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HIV testing and results in a research setting

New York State has updated its HIV laws, directly impacting research at the Mount Sinai Health System.

Retrospective records reviews of patient data can now include HIV information, assuming the IRB has reviewed the research and granted the appropriate waivers (HIPAA authorization and the research informed consent). Previous to this change the IRB could not grant a waiver of informed consent for HIV information, which significantly complicated such research. The IRB will consider the researcher's need for the data and the protections in place to assure confidentiality before granting such a waiver. The actual wording of the law NY Public Health Law Article 27-F § 2782(r), which allows for these disclosures without patient consent, provides that information can be released to:

- “qualified researchers for medical research purposes upon the approval of a research protocol by a human research review committee established and approved . . . by an institutional review board established and approved under [federal law], for the purpose of reviewing and monitoring research involving human subjects, provided that in no event shall any qualified researcher disclose information tending to identify the subjects of the research.”

The other significant change is that we will no longer require the use of a **separate HIV consent**. PPHS will follow the newly updated system wide policy.

The need for HIV testing has to be included in the research protocol and will be approved at the time of the PPHS review of the project. Research subjects shall be notified during the consent process and in the consent document itself that they will be tested for HIV as part of the research protocol. By law the consent process has to include certain information. The PPHS has developed suggested language to include in the consent that meets this requirement. The text has been incorporated into the consent template found on the PPHS site as written below:

- To take part in this research project we will have to test your blood for evidence of HIV infection. HIV is the virus that causes AIDS. It can be transmitted through unprotected sex (vaginal, anal, or oral sex) with someone who has HIV, and through contact with blood, as in sharing needles (piercing, tattooing, drug equipment including needles used to inject drugs). HIV-infected pregnant women can transmit to their infants during pregnancy or delivery or while breast feeding. There are treatments for HIV/AIDS that can help an individual stay healthy. Individuals with HIV/AIDS can adopt safe practices to protect uninfected people in their lives from becoming infected and to protect themselves or infected people in their lives from being infected with different strains of HIV.

By law, positive test results are reported to the NYS Department of Health for epidemiological (the study of the factors determining or influencing the presence or absence of disease) and Partner Notification purposes. If you wish to be tested anonymously you will be referred to a public testing center, but you will not be able to be in this study. Please know that New York State law protects the confidentiality of HIV test results and other related information. The law prohibits discrimination based on an individual's HIV status and services are available to help with such consequences.

You are free to refuse this test, but if you refuse you will not be allowed to join or remain in this research project.

Researchers are responsible to return HIV testing results to the research subjects. Negative results can be provided in person, verbally or in writing, or by phone. Positive results must be provided in person. Regardless of the result, the outcome must be provided as soon as possible.

When providing negative results counseling has to include the meaning of the test result and the possibility of HIV recent exposure and the possible need to re-test. Where appropriate, reinforce risk reduction strategies in relation to high risk sexual or needle sharing behavior.

Positive result counseling and follow up is beyond the scope of this document and should be consistent with all relevant Mount Sinai policies. The institutional HIV Testing and Counseling policy can be found on the intranet: [GPP-415](#)