

**MEMORANDUM OF AGREEMENT  
FOR  
CLINICAL-HIV TESTING COUNSELING AND TREATMENT SERVICES**

This Memorandum of Agreement (“Agreement”) is entered into between the **State of Florida, Department of Health, Orange County Health Department**, State of Florida agency (hereinafter interchangeably referred to as the DOH-Orange or Department) and **Orange County Florida on behalf of its Health Services Department** (hereinafter interchangeably referred to as OCHS or Provider).

THE PARTIES AGREE:

**I. DOH–Orange Agrees to:**

- A. Provide, as available, HIV testing supplies, DH 1628 Laboratory Request Forms (*Revision 06/19*), access to the Counseling, Testing, and Linkage System (CTLS), and laboratory services for HIV confirmatory testing at no charge to the provider.
- B. Provide training such as the *HIV/AIDS 500* prerequisite course, the *HIV/AIDS 501 Prevention Counseling, Testing, and Linkage Services* course, and the annual *HIV/AIDS 501 Update* course at no charge to the provider.
- C. Provide, as requested, copies of The Florida Department of Health, HIV/AIDS Rapid HIV Testing Site Guidelines, all applicable Florida statutes (Section 381.004 for HIV Test Site Rules & regulations and Florida Administrative Codes: Rule 64D-2.006 for initial registration process), Florida Department of Health (DOH) policies, protocols, Internal Operations Procedures (including but not limited to: IOP 360-09-17, IOP 360-07-20, IOP 360-07-23, and IOP 360-09-23), and Technical Assistance Guidelines (including but not limited to: TAG 345-17-15) regarding HIV Counseling, Testing, Referral and/or Linkage Services.
- D. Provide Targeted Outreach for Pregnant Women Act (TOPWA) and Statewide Prenatal Care Coordinator contact information.
- E. Provide technical assistance or additional training regarding HIV testing and Counseling best practices as needed to the provider or refer provider to the HIV/AIDS and Hepatitis Section for needed technical assistance.
- F. Provide additional technical assistance for linkage to care services and Rapid Start Treatment Program initiation support.
- G. Conduct quality improvement/technical assistance reviews as needed or scheduled.

**II. OCHS Agrees to:**

- A. Provide confidential HIV Testing, Counseling, Referral and/or Linkage Services, at no charge to the client, as a registered HIV testing program; clients will not be turned away for financial reasons.

- B. Follow all applicable Florida statutes and rules regarding confidential HIV Counseling, Testing, Referral and/or Linkage. State statutes may be provided by request.
- C. Provide, at a minimum, one hundred and twenty (120) rapid HIV tests annually and maintain a 1% positivity rate for newly identified HIV diagnosis to continue an active status as an HIV testing site. Rapid HIV testing should be provided to the population of focus and in zip codes with a high co-morbidity for HIV, as indicated on the community outreach plan provided to the Department, prior to execution. Testing numbers will be reported to the contract manager on the Quarterly HIV Testing Site Summary (Attachment III) every quarter starting from date of execution.
- D. Provide a screening for PrEP and nPEP eligibility to all clients who receive a rapid test for HIV. Ensure that clients who are found to be eligible for PrEP and/or nPEP services, are initiated into PrEP and/or nPEP medical care, regardless of the client's ability to pay. Assure that all clinicians (physicians, registered nurse practitioner and physician assistants) follow PrEP initiation and follow up guidelines recommended by the Department and CDC. The guidelines can be found at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf>. Maintain a 25% referral rate for new clients being entered in PrEP and nPEP services.
- (1) Clients who are HIV negative and have a general interest in starting shall be determined to be eligible for PrEP services and will be referred. In addition, clients who receive a positive diagnosis for a STI other than HIV, currently have a sexual partner who is living with HIV, currently completing and/or finishing a PEP regimen for a possible HIV exposure or has had more than one rapid HIV test in the past twelve months must be referred into PrEP services. Provide documentation indicating the reason(s) if clients who match this specified criterion are not referred into PrEP services on the Quarterly HIV Testing Site Summary (Attachment III).
  - (2) Clients who have or could have likely been exposed to HIV within seventy-two (72) hours at the initial interaction must be linked to and initiate nPEP services within seventy-two (72) hours of that likely exposure. Provide documentation indicating the reason(s) for clients who are not linked to nPEP services during the specified timeframe on the Quarterly HIV Testing Site Summary (Attachment III).

Document the number of PrEP and nPEP screenings provided, the number of PrEP and nPEP referrals made, and the number of PrEP and nPEP services initiated the Quarterly HIV Testing Site Summary (Attachment III) every quarter starting from date of execution.

