Subject: Procedure for HIV Testing in Human Research Participants

Procedure:
This procedure outlines the processes to assure that human immunodeficiency virus (HIV) testing associated with human research participants under the jurisdiction of the Human Research Protections Program (HRPP) is congruent with federal, state and local regulations.

I. Investigator Responsibilities.
   A. The Investigator will detail the method for obtaining informed consent for HIV testing in research as a part of the initial study submission to the IRB or provide a description of the process for de-identifying blood samples taken from participants. The Investigator may also request a waiver of informed consent, when appropriate (See HRPP Policy IV.C).
   B. Exceptions Pertaining to an Individual. When there are compelling and immediate reasons that justify not informing an individual participant of his or her seropositive results, the Investigator must promptly report this exception to the IRB without disclosing the participant’s identity to the IRB.
   C. Exceptions Pertaining to Protocol Design. In proposing research to the IRB with the exception incorporated as a part of the research activities, the Investigator must report to the IRB that:
      1. Research participants will be informed of their risk of infection;
      2. Research participants will receive risk reduction counseling whether or not they receive their test results;
      3. There is good reason to believe that a requirement for test notification counseling whether or not they receive their test results;
      4. There is a good reason to believe that a requirement for test notification would significantly impair collection of study information that could not be collected by other means; and
      5. The risk/benefit ratio to individuals, their partners, and society will be periodically reviewed by the IRB so that the study might be revised or terminated if it is determined that it is no longer justifiable to allow participants to continue to participate in the research without receiving their HIV test results.
   D. The Investigator must notify the Agency Head of the Public Health Service (PHS) supported research when an exception of notification has been granted by the IRB.
   E. In order to obtain legally effective informed consent from a research participant when the research involves HIV testing, the Investigator will provide the following additional explanations:
   F. In general terms, the type of test to be performed should be described, including an explanation that the test is for HIV infection and not for AIDS, the need for medical follow-up and/or counseling and social support if the test is positive, and the possibility of false negative and false positive test results;
   G. Any alternatives to performing the test must be stated. If the alternative of not having the HIV test completed would mean that a potential participant cannot enter the study, this must be explained;
   H. The risks of a positive test should be described to include significant anxiety, adverse effect on insurability, discrimination in housing, employment, or public accommodations, and changes in interpersonal relationship with loved ones; and
I. The Investigator must ask the participant if a more detailed explanation is desired or if he or she has any particular questions prior to obtaining consent for testing.

J. The Investigator must consider that research records are subject to subpoena by law enforcement agencies and therefore for added protection of participants, the Investigator may apply for a “Certificate of Confidentiality” from the NIH or funding source.

K. The Investigator will include in the informed consent document, that sponsors of funded studies (e.g., NIH, drug companies), or regulatory agencies (e.g., OHRP, FDA, PHS) will have access to research records that may contain confirmation of HIV positive test results and may be subject to mandatory infectious disease reporting.

II. IRB Committee Responsibilities.

A. During its review of an application, the IRB should consider and the Investigator’s protocol must address issues of obtaining informed consent, confidentiality, the notification process, the timeliness of informing individuals, and counseling of the individuals and others designated by the individual (e.g., sexual partners).

B. When reviewing research that includes HIV testing of participants, the IRB must render a determination that:
   1. The HIV testing is integral to the design of the proposed research and no alternative testing that yields comparable information is available;
   2. The Investigator has provided informed consent detailing the risks of performing HIV testing, which addresses confidentiality issues; and
   3. The Investigator is trained and capable of informing participants of positive findings and that he or she is qualified to impart sensitive information, inform the participant of privacy and confidentiality issues, and is prepared to impart participants with a reference for additional counseling and follow-up, when needed.

C. When the Investigator requests either an individual or a protocol design based exception for informing participants of their HIV antibody results, the IRB will consider the exception to informing participants of positive results as follows:
   1. Individual Exception. Where there is 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; or
   2. Protocol Designed Exception. Circumstances may exist in which extremely valuable knowledge might be gained from research involving participants who would be expected to refuse to learn their antibody results. An exception included in the research design may be proposed to the IRB Committee for possible approval under these circumstances; however, the Investigator must demonstrate to the satisfaction of the IRB that:
      (a) Research participants will be informed of their risk of infections;
      (b) Research participants will receive risk reduction counseling whether or not they receive their test results;
      (c) There is good reason to believe that a requirement for test notification counseling whether or not they receive their tests results; and
      (d) The risk/benefit ratio to individuals, their partners, and society will be periodically reevaluated by the IRB Committee so that the study might be revised or terminated if it is no longer justifiable to allow participants to continue without receiving their HIV test results.

III. Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA will review all new study submissions to verify that an adequate description of plans for HIV testing and informing participants of test results has been detailed in the IRB application and informed consent documents.
B. The RCA may request additional information in pre-review, or at the request of IRB Reviewers for clarification of any issues surrounding the testing of HIV in research participants as it pertains to the proposed research.