HIV Testing for Research Purposes

Modified: October 2019

Background:

HIV Florida Statute §381.004.

Florida law establishes the parameters for consents and disclosures of results relating to HIV testing in Florida and will apply to all human research where an HIV test will be performed during either the eligibility screening or the research study itself.

1. **Q: Is Informed consent for HIV testing in Florida mandatory and what must it include?**

Yes. The consent form must include the following:

- Prior explanation of the right to have the information (i.e., identity of the test subject and the results) treated confidentially;
- Disclosure that a positive HIV test result will be reported to the county health department with sufficient information to identify the test subject; and
- Availability and location of sites where anonymous testing is performed (this is available from the county health department).

2. **Q: Do you have to disclose the test results to the study subject?**

Yes. A reasonable effort must be made to notify the test subject of the results. If the test is positive, notification must include:

- Information on the availability of appropriate medical and support services;
- Information on the importance of notifying partners who may have been exposed; and
- Information on preventing the transmission of HIV.

3. **Q: In the event of a positive HIV test result, is confirmatory testing required?**

Yes. Confirmatory testing must be conducted before any positive test result is released to the person. The identity of the test subject and the test results are confidential and may not be disclosed except:

- to the person or the person’s legal representative;
- someone with a legally effective release for HIV test results executed by the person (a general release won’t do);
- agents and employees of the healthcare provider/facility who have a need to know as defined by the department of health;
- health care providers for consulting on treatment;
- the department of health/county health department;
- authorized medical researchers who may not disclose the results further or any identifying information;
• others as specified by statute.

4. **Q: Are there state mandated statements that must be made when informing a study subject about a positive HIV test result?**

Yes. Disclosure of test results to anyone on the exception list must be accompanied by the following statement: “This information has been disclosed to you from records whose confidentiality is protected by state law. State law prohibits you from making any further disclosure of such information without the specific written consent of the person to whom such information pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is not sufficient for this purpose.”

5. **Q: Does the IRB have a suggested template consent language if your research involves the testing for HIV?**

Yes. The HIV Informed Consent template draft language can be found at [http://irb.ufl.edu/wp-content/uploads/HIV-ICF-Template.docx](http://irb.ufl.edu/wp-content/uploads/HIV-ICF-Template.docx). The language is as follows:

To determine if you are eligible for this study a blood sample will be tested for the antibody to HIV. An antibody is a substance that blood cells make to fight infection. A positive HIV test means that your blood sample tested positive for HIV and that repeat testing will be performed to confirm (prove) this finding. If your sample is proved to be positive for HIV, it means that you are a carrier of HIV and that you can pass the virus to others by intimate sexual contact, by sharing needles, and through donating blood and organs. A negative HIV test means that no antibody to HIV was found in your blood sample based on the result of the initial screening test, repeat screening tests, or a confirmatory test.

There can be individuals who have HIV test results that are called “false positive,” i.e., for some reason, the test indicates that HIV antibodies are present in the blood when they are not. There can also be false negative results which can have two possible meanings; the person has been infected with HIV, but that person’s body has not yet made antibodies to the virus, or HIV antibody is present in the person’s blood, but for some reason the test failed to detect it.

A study doctor taking part in this study will meet with you before and after the HIV test. You may be asked to sign a separate consent form to have your blood tested for HIV. Because we will test your blood for HIV (the virus that causes AIDS), Florida Law requires that we tell you that:

- Your identity and HIV test result will be kept confidential to the extent provided by law.
- Any physician who performs an HIV test that has a positive result or lab that processes a blood sample for HIV that has a positive result must report this information to County Health Department with information that will identify you.
- If you want to get tested for HIV outside of this study, test sites that keep your results anonymous are available. You can contact the County Health Department for information on those sites.

When your test results are complete, you will be scheduled for an appointment to discuss your HIV results. If you test positive for HIV, we will do the following:

- Confirm the result by sending a sample of your blood for another HIV test.
- If the second test result is positive, the positive test result and your identity will be reported to the County Health Department. Florida law requires that we report this information.
- Provide information on medical and support services available to you; and
• Discuss information on the importance of notifying previous and current sexual partners that they may have been exposed to HIV and how to prevent HIV transmission.

Risks

Testing positive for human viruses (HIV) can be upsetting. You will be provided with information on medical and support services that may be available to you. If you test positive for HIV and that information were to become public, you could have problems getting insurance or a job.

Confidentiality

Your identity and test results will be kept confidential to the extent permitted by Florida Law. If test results are released in accordance with Florida Law, this disclosure will be accompanied by the following statement: “This information has been disclosed to you from records whose confidentiality is protected by state law. State law prohibits you from making any further disclosure of such information without the specific written consent of the person to whom such information pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is not sufficient for this purpose.”