Instructions for Completion of the Application to the UT Martin IRB

The Application to the University of Tennessee at Martin IRB for the Protection of Human Subjects in Research was designed to be self-explanatory. Occasionally there are some questions; therefore, the following is offered as a guide to assist you in completing the application thoroughly. Each form asks questions specific to a given type of research. The UT Martin IRB application was designed as “one form fits all” with the application answering all pertinent questions, appending attachments as appropriate. If any question does not apply to your research project, mark it N/A (not applicable). The application was designed to serve as a checklist for the researcher, ensuring the research plan includes all necessary elements.

You should answer all questions thoroughly. If you do not answer questions that are pertinent to your proposed research, or if you do not attach a copy of the research instrumentation, procedures, etc., your application will be returned to you or held for receipt of all necessary documentation. If you have any questions about what should be included in your application packet, please contact the Office of Research and Sponsored Programs.

1. Date Received in the Office of Research and Sponsored Programs: All applications are logged when they arrive at the ORSP.

2. Principal Investigator’s (PI) name, daytime phone number, email address, campus/home address, and status: This person, if there is more than one applicant, is the individual who is to serve as the lead contact for all correspondence and requests from our office regarding the application. Please ensure that all contact information listed is only that of the Principal Investigator.

3. Additional Investigators: Please list all additional investigators, other than the Primary Investigator. Everyone listed in this section must sign the original application form.

4. Advisor: Please list the full name and contact information of your advisor, if you are a student. Also remember to have your advisor sign your original application prior to forwarding to the ORSP.

5. Training Certification: Attach documentation for CITI training and any other sponsor-required training.

6. Project period: Provide approximate time period of subject involvement. The IRB must review ongoing projects every 12 months at a minimum. “Upon IRB Approval” may satisfy.

7. Title of project: Complete title of project. Do not abbreviate.
8. **Project Classification**: Refer to the Guide to determine either exempt, expedited, or full review.

9. **Site of work**: Where are you going to involve the subjects? On campus? At a local educational agency (school)? All over the state? The interest is in the subjects’ location, not the place of the data analysis.

10. **Funding source(s)**: Please disclose any funding source(s) whether external, internal, or personal. If this project is funded through a granting agency, provide information for sections a – d.

11. **Brief description of its general purpose**: List brief synopsis of your project including hypothesis(es), objectives, research questions.

12. **Details of the procedures that relate to the subjects’/participants’ participation**: Where did you get your subject population? Passers-by-at large? Random selection from the telephone book? The Psychology pool? Inmates of a prison? Residents or a nursing home? Students? Discuss how you selected population (e.g., through advertisement, paper, letter, announcement, transcript of verbal announcement, etc.). Append copies to Application.

13. **What inducement is offered?**: If subjects are to receive a stipend, grade points, or any other reward for participants, what is it? If there is no inducement, enter “N/A.”

14. **Number and salient characteristics of subjects**: How many subjects do you plan to involve? Do you plan on distributing 50 or 100 survey forms? What is the number of subjects you intend to involve? Also, characterize them (e.g., gender, ages, eye color, hair color, race, ethnicity, students of one grade, members of a specific church, or holders of a particular license, etc.). Give any specifics that characterize your subject population.

15. **If a cooperating institution is involved, has written permission been obtained?**: APPEND LETTER(S). Researchers must have written permission from the head of an organization or member of the administration with sufficient rank to grant such permission. For example, a teacher friend may not give you permission to enter her/his classroom in a particular school’s system to conduct research; this permission must be obtained from the Superintendent of Schools of that district, or the principal of the specific school, at a minimum. If there is no cooperating institution, enter “N/A.”

16. **Number of times observations will be made?**: Are you asking the subjects to complete one instrument once? Are you asking them to report activity(ies) for a certain number of weeks for a certain number of times? How much of the subjects’ time will you take up?

17. **What do the subjects do, or what is done to them, in the study?**: APPEND COPY OF QUESTIONANNAIRE(S), TEST INSTRUMENT(S), OR DESCRIPTION OF PROCEDURES TO BE CONDUCTED ON THE SUBJECTS INCLUDING OBSERVATIONS. If you are involved in internal research project or sponsored research, attach a copy of your research procedure. If not, give a clear, concise description of what you intend to do to or with the
subjects. The IRB is not interested in what type of analysis you intend to carry out on the data. It is interested in what you are going to measure and how.