- E. Provide medical treatment for clients who receive a positive diagnosis for HIV, regardless of the client's ability to pay, and verify that full linkage to medical care has been completed. Document the number of clients linked to HIV medical care on the Quarterly HIV Testing Site Summary (Attachment III) every quarter starting from date of execution.
- F. Provide screening for Sexually Transmitted Infections (STI), regardless of the client's ability to pay, as needed. Ensure that clients who receive a positive diagnosis for a STI receive medical treatment, regardless of the client's ability to pay. STI treatment should follow STI diagnosis, treatment, and quality assurance recommended by the Department and CDC. Guidelines may be found at <https://www.cdc.gov/std/treatment-guidelines/STI-Guidelines-2021.pdf>. Document the

number of clients screened, and the number of clients treated for STIs on the Quarterly HIV Testing Site Summary (Attachment III) every quarter starting from date of execution.

- G. Link pregnant women with identified risk factors for HIV or have a HIV positive diagnosis to their local TOPWA program. Ensure each case of pregnant woman with an HIV diagnosis is reported within seventy-two hours of diagnosis to the local TOPWA program, local perinatal HIV prevention program, DOH-Orange HIV/AIDS Surveillance Program, and the Department's Statewide Perinatal Coordinator.
- H. Screen all clients who receive a rapid HIV test and identify referral needs for essential support services. Document the number of screenings, referrals, and referral outcomes and referral types on the Quarterly HIV Testing Site Summary (Attachment III) every quarter starting from date of execution.
- I. Participate in the Area 7 Rapid Start Treatment Network. Rapid start shall be defined as the initiation of Antiretroviral Treatment (ART) no later than seven days of the initial HIV diagnosis or if previously diagnosed with HIV, the initial interaction with the client. Provider will also be advertised as a member of the Area 7 Rapid Start Treatment Network and be available to provide medical treatment for HIV, at no charge to client, within the time frame to clients. Provider will provide a written Standard Operating Procedure outlining how Rapid Start will be implemented in their location to the Department for approval before execution. Document the number of clients linked to HIV medical care through Rapid Start Treatment Program Network on the Quarterly HIV Testing Site Summary (Attachment III) every quarter starting from date of execution.
- J. Complete the DH 1628 (Revision 06/2019) with every state provided HIV test electronically using the Counseling, Testing, and Linkage System (CTLS) or by utilizing a physical form. Physical yellow copies of the DH1628 must be mailed and received by the 10<sup>th</sup> of every month to:

HIV/AIDS Section  
4025 Esplanade Way  
Tallahassee, FL 32399  
Attention: Rapid Testing Data/Room 304

Green copies must be kept in a double locked containment for up to seven years.

- K. Follow all policies, procedures, and state laws including: The Florida Department of Health, HIV/AIDS Rapid HIV Testing Site Guidelines, all applicable Florida statutes (Section 381.004 for HIV Test Site Rules & regulations and Florida Administrative Codes: Rule 64D-2.006 for initial registration process), Florida Department of Health (DOH) policies, protocols, Internal Operations Procedures (including but not limited to: IOP 360-09-17, IOP 360-07-20, IOP 360-07-23, and IOP 360-09-23 ), and Technical Assistance Guidelines (including but not limited to: TAG 345-17-15) regarding HIV Counseling, Testing, Referral and/or Linkage Services.
- L. Report positive test results with identifying information (including client name, address, telephone number, date of birth, race, sex, country of birth, ethnicity), pregnancy status of female clients, social security number, risk information, test date, and type of test performed for all clients testing confidentially to the DOH-Orange, HIV/AIDS Surveillance Program. Adult cases, (clients  $\geq$  13

years of age at time of diagnosis) shall be reported on the Adult HIV Confidential Case Report form, CDC 50.42A (Revision 01/2023)(Attachment IV). All confidential reports must be placed in a double sealed envelope (with the inner envelope marked CONFIDENTIAL) prior to hand delivery or by mail. The reports are due to DOH-Orange within seventy-two (72) hours of diagnosis to:

State of Florida, Department of Health, Orange County Health Department  
Attn: Area 7 Surveillance  
6101 Lake Ellenor Drive  
Orlando, FL 32809  
(407) 723-5065

