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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 study, your blood will be tested for evidence of HIV, the virus that causes AIDS. People can get HIV through unprotected sexual contact with someone who has HIV, and through contact with blood (as in sharing needles including for piercing, tattooing, and injecting drugs). People who are pregnant with HIV infections can transmit HIV to their infants during pregnancy, delivery or while breastfeeding. There are treatments for HIV/AIDS that can help people stay healthy. People with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from getting HIV or getting infected with a different strain of HIV.

By law, positive test results for HIV/AIDS (as well as other communicable diseases such as hepatitis B, hepatitis C, and syphilis) are reported to the NYS Department of Health so they can study how people get and transmit the disease and notify sexual or needle-sharing partners they may have been exposed. If you wish to be tested anonymously for HIV/AIDS, the research team can refer you to a public testing center, but you will not be able to be in this study. New York State law protects the confidentiality of HIV test results and other related information. It is illegal to discriminate against a person based on their HIV status and services are available to help if this happens. You are free to refuse to get an HIV test, but if you refuse you cannot be part of this research study.

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



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policy can be found on the intranet: [GPP-415](#)

REVISION: 12/8/2022 Updated with 2023 revised ICF template language