18. Is it clear to subjects that their participation is completely voluntary?: Does your informed consent form or statement make this clear to the subjects/participants? Is it written in language they can understand? If you plan to orally consent participants, you MUST include a script of what will be said (The IRB will determine if oral consent is appropriate).

19. Is it clear to the subjects that they may withdraw at any time?: see 15 above

20. Is it clear to the subjects/participants that they may refuse to answer any specific question that may be asked them?: see 15 above

21. Cite your experience with this type of research: The IRB’s interest here is mainly in projects where there is an element of risk for the subjects/participants – physical, emotional, through potential breach of confidentiality, etc. In such cases when the researcher does not have adequate experience, the IRB will work to ensure the subjects’ safety by having someone with adequate experience monitor the project. Attach a 2-page vitae.

22. How do you intend to obtain the subjects’/participants’ informed consent?: If in writing, attach a copy of the consent form. If not in writing, include a written summary of what is to be said to the subjects, and justify the reason that oral rather than written consent is being used. Also, explain how you will ascertain that the subjects/participants understand what they are agreeing to (The IRB will determine if oral consent is appropriate). The UT Martin IRB may allow consent to obtained other than through the full consent form, provided: (1) there is no risk, or risk to the subject is minimal, (2) the written consent procedure would not be normally used outside the research context, and (3) the consent document would be the only link between the subject and the research data.

The decision as to whether an informed consent document is required is reserved to the UT Martin IRB. However, the IRB does specifically require that potential subjects/participants be informed that:

a. Participation in the research project is voluntary
b. The title of the project is stated
c. State who is conducting the research and under whose auspices
d. Explain what they are being asked to do or what will be done to them. Tell them how much of their time will be involved in the study
f. Explain that participation is fully voluntary, the subject/participant may quit at any time, and the subject/participant may refuse to answer a question(s)
g. Define the method of ensuring subjects'/participants' confidentiality
h. Provide the name of the person who would furnish subjects/participants with additional information about the research project
i. Offer to answer any questions the subjects/participants might have about the study
23. **In your view, what benefits may result from the study that would justify asking the subjects/participants to participate?:** What expected value is there to the study that gives the researcher the right to ask the subjects/participants to participate?

24. **Discuss risks to subjects/participants to participate in the study:** Do you see any chance that subjects/participants might be harmed in any way? Do you deceive them in any way (The UT Martin IRB does not approve of deceit in research. It will review and may approve applications that involve limited deception, with the provision that subjects/participants receive a comprehensive debriefing within a reasonable time frame). Are there any physical risks? Psychological? (Might a subject/participant feel demeaned or embarrassed or worried or upset? Possible loss of status, privacy, reputation?) This is the part of the application concerned with the cost/benefit ratio of the proposed research, and calls for an honest elevation by the researcher of these considerations from the point of view of the subject/participant. Please review the types of risk(s) in the Guide before answering “No.”

25. **Confidentiality of the information collected:** How will you ensure that data collected will be kept confidential? How will data be stored? Will coding lists be destroyed after data entry? See discussion of “confidentiality” in the Guide.

26. **UT Martin facilities and equipment to be used in the research:** Please explain. If grant funds are providing equipment, travel, supplies, etc. for you to carry out your research, please denote which grant(s) is/are funding the research.

**Signatures and Copies:** The Principal Investigator (PI) signs and dates the application where designated. Co-PI’s sign and date the application, if applicable. If the applicant is a student (serving as either the PI or co-PI), the student advisor must also sign and date the application accordingly. This student advisor signature indicates that the advisor has reviewed the proposed research and approves of it as being methodologically and ethically sound, taking full responsibility for the conduct of the research, if approved. Once the Departmental Review Committee has reviewed the application and marks its recommendation as either “exempt,” “expedited,” or “full,” the Departmental Review Committee Chair, along with the applicant’s department chair, signs and dates it before the Application is submitted to the IRB.

Exempt applications require original application. Expedited applications require original and two copies. Full Review applications require original and six copies.

If you have any questions, please contact the Office of Research and Sponsored Programs, 100 Administration Building, orsp@utm.edu.