

Students' Guide for Studies Involving Human Participants

If you plan to use human participants in your thesis or dissertation research, be sure you comply with the UT human subjects regulations BEFORE you contact any potential participants. If your thesis or dissertation research involves human participants and you do not comply with UT human subjects regulations, you may not receive your degree.

The following steps will help you satisfy UT human subject/participant regulations:

1. Speak with your Departmental Review Committee Chair or faculty advisor about your project to help determine the correct form to use (Form A or Form B).
2. View the **Human Subjects - Bookshelf** section of this website to find current guidelines for human participants. Or view the **Human Subjects - Forms** section of this web site to find current forms relating to human participants research. Contact the Office of Research Compliance Officer at 1534 White Avenue or by phone at (865) 974-3466 should you have any questions.
3. Your completed Form A or Form B should:
 - a. Address the protection of rights and welfare of human participants in your research.

Form A or Form B is a document in which you show your concern for protection participants' rights and welfare.

- b. State risk faced by research participants.

Even if the risks are minimal, state that point in your protocol. Researchers proposing studies that expose participants to more than minimal risk should clearly identify the risks, articulate the implications of the risks, discuss the means used to mitigate the risks, and communicate their assessment of the anticipated benefits versus the risks.

Minimal risk is defined as follows: "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests."

- c. State the means used to recruit participants.

Describe your recruiting methods and materials. Describe how you gain initial access to potential participants. Indicate how participants are adequately informed about your study's purpose and procedures. If you are reaching potential participants through third parties (e.g., hospitals, schools, etc.), be sure the person granting you access has the right

to permit that access, and gives you permission in writing. That permission should be dated, on letterhead, and indicate the extent to which you will have access to potential participants or data. Attach these letters to your application.

d. Identify any involvement of "vulnerable populations" requiring special precautions to minimize risks and to avoid coercion:

Vulnerable populations include children, pregnant women, cognitively impaired persons, and prisoners. Sometimes, economically or educationally disadvantaged persons, patients recruited by their own physicians, students recruited by instructors, and employees recruited by their employers may be considered vulnerable populations. Usually if participants are under the age of 18, parental consent must be obtained.

e. Address equity among gender, racial, and ethnic groups recruited as research participants.

f. State the informed consent procedure.

Your informed consent procedure is a critical aspect of your protocol. The IRB needs to know that your participants are fully informed about their rights and the study's research procedures. Whether the informed consent is verbal or written, it must include the **eight basic elements of informed consent**. The use of additional consent elements may be needed depending on the nature of your study.

g. Present the content of the interview instruments. All written surveys, tests, and procedures that will be used should be included in your protocol. For more informal interviews, provide a thorough description of the initial interview questions and subsequent interview procedures.

h. Describe who will have access to the data once it is collected; how the data will be used and presented; how the data will be stored; where the data will be stored; and what happens to the data when the study is completed.

Review Process

Check deadlines for Form B application reviews requiring full IRB review. Allow enough time for your thesis/dissertation committee, your departmental review committee, and the IRB to review your Form A or Form B. For further information about the review process read the Departmental Review Committee (DRC) Guide (Adobe PDF Document).

Submit **the correct number of copies** of your completed Form A or B to your thesis/dissertation committee advisor.

Be sure your approved Form A or Form B application contains the **original signatures** of all investigators, Departmental Review Committee Chair, Department Head, and your

thesis/dissertation committee advisor's signature must be included. For student projects (not theses or dissertations) then supervising faculty member's signatures are required.

Please remember that the IRB is concerned with: a) procedures that place participants "at risk"; b) steps taken to ensure participants' informed consent; and c) the protection of the confidentiality of the participants' responses.

Other Important Details

IRB approval may not be used as an endorsement of your study. IRB approval should not be represented to participants as approval of the study in any materials used in your research. Specifically, consent forms may NOT state that the IRB has approved the study.

There are certain deadlines for submitting applications. Please view the **Human Subjects - Bookshelf** section of this web site or contact the Compliance Officer for the Office of Research at (865) 974-3466 for further details.

Remember, you may not initiate human participant research until you have received final approval from the IRB (or your DRC for some Form A applications). Do not assume you have final approval just because you have submitted your application.