Model Protocol for HIV Counseling and Testing In Health Care Settings

"Health care setting" means any setting devoted to both the diagnosis and care of persons, such as county health department (CHD) clinics, hospital emergency departments, urgent care clinics, substance abuse treatment clinics, primary care settings, community clinics, mobile medical clinics, and correctional health care facilities.

The protocol is divided into three sections. Section 1 of the protocol provides guidelines for HIV testing in CHD clinics. Section 2 provides guidelines for HIV testing in other health care settings, including hospital emergency departments, urgent care clinics, substance abuse treatment clinics, primary care settings, community clinics, and correctional health care facilities. Section 3 describes the release of preliminary test results and the special provisions for testing pregnant women. This section applies to HIV testing conducted under both Sections 1 and 2.

Section 1. HIV Testing in CHD Clinics

1. Pre-Test Counseling

All CHD clinics must provide the opportunity for HIV pre-test counseling prior to testing for HIV. Pre-test counseling should include the following:

- Purpose of the HIV test, including medical indications
- Possibility of false positive or false negative result
- Possible need for confirmatory testing
- Possible need for retesting
- For positives, availability of medical and support services
- Need to eliminate high-risk behavior

2. Informed Consent

No person shall perform an HIV testing without first obtaining the informed consent of the test subject or his or her legal representative. The limited exceptions for obtaining informed consent can be found in s. 381.004(2)(h), F.S. and in Rule 64D-2.004(2), F.A.C. Written consent is not required if the person conducting the test documents in the medical record that the test was explained and informed consent was obtained. When obtaining informed consent, explain that:

 HIV test results and the fact that a person is tested are confidential and protected by law. Persons with knowledge of an individual's HIV test result have legal obligations to protect this information from unauthorized disclosure. Florida law imposes strict penalties for breaches of confidentiality.

- Positive test results, along with identifying information, will be reported to the county health department's surveillance unit for follow up purposes.
- A list of anonymous test sites, including the locations, phone numbers, and hours of operation is available at the local CHD or at www.floridaaids.org.

3. Post-test Counseling

The person ordering the test or that person's designee shall ensure that all reasonable efforts are made to notify the test subject of his or her test result. All CHD clinic sites must provide the opportunity for face-to-face post-test counseling. Post-test counseling should include the following:

- The meaning of the test results
- The possible need for additional testing
- The need to eliminate risk behavior
- Post-test counseling for positive test results must also include information on the availability of medical and support services; on the importance of notifying partners who may have been exposed, including spouses from the past ten years of their potential exposure; and on preventing HIV transmission.

Section 2. HIV Testing in Other Health Care Settings

- 1. Pre-test counseling is not required.
- 2. Informed Consent: No person shall perform an HIV test without first obtaining the informed consent of the test subject or his or her legal representative. (The limited exceptions are outlined in s. 381.004(2)(h), F.S.) Consent need not be in writing if documentation is included in the medical record indicating that information on the test was provided and informed consent was obtained. (A few limited exceptions are included in Rule 64D-2.004(4), F.A.C.) When obtaining informed consent, provide the following information:
 - Patients have the right to confidential treatment of information identifying the subject of the test and the results of the test. (Special provisions for hospitals are listed in s. 381.004(2)(g), F.S.)
 - Positive test results will be reported to the local CHD. Health department staff may contact persons who test positive to offer follow-up services.
 - Information regarding the availability and location of anonymous test sites is maintained and available through the local CHD or at www.floridaaids.org.
- 3. Notification of Test Results: The person ordering the test or that person's designee shall ensure that all reasonable efforts are made to notify the test subject of his or her test result. In the case of a hospital emergency department, detention facility, or other facility where the test subject has been released before being notified of positive test results, informing the CHD for the department to notify the test subject fulfills this

responsibility. When test subjects are given their test results, Florida law requires that, at a minimum, the following information be provided:

- For positives: Information on preventing transmission of HIV, the availability of medical and support services, the importance of notifying sex and/or needlesharing partners including spouses and former spouses, and the voluntary confidential partner services available through the CHD.
- For negatives: Information on preventing the transmission of HIV and retesting, if appropriate.
- **4. Physician Reporting:** The physician or his designee must report positive HIV test results to the DOH in accordance with s. 384.25, *F.S.*, and Rule 64D-3.016, *F.A.C.*

<u>Section 3. HIV Testing in CHD Clinics and in Other Health Care</u> Settings

Release of Preliminary HIV Test Results

Pursuant to s. 381.004(2)(d), *F.S.*, preliminary test results may be released to health care providers and to the person tested when decisions about medical care or treatment cannot await the results of confirmatory testing. Positive preliminary HIV test results shall not be characterized as a diagnosis of HIV infection. The health care provider who ordered the test must document justification for the use of preliminary test results in the medical record. This does not authorize the release of preliminary test results for the purpose of routine identification of HIV-infected individuals or when HIV testing is incidental to the preliminary diagnosis or care of a patient. Corroborating or confirmatory testing must be conducted as follow up to a positive preliminary test. Results shall be communicated to the patient according to statute regardless of outcome. The results of rapid testing technologies are considered preliminary; however, these results may be released in accordance with the manufacturer's instructions as approved by the U.S. Food and Drug Administration.

<u>Special Provisions for Pregnant Women</u> (This requirement was effective June 10, 2005)

Florida law (s. 384.31, *F.S.* and Rule 64D-2.004, *F.A.C.*) requires a health care provider who attends a pregnant woman for conditions relating to her pregnancy to test for HIV and other STDs at the initial visit and counsel her on the availability of treatment if she tests positive. If a pregnant woman tests HIV negative, test again at 28-32 weeks gestation and at labor and delivery under the circumstances outlined in Rule 64D-3.042, *F.A.C.*

The physician shall inform the woman she will be tested for HIV and other STDs and of her right to refuse. If the pregnant woman objects to testing, a reasonable attempt must be made to obtain a written statement of objection, signed by the patient, which shall be placed in her medical record.

Emergency departments of hospitals licensed under Chapter 395, *F.S.* may satisfy the testing requirements under this rule by referring any woman identified as not receiving prenatal care after the 12th week of gestation, to the CHD. The referral shall be in writing and a copy shall be submitted to the CHD having jurisdiction over the area in which the emergency department is located. Emergency rooms and the local CHD should develop protocols.

Repeat Testing

Health care providers should test all persons likely to be at high risk for HIV at least annually. The following criteria should be used to help the test subject determine his or her level of risk: sexual behavior, substance use/abuse, needle sharing, occupational exposure, blood/blood products/transplants, partners at risk for HIV, history of sexually transmitted disease(s), child of woman with HIV/AIDS, history of sexual assault/domestic violence, and sex for drugs/money. Testing should also be based on local HIV prevalence. Men who have sex with men (MSM) should be tested at least twice annually.