Concord University
Human Subjects Review Board

HSRB Project Proposal Questionnaire

The information provided in response to this questionnaire must be typed. Please number paragraphs corresponding to the question numbers appropriate for your research project. Please include the individual questions that you will be answering. If an item is not applicable, please mark it 'NA' (not applicable).

Question Numbers 1-7 are <u>REQUIRED</u> for <u>ALL</u> HSRB categories (Categories I, II, & III)

1. Provide a brief project description. In a few words, describe the objectives, methods, and procedures of the research project. The emphasis should be on the human subject involvement in the project. Discussion of theoretical or statistical aspects of the project should be avoided.

    a) If a questionnaire and/or testing instrument is to be used, describe how it will be administered, by whom, and cite the original source. If interviews are to be conducted, describe the nature of the interview and how responses will be recorded.

2. Include the number and the relevant characteristics of the research subjects.

3. Describe how research subjects will be selected for participation in the project. Include information related to fees, extra credit, or other items they will receive for their participation, if any.

4. Provide the status and qualifications of research assistants, if any.

5. Indicate the source of funding, if any, for the project.

6. Indicate the expected start and completion dates for the research project. **The research project cannot begin until approval has been received from HSRB**. Projects are given approval for a maximum of one year. If the project continues past that point, the principle investigator(s) must apply and receive HSRB renewal approval.

7. Attach copies of all questionnaires, testing instruments, or interview protocols. Also include any cover letters or instructions to research subjects.

Question Numbers 8-11 are <u>REQUIRED</u> for HSRB review <u>Categories II and III</u>

8. Specify steps to be taken to guard the anonymity of research subjects and/or the confidentiality of their responses. Indicate what personal identifying indicators will be kept on subjects. Specify procedures for storage and the ultimate disposal of personal information.

9. Include a written or read statement of informed consent that includes the following:

    a) A statement that the study involves research.

    b) Explanation of the purpose of the research and the expected duration of the research subject's involvement (e.g. how long will it take to complete the study).

    c) Description of the procedures to be followed, and the identification of any procedures that are experimental.

    d) Description of any benefits to the research subject, or others, that may be reasonably expected from the research.

    e) Description of any reasonably foreseeable risks and discomforts to the research subject.

    f) Statement describing the extent, if any, to which confidentiality of records identifying the research subject will be maintained.

    g) For research involving more than minimal risk, an explanation as to whether any treatments are available if harm occurs, and if so, what they consist of, or where further information may be obtained.

    h) Explanation of who to contact for answers to pertinent questions about the research and the rights of research subjects, and who to contact in the event of a research related injury to the subject.

    i) Statement that participation is voluntary, and that refusal to participate will involve no penalty or loss of benefits to which the research subject is otherwise entitled.

    j) Statement that research subjects may discontinue their participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

k) When studying young children (ages 0-10), the researcher must exert special vigilance that the child's assent to participation remains freely given, and must reassure the child that he/she may discontinue participation in the study at any time. Explain how you ensure this, if it is relevant.

l) The HSRB must be provided with a written description of these elements of informed consent to be presented to the research subjects. If the project cannot practicably be completed without this requirement being waived or altered, please say so here, and include a debriefing procedure.

10. If the research subjects are to be drawn from an institution or organization that has the responsibility for the subjects (e.g. hospital, social service agency, prison, school, etc.), then documentation of permission from that institution must be submitted to the HSRB before final approval can be given.

11. If the subject will come into contact with any mechanical, electrical, or any other type of equipment, Form 1A and a complete description of the equipment must be included in order for the safety of the equipment to be checked.

Question Numbers 12-16 are <u>REQUIRED</u> for HSRB review <u>Categories III ONLY</u>

12. Specify any special subject populations (e.g. minors, prisoners, or the cognitively impaired) involved in this research project and describe the procedures for obtaining the appropriate consent.

13. If the research subjects will be exposed to any psychological intervention such as deception, contrived social situations, manipulation of the subject's attitudes, opinions, or self-esteem, psychotherapeutic procedures, or other psychological influences, complete Form 1A.

14. If there will be any treatments upon the body of the research subjects by mechanical, electronic, chemical, biological, or any other means, complete Form 1A. A complete description of the equipment must be provided in order for the safety of the equipment to be verified.

15. If the research subjects in the project may be exposed to the possibility of injury, including physical, psychological, or social injury, complete Form 1A.

16. Documentation of legally effective Informed Consent is required. A copy of the consent document must be submitted with the proposal. If the project cannot practicably be completed without the waiver or alteration of this requirement, please say so here and include a debriefing procedure.