

HIV Record Review Guidance

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Scope: This guidance is regarding research on medical records that involves HIV infection information. It primarily deals with the situation when an investigator wishes to do such research in the absence of obtaining informed consent from the individuals whose records are being accessed. This guidance does not cover any research that involves interacting/establishing an HIV data repository.

Background: New York State HIV confidentiality laws governing the use and disclosure of clinical HIV information are more restrictive than federal HIPAA and research regulations. If researchers wish to do research under a waiver of informed consent that specifically involves *records of patients with HIV infection*, or if the research is done with any records in which *HIV information, including testing information, is recorded*, there are legal implications under the New York State HIV confidentiality laws.

Guidance:

1) Under New York State law, a clinician who has a right to access HIV data for clinical reasons can also use the data for research purposes without obtaining a new consent from the patient, assuming the research has IRB approval, HIPAA waivers etc. This means that a waiver of informed consent for chart reviews can be granted by the IRB if other necessary criteria are met. But this waiver of informed consent is only applicable to those who have legitimate clinical access to the HIV information. It would, for instance, allow a clinician working in a true group clinical practice with cross coverage responsibilities to access the group's charts, since s/he has true clinical access to the information.

2) Conversely, someone who does not have a right to the HIV data would not be allowed to see the identified data. This would be true for anyone—from those who simply supervise those who treat those with AIDS (like a department chair or head) but do not have a right to the clinical data themselves, as well as research staff who are not treating clinicians.

3) However, clinicians and their day-to-day clinical support staff would be able to abstract data in an anonymized fashion for use by those without clinical access! The catch is that the research data would have to be recorded in a strictly confidential manner (totally anonymized) though not necessarily HIPAA de-identified (e.g. dates of service can be maintained). Researchers cannot maintain HIV data along with a code that links back to the identifiable information, even if the link was kept securely on a another computer, etc. The exception is that a temporary code for short-term use (at most hours) to be held just long enough to pull data from several sources, such as other charts or the EMR would be permissible, but not a code to be maintained for days.

If researchers are interested in pursuing a research project of this type, the IRB's HIV Record Review form will need to be completed, which will deal with key issues of who will have direct access to the records and the method of recording the data.