

## GUIDELINE FOR RESEARCH INVOLVING HIV TESTING

Research which includes human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) screening as a condition for inclusion in a research study, or as part of the research procedures, poses increased psychological, social, and economic risk to subjects. As such, this guideline provides information regarding additional safeguards when subjects are asked to have HIV testing during a research study.

According to the New York State (NYS) Public Health Law section 2786 and Article 21 Part 63 governing HIV testing and the release of confidential HIV/AIDS information, an HIV-related test is defined as any laboratory test or series of tests for any virus, antibody, antigen or etiologic agent whatsoever thought to cause or to indicate the presence of AIDS. NYS law defines confidential HIV/AIDS related information as: any information indicating that “an individual has been the subject of an HIV test, or has HIV infection, HIV-related illness or AIDS, or information which identifies or reasonably could identify an individual as having one or more of such conditions, including information pertaining to such individual’s contacts.” Any unauthorized release of confidential AIDS/HIV information is a misdemeanor.

**Counseling:** Any person tested for HIV infection should receive the results of their tests and counseling in a timely fashion from an individual qualified to provide the counseling, including partner notification services. It does not necessarily need to be an individual on the research team.

**Confidentiality:** Perhaps the most sensitive aspect of research that includes HIV testing from the perspective of the rights and welfare of the subject is the matter of confidentiality.

Improper disclosure could have serious consequences for research subjects, by threatening family relationships, job security, employability, or ability to obtain credit or insurance. In light of these risks, special precautions should be taken to preserve confidentiality, and potential subjects should be advised with care of the limits of that confidentiality, so they can make thoughtful, informed decisions as to whether to participate.

Each study must be designed with administrative, management and technical safeguards to control use and disclosure of information and to protect against unauthorized disclosure. Where identifiers are not required by the study design, they are not to be recorded. If identifiers are recorded, they should be maintained separate from the study data, if possible, and stored securely, with linkage restored only when necessary to conduct the research. No lists (e.g. screening logs) that identify those who elected not to participate should be retained; de-identified lists are acceptable. Subjects must be given a fair, clear explanation of how information about them will be handled.

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 into account the possibility of review of records by the funding agency, OHRP, and by FDA officials, if the research is subject to FDA regulations.

The RSRB will consider what information will be recorded in the subjects’ electronic health record (EHR), and may wish to minimize the recording of data from AIDS-related studies in the EHR. NYS requires determinations or diagnoses of Human Immunodeficiency Virus (HIV) infection, HIV-related

illness and Acquired Immune Deficiency Syndrome (AIDS) to be reported [[Section 63.4 Filing of Reports](#)] and may require follow-up. Participation in research does not exempt compliance with those laws, but potential study subjects must be fully informed of laws requiring disclosure of information before they volunteer for the study.

### **Informing Subjects about HIV Serostatus:**

When HIV testing is conducted as part of research procedures, including screening tests for purposes of determining eligibility, individuals must be informed of their test results and provided with the opportunity to receive appropriate counseling. Individuals may not be given the option “not to know” the result.

An HIV-related test **may not** be performed without the written, informed consent of the subject and without providing the subject pre-test counseling as mandated by NYS law. A separate HIV testing consent form is not required, as long as all of the required elements are contained in the research consent form. During the informed consent process and pre-test counseling, the following information must be explained to the subject and included in the consent form:

- Research procedures will include HIV testing;
- Purpose of the test, the meaning of its results, and the benefits of early diagnosis and medical intervention;
- An explanation of the procedures to be followed, including that the test is voluntary, that consent may be withdrawn at any time, and a statement advising the subject that anonymous testing is available outside of the research;
- The result of the test will be given to the subject;
- 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;
- The risks of HIV testing, including but not limited to physical, psychological, and social risks (e.g., discrimination, impact upon insurance, freedom to travel to other countries); and,
- An explanation of the confidentiality protections under NYS Law, including the circumstances under which and to whom disclosure of such information may be required or authorized, both within and external to the study team.

When the test result is communicated to the subject, the person ordering the test must provide the subject with mandated post-test counseling. Post-test counseling shall consist of information regarding:

- Coping with the emotional consequences of learning the result;
- The discrimination problems that disclosure of the result could cause;
- Changes in behavior to prevent transmission or contraction of HIV infection;
- Available medical treatments; and,
- The subject’s need to notify his or her contacts.

With respect to the release or disclosure of confidential HIV-related information, with limited exceptions, NYS law prohibits the release of confidential HIV/AIDS information without the written consent of the subject. Moreover, the law requires that a special HIV/AIDS release form be utilized. An ordinary release of medical information/records form is not sufficient for the release of confidential HIV/AIDS information.

Any authorized disclosure of HIV/AIDS information must be accompanied or followed within 10 days by the following written statements prohibiting further re-disclosure:

*This information has been disclosed to you from confidential records which are protected by State law. State law prohibits you from making any further disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law. Any unauthorized further*

*disclosure in violation of State law may result in a fine or jail sentence or both. A general authorization for the release of medical or other information is not sufficient authorization for further disclosure.*

NYS law also sets forth a required process for contact notification where the physician determines that disclosure is medically appropriate and there is a significant risk of infection to the contact.

**Exceptions to Informing Subjects about HIV Serostatus:**

- **Pertaining to an Individual:** Where there are compelling and immediate reasons that justifies not informing a particular individual that he or she is seropositive (e.g., indication that an individual would attempt suicide), the particular individual need not be informed of HIV test results. When this exception is made to the policy of informing individuals, the details of the exception shall be documented by the investigator, who then must promptly report the exception to the RSRB.
- **Pertaining to Foreign Sites:** Research 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 (see [Guideline for Conducting International Research](#)). The RSRB will consider if any modification to this guidance is significantly justified by the risk/benefit evaluation of the research. The RSRB may seek expert advice (e.g., local public health experts) in evaluation of these projects.