

PLEASE FORWARD ORIGINAL COPY TO THE IRB CHAIR

Principal Investigator: _____

Name of Project: _____

Date received by departmental reviewer: _____

Date received by IRB chair: _____

Date approved by IRB: _____

Date received by Grants Office: _____

IRB Form B-4

**Checklist for Research Requiring Full Committee Review
and Guidelines for Protocol Preparation**

DIRECTIONS: Submit this form to the chair of the IRB if you believe that your project requires full committee review. Please check all applicable items in Part A and include a full research proposal that explicitly provides all relevant information requested in Part B.

Part A:

1. The research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects. **[NB: The accompanying proposal must indicate clearly why the use of subjects in any of these categories is scientifically necessary.]**
2. The research involves the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subject's financial standing, employability, insurability, or reputation. **[NB: The accompanying proposal must indicate clearly why the collection or recording of such behavior is scientifically necessary and what steps will be taken to preserve subjects' anonymity/protect subjects' confidentiality.]**
3. The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior). **[NB: The accompanying proposal must indicate clearly why the collection of such information is scientifically necessary and what steps will be taken to preserve subject's anonymity/protect subject's confidentiality.]**
4. The procedures of this research involve **more than minimal risk** to the subject (where more than minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests). **[NB: The accompanying proposal must identify all risks (physical, psychological, financial, social, legal, other) connected with the proposed procedures, indicate clearly how such risks to subjects are reasonable in relation to anticipated benefits, describe procedures designed to protect against or minimize such risks, and assess their likely effectiveness.]**
5. This research does not fall into any of the categories explicitly identified as qualifying for exempt c

expedited status.

Part B

Please provide a copy of the full research proposal. In the spaces below, indicate where in the proposal (give page, line numbers) relevant information can be found. If any of the following are not explicitly covered in the proposal, address them in a supplementary statement.

1. What is the purpose of the proposed study?

2. Describe the proposed subject sample. If subjects under the age of 18 will participate in your research, indicate the sample's expected age range. If your research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects, you must indicate clearly why the use of these subjects is scientifically necessary.

3. How will subjects be recruited and selected?

4. Briefly describe all research procedures that will apply to human subjects. Be sure to indicate:
 - a) approximately how much time each subject is expected to devote to the research.
 - b) how data will be collected and recorded (with or without identifiers? what instruments, materials, or equipment will be used? will audio- or videotapes be employed in data collection?). **Attach copies of all written instruments and/or describe any apparatus with which subjects will be in direct contact.**
 - i) if the research involves the collection or recording of behavior which, if known outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation or the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior), indicate clearly why the collection or recording of such behavior is scientifically necessary and what steps will be taken to preserve subjects' anonymity/protect subjects' confidentiality.
 - ii) if the research presents more than minimal risk to the subject (where more than minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests), you must: a) identify all risks (physical, psychological, financial, social, legal, other) connected with the proposed procedures; b) indicate clearly how such risks to subjects are reasonable in relation to anticipated benefits; c) describe procedures designed to protect against or minimize such risks; and d) and assess the likely effectiveness of any

such procedures.

iii) if the research involves any of the following: covert observation, studies of ethnic and group differences, intervention research, invasion of privacy, aversive (noxious) stimulation, induction of mental or physical stress or deprivation (e.g., food, water, sensory, sleep), invasive procedures (e.g., drugs, blood, samples, surgery), potentially embarrassing situations, or other ethical issues concerning the dignity and welfare of the participants, describe these in detail, indicate why they are scientifically necessary, and describe any steps that will be taken to minimize risk and maximize benefit to the subjects.

c) methods for obtaining informed consent and assent in the case of minors. For minors, indicate how their assent and the consent of parents or legal guardians will also be obtained. **Attach copies of all materials used to obtain informed consent or assent. Model consent and assent forms can be found in the Appendix.**

d) methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records at the conclusion of the research).

e) if deception is to be employed, provide a scientific justification for its use and describe debriefing procedures. If, for any reason, it will not be possible to debrief subjects regarding the deception, this must be explained and justified.

5. Describe any relationship between researcher and subjects, such as: teacher/student; superintendent/principal/teacher; employer/employee. If such a relationship exists, how will it affect the subject's ability to participate voluntarily and how will the principal investigator handle it?

6. Indicate any benefits that are expected to accrue to subjects as a result of their participation in the research. In the event that subjects will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research.

7. If the research presents more than minimal risk to subjects, discuss benefits to the subjects, to science, and/or to society that will result from this work in relationship to those risks. **[NB: You must be able to show that the overall benefits to be gained from the research justify whatever risks subjects are asked to take.]**

July 2001