

Institutional Review Board (IRB)

Section A, Cover Sheet & Signature Page

These instructions will take you through the Cover Sheet and the Signature Page, which are part of Section A. The checklist in Section A should be done after the Cover Sheet, Signature Page, Section B and Section C are completed. Below you will find the text portions of Section A in black (although not necessarily in the same format as on the IRB forms). All additional information and comments are in blue.

Human Subjects Research COVER SHEET

Date:

Give the date you complete the IRB forms

Investigators (status: student, faculty, others)

List the primary investigators and their status. For example:

Xxxxx Xxxxx, Ph.D., Professor

Xxxxxxx Xxxxx, Undergraduate, Psychology Major

Xxx Xxxxx, M.D., Geisinger Medical Center

Department(s):

List the academic departments involved. For example:

Psychology

Title of Project:

This is the title the IRB will use to catalog your submission. This title should be descriptive, but it does not have to be the exact title you use when you disseminate the research at a later date (i.e., for publication, Honors Thesis, or conference presentation).

Funding Agency: (if any)

If you have already secured funds for this research then simply name the agency.

If you have not secured funds but plan to submit the research to an agency, then state your intentions. For example: This research will be submitted to the National Science Foundation for possible funding.

If you do not have funding and you do not intend to submit this research for funding, simply state "None."

Category of Review (circle one)

If you do not know which type of review you should request please review the Type of Review pages.

The area marked (Committee use only) should be left alone.

SIGNATURE PAGE

Fill in the number of estimates:

Average amount of time required for subject's participation (hrs):

Try your best to get a **realistic estimate**. Time participants in a pilot test (trial run) situation or time yourself completing the tasks. Notice that the estimate should be in hours, so you may want to report this in fractions or decimal form.

If questionnaires or tests are involved, the total number of items:
Just as the time estimate, this gives the IRB a better understanding of what is requested of the participants.

Number of volunteers (subjects) to be involved in the study:
This should reflect the number of participants you plan to include in your study. We realize that the final number of participants may be slightly more or less than the estimate.
Knowing the number of volunteers helps the IRB determine the feasibility of your study. The number of volunteers is also a consideration in assessing measures of confidentiality. For example, if the research is designed as a case study with a very small number of participants then special precautions may be needed to protect confidentiality.

Beginning date and ending date of involvement of human subjects.
Notice this is not the time frame for the entire study from literature review to write-up, but rather the time during which you will be collecting data from human subjects. The maximum time approved is 1 year. Should you need more time than is approved by the IRB you can write a letter to the IRB requesting an extension.

Note the following paragraph on the Signature Page. Make sure you are aware and agree to these conditions:

- The investigator confirms that the project or activity described in the attached Section B is planned to **adhere to University policies** and, if applicable, to the institutional assurance with the U.S. Department of HHS regarding the use of human subjects.
- The investigator agrees that **major additions and changes** in procedures involving human subjects that occur after review of the application will be brought to the **attention of the review committee** by the investigator.
- In addition, the committee will be notified of any unanticipated events that do or could affect the safety and well being of subjects. University review and approval is requested.

ADDRESSES & SIGNATURES

Students must have their primary advisor for the investigation sign the form.

Please give your local address and phone number (including area code if you are out of town) in legible writing. The IRB will use the address given here to contact the investigator.

If possible please include an e-mail address as well.