IRRB CRITERIA FOR ETHICAL RESEARCH

The following requirements for the approval of research is based upon the Code of Federal Regulations, Title 45, Public Welfare, Part 46, Protection of Human Subjects (revised Oct 1, 1997). The scope and interpretation of this checklist are determined by reference to that original document.

Requirements of All Research:

- Risks to participants, where they exist, will be minimized and are reasonable in relation to anticipated benefits. (46.111a 1-2)
- Participants will be equitably chosen, especially in the case of vulnerable populations—children, persons with disabilities, the homeless, etc. (46.111a 3)
- Documentation of informed consent will be obtained from each participant or participant's legal representative. (46.111a 4-5; see Required Elements for Informed Consent below)
- Measures will be taken to monitor data collected to insure the safety and privacy of the participants. (46.111a 6-7)
- In the case of vulnerable populations, additional safeguards will be included to prevent coercion or undue influence by the researcher. (46.111a 8)

Required Elements for Informed Consent:

- The consent form provides a clear and non-technical explanation of the research project—sufficient to inform a participant's decision to participate or not. (46.116a 1)
- The consent form describes any foreseeable risks or discomforts, as well as possible benefits to the participant. (46.116a 2-3)
- The consent form informs the participant of the extent to which confidentiality will be maintained. (46.116a 5)
- The consent form identifies a person to contact should questions regarding the research or the participant's rights arise. (46.116a 7)
- The consent form provides a statement that participation is voluntary and that refusal to participate or termination of participation will result in no harm to the participant. (46.116a 8)
- Note: When obtaining consent for minors to participate in research studies,
  - an agreement to participate in research constitutes a valid consent only if voluntarily given. Informed consent requires conditions free of coercion and undue influence. (See the section on Voluntariness, page 9 of the IRRB monograph for a definition of coercion and undue influence.) It is important that the voluntary nature of agreement continue throughout the research.
  - regardless of the age of the minors (participants who are not yet eighteen years old), parental or guardian consent is required to participate in a study. Describe the procedures to obtain parental or guardian consent.
  - in addition to obtaining the consent of parents or guardians, if the minors participating in the study are able to give their consent, describe the procedures for obtaining their consent to participate. If you do not obtain the consent of minors, please explain why you do not consider them able to provide it.
  - all minors and/or their parents or guardians should be given a copy of any consent document that they have completed.

When appropriate, the following should also be included:

- If relevant, the consent form describes any alternative treatments being withheld by the researcher that might be advantageous to the participant. (46.116a 4)
- The consent form explains any compensation to be provided should harm to the participant occur. (46.116a 6)