### [AIDS/ HIV+ Subjects](http://www.virginia.edu/vpr/irb/hsr/vulnerable_subjects.html%22%20%5Cl%20%22hivaids)

Subjects involved in HIV-related research (HIV-infected persons and persons at risk of HIV-infection) are particularly vulnerable because of their disease status and because the disease disproportionately affects certain populations.

Principal Investigators should be aware of the numerous ethical concerns presented by HIV, including considerations of confidentiality, privacy and justice and follow Virginia State regulations.

An overriding concern in HIV research is confidentiality and privacy, since breaches of confidentiality could have severe adverse consequences.

In ensuring that research adequately protects subjects' confidentiality, Principal Investigators should consider the following criteria:

* where identifiers are not required by the study design, they are not to be recorded.
* if identifiers are recorded, they should be separated, to the greatest extent possible, from data and securely stored, with linkage restored only if necessary to conduct the research.
* if subjects will be given a fair and clear explanation of how information about them will be handled, including whether and how the information will be recorded in their medical records.
* whether the protocol will specifically set forth how to respond to attempts to force disclosure of subjects' medical records or requests by third parties who have authorizations for disclosure signed by subjects; and
* whether the protocol will clearly state what information will be recorded, who is entitled to see records with identifiers, and whether any state laws require the reporting of HIV infection or the disclosure of other information.

**Sharing of HIV Test Results**

In research protocols that involve HIV testing, investigators should consider the circumstances under which subjects should or must be told of their HIV sero status. In general, IRB policy requires that individuals whose test results are associated with personal identifiers be informed of their HIV test results and provided the opportunity to receive counseling, unless the situation is a special circumstance calling for an exception ( e.g. , compelling evidence that a given individual would attempt suicide if informed that he/she is seropositive). When individuals will be informed of their HIV antibody test results, Principal Investigators should ensure that the protocol provides for appropriate pre-test and post-test counseling.

OHRP:  IRB Guidebook, Chapter 5, Section F [[PDF](http://www.research.uky.edu/ori/ORIForms/T15-OHRP-HIV.pdf)] [T15.0000]

Protection of Human Subjects in Research Involving HIV Testing [[PDF](http://www.research.uky.edu/ori/ORIForms/65-HIV-Research.pdf)] [D65.0000]