Policy
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: X.E
Section: Conduct of Research
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: September 15, 2000
Revision Dates: March 19, 2004; August 30, 2004; July 1, 2015

Subject: HIV Testing in Human Research Participants

Definitions:
1. Certificate of Confidentiality: A document that provides additional protection of data from legal subpoena. The Certificate provides protection against compelled disclosure of identifying information or other identifying characteristics of a research participant enrolled in biomedical, behavioral, clinical, and other forms of sensitive research.
2. Human Immunodeficiency Virus (HIV): Any of the lentiviruses and especially HIV-1 that infect and destroy helper T-cells of the immune system causing the marked reduction in their numbers that is diagnostic of AIDS.
3. Sensitive Information: Includes, but is not limited to, information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information, that if released, might be damaging to an individual’s financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual’s psychological well-being or mental health; and genetic information.

Policy:
It is the policy of the Human Research Protections Program (HRPP) to assure that HIV testing associated with human research participants is congruent with federal, state and local regulations.

I. HIV Testing.
A. Investigators must comply fully with all applicable federal, state and local policies and guidelines for testing, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality where research activities directly or indirectly involve the study of HIV.
B. Tennessee State law requires that written informed consent be obtained prior to HIV testing. The IRB may grant an exception to obtaining informed consent when blood is collected for research without identifiers and there is no mechanism to track the results to an individual.
C. Special precautions should be taken to preserve confidentiality and potential research participants should be advised of the limits of confidentiality so they can make an informed decision whether to participate in the research activities.
D. Investigators should be aware that research records are subject to subpoena by law enforcement agencies and additional protection may be sought under provisions of “Certificates of Confidentiality” (See HRPP Policy VI.D) to prevent compelling disclosure.

II. HIV Results.
A. Where HIV testing is conducted or supported by the Public Health Service (PHS), including both research and health services activities, domestic and foreign, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided the opportunity to receive appropriate counseling unless the situation calls for an exception. Additionally, to the extent possible, known partners of a person with HIV infection shall be notified that they may have been exposed to HIV and should be encouraged to be counseled and tested.
B. Exceptions Pertaining to an Individual. Where there are compelling and immediate reasons that justify not informing a particular individual that he or she is seropositive(e.g.,
indicating that an individual would attempt suicide), the particular individual need not be informed of HIV test results. When this exception is utilized, the details of the exception must be documented by the Investigator or another responsible individual at the testing facility. The Investigator must promptly report the exception to the IRB without identifying the individual. It will be presented to the next scheduled IRB Committee meeting for review and approval of the exception.

C. Exceptions Pertaining to Protocol Design. Because circumstances may exist in which extremely valuable knowledge might be gained from research involving participants who would be expected to refuse to learn their HIV antibody results, an exception included in the protocol design may be proposed to the IRB Committee reviewing the research proposal.

D. Disclosure of an individual’s positive HIV test results to anyone other than the individual without the individual’s written permission is forbidden. This includes funding agencies such as the NIH, sponsors, and regulatory agencies such as the FDA.

E. Positive HIV test results and the individual’s name are required by law to be reported to the State of Tennessee AIDS Program by the Investigator or clinician associated.

F. Activities conducted at foreign sites should be carefully evaluated to account for cultural norms, the health resource capabilities, and official health policies of the host country.

References:
PHS Policy on Partner Notification May 3, 1990