed by the minor as well as collecting parental informed consent.
4. Administrators at sites where research is to be carried out MUST provide written confirmation that the proposed research is fully acceptable as proposed and APPROVED by the appropriate administration of the site (e.g., Principal or Superintendent of schools, CEO or Director of an agency). Students MUST include this letter in their application to IRB.
5. *A supporting letter from the faculty advisor must be included if the application proposes research to be completed by a student researcher.* If a faculty member assigns research projects to members of a class (e.g., research methods courses, class projects for evaluative research design) AND the faculty member submits all class applications in aggregate, one letter of faculty support and oversight will suffice for this purpose.
6. If the research requires the use of surveys, a copy of all surveys should be included. If the surveys are still under construction, an explanation of the nature of the questions and a brief list of sample questions to be used may suffice in some cases.

In addition, the Committee may require further information about the proposed research project; or it may request the investigator to attend a meeting to supply additional information or answer questions posed by the research. After the review is completed, the investigator will be notified of the Committee action in writing (i.e., e-mail). Formal acceptance letters are available upon request (e.g., for inclusion with grant proposals).

Send completed applications to:

Dr. Steven J. Haase
Chair, Committee on Research on Human Subjects
Dept. of Psychology
114 Franklin Science Center
Shippensburg University of Pennsylvania
Shippensburg, PA 17257-2299
717-477-1160

Application to Use Human Subjects in Research

1. Activity or Project Title*:

2. Check: Initial Application _____ Continuing Application _____
(date of initial application _____)

3. _____
Name & Phone# of Principal Investigator Department e-mail
(Attach list of all other investigators' names)

4. _____
Faculty Sponsor (if #3 is a student) Department e-mail
Name & Phone#

5. RISK

A. Are there risks to human subjects? _____ Yes _____ No
If yes, briefly describe.

B. Describe the benefits of the research.
(1) to the subjects:

(2) to the discipline/profession:

* Applicants must provide all required information requested at the time the application is made. Any changes researchers may wish to make following the initial approval of your application MUST be resubmitted for amendment or reconsideration.

6. SUBJECTS

A. Briefly describe the subjects/participants. (Include age).

B. Describe procedure for recruiting/selecting subject/participants.

7. Informed consent is required by University policy and by the Department of Health and Human Services regulations. Informed consent will be obtained in writing () and/or verbally (). *Please attach a copy of your informed consent.*

8. Confidentiality of information from or about subjects must be safeguarded. Briefly describe how confidentiality of this information will be maintained.

9. Please attach additional information which will assist the *Committee on Research on Human Subjects* in making a decision on your project. This should include copies of questionnaires or other assessment instruments, and/or a summary of the research procedure and/or experimental manipulation(s).

Send completed applications via Campus Mail to:

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