- M.** Report positive STI test results with identifying information (including client name, address, telephone number, date of birth, race, sex, country of birth, ethnicity), pregnancy status of female clients, social security number, risk information, test date, and type of test performed for all clients testing confidentially to the DOH-Orange STD Surveillance Program. Adult cases, (clients  $\geq$  13 years of age at time of diagnosis) shall be reported on the STD Reporting Form (Attachment V) and/or the STD Reporting Form Syphilis (Attachment VI). All confidential reports must be placed in a double sealed envelope (with the inner envelope marked CONFIDENTIAL) prior to hand delivery or by mail. The reports are due to DOH-Orange within seventy-two (72) hours of diagnosis to:

Florida Department of Health in Orange County  
Attn: STD Program  
832 W Central Blvd. Orlando, FL 32805  
Fax: 407-836-7101

Reporting forms are updated regularly and can be found at the website:

<https://orange.floridahealth.gov/programs-and-services/infectious-disease-services/std/reporting-guidelines.html>

- N.** Participate in quality improvement/technical assistance reviews by the DOH-Orange, the assigned Early Intervention Consultant, the assigned contract manager, and/or HIV/AIDS and Hepatitis Section.
- O.** Participate and ensure representation at DOH-Orange Area 7 Program Office Quarterly Provider meetings and provider engagements.
- P.** Information Confidentiality and Security: The Provider shall maintain confidentiality of all data, files, and records including client records related to the services provided pursuant to this Agreement in accordance with applicable state and federal laws, rules, and regulations and any department program-specific (DOHP 50-10-16) supplemental protocols, which are incorporated herein by reference and the receipt of which is acknowledged by the provider upon execution of this agreement. The Provider is required to have written policies and procedures ensuring the protection and confidentiality of Protected Health Information. The department reserves the right to review the provider's policies and procedures.

- Q. Follow the DOH *Model Protocol for HIV Counseling and Testing in Health Care Settings (Attachment I)*, and the DOH *Model Protocol for HIV Counseling and Testing in Non-Health Care Settings (Attachment II)*.
- R. Submit the Quarterly HIV Testing Site Summary (Attachment III) to the contract manager every quarter starting from date of execution. Quarterly HIV Testing Site Summary is due within 20 days following the end of each quarter. See table below:

| Execution Date | First Summary Due Date | Second Summary Due Date | Third Summary Due Date | Fourth/Year-End Summary Due Date |
|----------------|------------------------|-------------------------|------------------------|----------------------------------|
| January 1      | April 20               | July 20                 | October 20             | January 20                       |
| April 1        | July 20                | October 20              | January 20             | April 20                         |
| July 1         | October 20             | January 20              | April 20               | July 20                          |
| October 1      | January 20             | April 20                | July 20                | October 20                       |

### III. The Provider and The Department Mutually Agree:

#### A. Effective and Ending Dates

- (1) This Agreement shall begin on **July 1, 2024**, or on the date on which the Agreement has been signed by both parties, whichever is later. The agreement shall end on **June 30, 2026**.

#### B. Renewal

This agreement may be renewed on a yearly basis for no more than three years beyond the initial contract or for the original term of the contract, whichever is longer and will be subject to the same terms and conditions set forth in the initial agreement. Renewals must be requested in writing no later than sixty (60) days prior to the agreement end date, made by mutual agreement, and will be contingent upon satisfactory completion of all tasks as specified in Section II.A through II.R. Satisfactory completion of all tasks will be determined by the Department and the received Quarterly HIV Testing Site Summaries (Attachment III). See table below:

| Execution Date | End Date (2 Years) | Deadline to Request a Renewal |
|----------------|--------------------|-------------------------------|
| January 1      | December 31        | November 1                    |
| April 1        | March 31           | February 1                    |
| July 1         | June 30            | May 1                         |
| October 1      | September 30       | August 1                      |

#### C. Non-Compliance

- (1) Initial failure to provide rapid HIV testing quarterly in accordance with Section II.C or failure to perform the tasks as specified in accordance with Section 11.A through Section II.R will result in a notification of non-compliance to be issued. Upon receipt of notification of non-compliance, a Corrective Action Plan (CAP) will be required to be submitted to the Department for review and approval within five (5) days of the notice of non-compliance. The Department will review the progress of the CAP the next quarter from the date of initial notice of non-compliance to determine if a breach of contract has occurred.
- (2) Failure to perform the outlined requirements may constitute a material breach of this agreement and subject to a Termination of Breach as specified in Section III.D.(2) in accordance with Section III.B.(1).
- (3) Such termination will be reported to the Florida Bureau of Communicable Diseases and to HRSA 340B Program.

#### D. Termination

##### (1) Termination at Will

This Agreement may be terminated by either party without cause upon no less than thirty (30) calendar days' notice in writing to the other party unless a lesser time is mutually agreed upon in writing by both parties. Said notice shall be delivered by certified mail, return receipt requested, or in person with proof of delivery.

