

HIV Guidelines

Investigators conducting research in which HIV testing is a planned or anticipated component, must comply with the following requirements as mandated by New York State Public Health Law. **Note that unlike consent for testing for clinical purposes, the research consent is only valid for the research study and may NOT be used as consent for re-testing the patient in the future. A new consent will need to be obtained at that time.**

Before testing:

- NY State permits consent for HIV testing to be included within the research informed consent document. Oral consent is allowed for rapid HIV tests. Requests for oral consent must be approved on a case-by-case basis by the IRB.
- The research consent document must be signed before the HIV test is performed. (When oral consent has been approved by the IRB this must be documented.)
- The consent document must include the following HIV-related language:

Will there be testing for HIV? Yes, HIV testing will be done during this research study. The following is important information about HIV, HIV testing and your test results:

- HIV causes AIDS and can be spread through sexual activity, sharing needles, by pregnant women to their fetuses, and through breastfeeding infants.
- There is treatment for HIV that can help you stay healthy.
- People with HIV or AIDS should adopt practices to protect people in their lives from becoming infected with HIV.
- HIV testing is voluntary and can be done anonymously at a public testing center. However, testing is required if you would like to be in this research study.
- The law protects the confidentiality of HIV related test results.
- The law prohibits discrimination based on your HIV status and services are available to address any discrimination.
- If as a result of participation in this study you are INITIALLY diagnosed with HIV, the results must be reported to the New York State Department of Health for contact tracing purposes.
- If as a result of participation in this study you are diagnosed with HIV, you will be given HIV counseling or a referral for HIV counseling.

After testing:

- If the subject tests **positive** (either a confirmed or preliminary positive), the research team must provide the result to the subject along with counseling or referrals for counseling. This includes making appointments for newly diagnosed, confirmed positive persons to receive follow-up HIV medical care. The counseling or referral for counseling must be documented in the research record.
 - Under New York State law, attending physicians fellows and nurse practitioners are considered qualified to do post-test counseling. Others can become certified to do HIV counseling by attending a three- day course taught by the AIDS

- Institute. Registered nurses, social workers and others who have taken this course are, therefore, certified. Residents will only be considered qualified if they have been specifically credentialed by their department for this purpose.
- If the subject tests **negative**, the research team must provide information about risky behavior, either orally or by written materials, either at the time of testing or thereafter. This must be documented in the research record.