Project Information

This information must be typed. Please number paragraphs according to the number of items appropriate for your project. Please include the individual questions that you will be answering. If an item is not applicable, please mark it 'NA' (not applicable).

Items 1-7 are <u>required</u> for <u>all</u> categories.

1. Provide a brief project description. In a few words, describe the objectives, methods, and procedures of the 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. 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 subjects.

3. Describe how 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 appropriate.

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 starting and completion dates for the project. **Note that the project cannot begin until approval has been received from the HSRB. Projects are given approval for a maximum of one year. If they continue past that point, they must again receive HSRB approval.**

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

Items 8-11 are required for Categories II and III

8. Specify steps to be taken to guard the anonymity of 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. Specify how subjects will be informed of the following basic elements of informed consent (these would be included in the written or read statement of consent and so labeled):

(a) A statement that the study involves research.

(b) Explanation of the purpose of the research and the expected duration of the 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 subject, or others, that may be reasonably expected from the research.

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

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

(g) For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury 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 subject is otherwise entitled.

(j) 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.

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

10. If the subjects are to be drawn from an institution or organization (e.g. hospital, social service agency, prison, school, etc.) that has the responsibility for the subjects, 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.

Items 12-16 are required for Category III only.

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

13. If the 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 subjects by mechanical, electronic, chemical, biological, or any other means, complete Form 1A. A complete description of the equipment must be written in order for the safety of the equipment to be checked.

15. If the 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 you will use 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.