

Protection of Human Subjects in Research Involving HIV Testing

Research which includes human 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.

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. This is particularly relevant when screening normal volunteers.

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.

The IRB requirements for protocols of this type are delineated on the attached page.

Medical IRB Requirements for Screening for HIV/AIDS

1. Each subject must be informed of the result of the HIV test.
2. If the result of the test is positive, counseling and/or referral for HIV care must be provided at the time the subject is given the result of the test. The procedures for meeting this requirement must be described in the IRB application.
“Post-test counseling” can include: informing the patient of the results and meaning of the test results; providing education about avoiding risks of sexual and injection drug exposures; assessing the impact of test results for the patient and family; explaining treatment options; discussing partner counseling and disclosure of test results to others; and initiating a support and treatment plan.

Positive HIV test results should be communicated confidentially through personal contact by a clinician, nurse, mid-level practitioner, counselor or other skilled staff.
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 can have false positives, particularly in low-risk populations; therefore, a subject should not be excluded from participation on the basis of a single positive Elisa test. 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 and/or referral for HIV care at the time the subject is given the test result;
 - d. the risks of HIV testing. These risks include physical, psychological, and social risks (impact upon employment, insurance, freedom to travel to other countries, etc.) and;
 - 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, birth date, address, phone number and county of residence will be reported to the local health department serving the jurisdiction in which the subject resides; or Department for Public Health in accordance with state law (902 KAR 2:020.).

6. Researchers must report HIV positive test results to the local health department serving the jurisdiction in which the subject resides; or Department for Public Health in accordance with state law (902 KAR 2:020.)
7. No lists should be retained identifying those who elect not to participate.

Available Resources for HIV/AIDS information:

Kentucky Cabinet for Health & Family Services HIV/AIDS Branch:

<https://chfs.ky.gov/agencies/dph/dehp/hab/Pages/default.aspx>

Lexington-Fayette County Health Department: <http://www.lexingtonhealthdepartment.org>

Bluegrass Care Clinic - University of Kentucky, Department of Infectious Disease:

<https://ukhealthcare.uky.edu/obstetrics-gynecology/primary-care/conditions-we-treat/hiv>

Center for Disease Control (CDC) and Prevention: <http://www.cdc.gov>

CDC's Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health Care Settings:

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>