

UNIVERSITY OF KENTUCKY
Protection of Human Subjects in Research Involving HIV Testing

Research which includes immunodeficiency virus (HIV) screening as a condition for inclusion in a research protocol poses considerable psychological, social, and economic risk to subjects. Consequently, the Medical 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 on the attached page.

Before implementing a study involving HIV screening, the IRB recommends that investigators consider whether it is ethically justified to include HIV testing simply for screening purposes. Meyers and Dunton, in the January 1988 issue of the IRB publication, summarize some of the issues which need to be considered in making a risk/benefit analysis. Their assessment is included below:

The position of a pharmaceutical sponsor could be as follows:

1. That its purpose is valid, that it is appropriate to screen all volunteers for HIV antibodies in order to protect the research unit's personnel from the risk of infection.
2. That the test employed can be used effectively for this purpose.
3. That the informing process meets the prerequisite requirements that take into account the rights and interests of the volunteers and the obligation to obtain an informed consent.

Those opposing this argument would state:

1. That the evidence indicates that screening is not warranted in this setting to prevent transmission of HIV infection.
2. That there are questions regarding the predictive value of the HIV test results.
3. That it is not possible to obtain truly informed consent since one cannot adequately assess the negative consequences of a positive HIV test.

If it is determined that HIV screening is ethically acceptable, it is important that IRB requirements for designing the study, preparing the IRB application and implementing the research are met. In particular, investigators should exercise care in ensuring that the informed consent procedures and documentation provide prospective subjects with necessary information for making informed decisions.

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Medical IRB Requirements for Research Involving HIV Testing

1. Each subject must be informed of the result of the HIV test.
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 result of an HIV test should not be recorded on any identifiable records intended to be seen by persons 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; any limits to confidentiality should be discussed with the potential subject during the informed consent process.
4. The Elisa test has a high percentage of false positives, particularly in low risk populations; therefore, a subject should not be excluded from participation on the basis of a single positive test result. If the first test is positive, the Elisa test must be repeated and if still positive, must be followed by a Western Blot test.
5. 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 risks (e.g., impact upon employment, insurance, freedom to travel to other countries, etc.);
 - e. potential limits to confidentiality. The 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. The consent should also state that HIV positive test results including the subject's name will be reported to health authorities in accordance with state law (902 KAR 2:020).
6. No lists should be retained identifying those who elect not to participate.