Background

Research designed to answer the many biomedical and behavioral questions presented by HIV poses numerous ethical concerns. Primary among them are considerations of privacy, confidentiality, and justice (fairness in the distribution of the benefits and risks of research). The subjects involved in HIV-related research, HIV-infected individuals, and persons at risk of HIV infection, are particularly vulnerable, both because of their disease status, and because the disease disproportionately affects certain populations: male homosexuals and bisexuals, intravenous drug users, minorities, and, increasingly, women and children.

IRB Considerations

The most sensitive aspect of HIV/AIDS research from the perspective of the rights and welfare of research subjects is the matter of confidentiality. Subjects included in HIV-related studies are understandably concerned about the confidentiality of the data, since breaches in confidentiality could have severe adverse consequences such as loss of employment or insurance coverage, or criminal charges.

The IRB asks that investigators conducting HIV studies consider the following:

1. 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.

2. 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.
3. Investigators should also consider whether and how information from HIV-related studies will be recorded in subjects’ medical records. The IRB may decide to impose limits on the recording of such data. Before agreeing to participate in an HIV study, subjects should be informed of exactly what information will be recorded, and whether any state laws require the reporting of HIV infection or other disclosures of information. The research protocol should also deal with 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. Please be aware that the IRB may require investigator to obtain a federal certificate of confidentiality prior to beginning the study. Research protocols should specifically set forth how to respond to requests by third parties who have authorizations for disclosure of information signed by subjects.

4. The giving of voluntary consent, axiomatic to all research involving human subjects, applies equally in HIV-related research. Complicating the consent issue, however, is that HIV-related illness, particularly in its later stages, can cause dementia, thus affecting the ability of subjects to give consent or continue to consent to ongoing research. Research protocols should deal with this possibility. The IRB will ensure that subjects in this particularly vulnerable condition are adequately protected.

5. Research on vaccines and treatments poses some of the most difficult questions, including the level of acceptable risk to subjects when the disease is fatal and no effective therapy is available; whether HIV-infected patients can be used as a placebo group that is not given experimental treatments; how subjects should be selected to receive experimental therapies; whether and under what circumstances healthy and at-risk but not-yet-HIV-infected persons can ethically be asked to participate in vaccine trials.

**IRB Requirements for Research Involving HIV/AIDS Testing**

The IRB has developed additional safeguards for the protection of volunteers who are asked to participate in research involving HIV screening. The IRB requirements for protocols of this type are delineated below:

1. Each subject must be informed of the result of the HIV test. Subjects may not be given the option "not to know" the result, either at the time informed consent to be tested is obtained or thereafter.
2. If the result of the test is positive, counseling must be provided at the time when the subject is given the result of the test. The procedures for meeting this requirement must be described in the IRB application. Investigators must ensure that the counselor has appropriate expertise.

3. In designing the research procedures, investigators must develop safeguards to ensure the confidentiality of the records. These safeguards must be described in the IRB application. Except in the case of official hospital records, the results of an HIV test should not be recorded on any identifiable records intended to be viewed by individuals other than investigators. The IRB protocol should clearly state who is entitled to see records with identifiers and to whom the results will be made available both within and outside the project; and limits to confidentiality should be discussed with the potential subject during the informed consent process.

4. During the informed consent process, the following information must be explained to the subject and included in the consent form:

   A) The research procedures will include an HIV test;
   B) The result of the test will be given to the subject;
   C) If the subject tests positive, the subject will meet with a qualified professional who will provide counseling at the time the subject is given the test result;
   D) The risks of HIV testing including physical, psychological and social risk (e.g., impact upon employment, insurance, freedom to travel to other countries, etc.);
   E) Potential limits to confidentiality. The informed consent should clearly state who is entitled to see records with identifiers and to whom the results will be made available both within and outside the project.

5. No lists should be retained identifying those who elect not to participate.