FRIENDS RESEARCH INSTITUTE, INC.
1040 Park Avenue, Suite 103
Baltimore, MD 21201

Subject: Reviews Requiring Special Consideration
Division: IRB
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IRB Policy 110.1: AIDS RELATED RESEARCH

Policy

Because of the special sensitivity of AIDS research, the IRB will exercise particular care in observing all applicable regulatory provisions. The IRB will see that risks to subjects are minimized consistent with sound research design, and that risks to subjects are reasonable in relation to benefits and the importance of the knowledge that may reasonably be expected to gain. Whenever appropriate, procedures already being performed on subjects for diagnostic or treatment purposes should be used. To ensure adequate review of AIDS studies, the IRB may consult with persons who have special expertise and with persons who are qualified to represent the interests of the subject population.

Ethical Considerations

There are three ethical considerations that must be observed in the conduct of AIDS related research.

1. THERE MUST BE FAIRNESS IN THE DISTRIBUTION OF BOTH RISKS AND BENEFITS OF RESEARCH: Caution is needed to make sure that age, competence, experience, education, position, life style, etc., are not used to determine eligibility for entrance into a study unless these factors are necessary for the research design.

2. POSSIBLE BENEFITS OF THE RESEARCH MUST BE MAXIMIZED AND POSSIBLE HARMS MINIMIZED: As the research develops these matters will have to be reviewed from time to time to clarify what benefits may accrue to society as a whole, what benefits may accrue to subjects, and what possible harms may come to subjects. Special care must be taken to establish safeguards to prevent accidental or careless disclosure of confidential information. Improper disclosure could threaten family relationships, job security, employability or ability to obtain credit or insurance. Therefore, staff persons must be trained to handle information and data with due regard for the rights of subjects.

3. THE RIGHTS OF RESEARCH SUBJECTS TO MAKE CHOICES BASED ON INFORMED JUDGMENTS MUST BE RESPECTED: These rights must be protected through a consent procedure which:

    a) is legally effective;
    b) is obtained in non-coercive circumstances with sufficient time and opportunity for subjects to make an informed decision;
    c) does not attempt to waive the rights of subjects, or contain exculpatory language which is intended to limit the legal liability of the institution; and
    d) is presented to subjects in language that is understandable to them--if necessary in language

other than English.

Confidentiality

Perhaps the most sensitive aspect of AIDS research from the perspective of the rights and welfare of the subjects is the matter of confidentiality. 45 CFR 46.116(a)(5) and 21 CFR 50.25(a)(5) require a statement of the extent to which confidentiality of records identifying the subject will be maintained.

Improper disclosure could have the most serious consequences for research participants, by threatening family relationships, job security, employability, or ability to obtain credit or insurance. In light of these risks, special precautions should be taken to preserve confidentiality, and potential subjects should be advised with care of the limits of that confidentiality, so they can make thoughtful, informed decisions, in light of their own circumstances, as to whether to participate.

Each study is to be designed with administrative, management and technical safeguards to control authorized use and disclosure of information and to protect against unauthorized disclosure of information and to protect against unauthorized disclosure. Where identifiers are not required by the design of the study, they are not to be recorded. If identifiers are recorded, they should be separated, if possible, from data and stored securely, with linkage restored only when necessary to conduct the research. No lists should be retained identifying those who elected not to participate. Participants must be given a fair, clear explanation of how information about them will be handled.

As a general principle, information is not to be disclosed without the subject's consent. The protocol must clearly state who is entitled to see records with identifiers, both within and outside the project. This statement must take account of the possibility of review of records by the funding agency, and by FDA officials if the research is subject to FDA regulations (21 CFR 50).

IRBs should consider what information will be recorded in the subjects medical records, and may wish to minimize the recording of data from AIDS related studies in the medical records. Some states or other jurisdictions may require AIDS to be reported and may require followup. Participation in research does not exempt compliance with those laws, but potential study participants must be fully informed of laws requiring disclosure of information before they volunteer for the studies.

IRBs should take account of the possibility of attempts under compulsory legal process to force disclosure of records, how such attempts will be responded to and whether individuals will be notified of such attempts. The IRB should consider and establish procedures for information disclosure in emergency situations involving the health either of research subjects or others. Whether and how to notify subjects; physicians of findings about a subject should be addressed.
The protocol should contain information setting forth how to respond to requests by third parties who have authorizations for disclosure of information signed by subjects. (Particular attention should be given to handling blanket authorizations that purport to authorize disclosure of all the data relating to a given person.)

The informed consent requirements set forth in the regulations are based on legal decisions, recommendations of national advisory bodies and years of experience and careful application by researchers and research institutional officials. The procedures have been designed to afford full opportunity for potential subjects to make informed decisions and for protection of the rights, welfare and dignity of those who agree to assist in obtaining important knowledge that will benefit society.

Applicable Regulations and Guidelines

The Belmont Report
45 CFR 46

21 CFR 50
OHRP IRB Guidebook
OHRP Guidance for Institutional Review Boards for AIDS studies