##### (2) Termination for Breach

This Agreement may be terminated for either party's non-performance upon no less than twenty-four (24) hours' notice in writing by the non-breaching party. Waiver of breach of any provisions of this Agreement shall not be deemed to be a waiver of any other breach and shall not be construed to be a modification of the terms of this Agreement. In the event of default, in addition to the Department's right to terminate the contract, the Department may pursue any of its remedies at law or in equity, including but not limited to, any losses or expenditures of the Department in obtaining replacement services or commodities, investigating, monitoring or auditing, including legal fees, professional fees, consulting fees and witness fees. These remedies shall include offsetting any sums due to the Provider under the Contract, and any other remedies at law or in equity. Without waiving any of the provisions or protections under this Agreement or pursuant to Florida law, under no circumstances shall the County be liable to the Agency under any contract, negligence, strict liability, or other legal or equitable theory for any amounts in excess of those limits per claim and per occurrence set forth for tort liability in Section 768.28 of the Florida Statutes, which limits are hereby made applicable to all manner of claims against the County related to this Agreement and are not confined to tort liability.

#### E. Indemnification

Both parties are State and County government agencies, and each party will be liable for any damages resulting from the negligence of its employees or agents acting within the scope of their

employment or agency, in accordance with Section 768.28, Florida Statutes. Nothing contained herein shall constitute a waiver of sovereign immunity or the provisions of Section 768.28, Florida Statutes. The foregoing shall not constitute an agreement by either party to assume any liability of any kind for the acts, omissions, and/or negligence of the other party, its officers, officials, employees, agents, or contractors.

F. Relationship

In the performance of this agreement, it is agreed that the Provider is an independent contractor and that the Provider is solely liable for the performance of all tasks contemplated by this Agreement, which are not the responsibility of the Department. The Provider, its' employees, officers, agents, and subcontractors, in performance of this agreement, shall act in the capacity of an independent contractor. Nothing herein shall create or be construed to create an employer-employee, agency, joint venture, or partnership relationship between the parties.

G. Renegotiation or Modification

Provider will notify the Contract Manager in writing a minimum of five (5) days prior to making any changes in Provider's location, contact information, or primary contact staffing.

Modifications of provisions of this Agreement shall only be valid when they have been reduced to writing and duly signed by both parties.

H. The provision of services in accordance with the terms and conditions of this MOA are non-monetary. No clause or element of this agreement will be imputed to imply any form of financial obligation or liability, nor to confer on either Party the capacity to represent or act as an agent of the other. The DOH-Orange's performance and obligations for the program under this agreement are contingent upon an annual appropriation by the Legislature and are subject to the availability of funds.

I. Insurance

Both Parties are State and County government agencies, or subdivision, are self-insured through the State of Florida Risk Management Trust Fund, established pursuant to Section 284.30, Florida Statutes, and administered by the State of Florida, Department of Financial Services. DOH and the County agree to be fully responsible for its own acts of negligence by its officers, employees or agents, when acting within the scope of their employment or agency and agrees to be liable for any damages resulting from said negligence, as provided in Section 768.28, Florida Statutes. Nothing herein is intended to serve as a waiver of sovereign immunity by any party to which sovereign immunity applies. Nothing herein shall be construed as consent by a County government or State Agency or subdivision of the State of Florida to be sued by third parties in any matter arising out of any contract or agreement.

J. Services provided by the HIV Prevention Grant, PS18-1802 shall be funded exclusively by the HIV Prevention Grant, PS18-1802. The provider acknowledges and accepts responsibility that they will in good faith perform the services to be provided to any client at no charge whatsoever. Provider agrees to fully comply and follow any and all federal and state laws, administrative codes, rules,

Florida Statutes, procedures, policies, guidelines, and protocols relative to the services and HIV Prevention Grant.

**K. Health Insurance Portability Act of 1996 (HIPAA)**

- (1) Where applicable, the parties will comply with HIPAA as well as all regulations promulgated thereunder (45CFR Parts 160,162, and 164).
- (2) Where applicable, the parties incorporate by reference the operative obligations of the respective parties specified in 45 C.F.R. §§ 164.502(e) and 164.504(e, f, and g, and subdivisions thereunder as applicable) of HIPAA privacy regulations, only insofar as either individual party is a business associate as defined in 45 C.F.R. § 160.103, for purposes of this Agreement. This provision for HIPAA business associate obligations shall remain in effect as long as the business associate has possession of protected health information received from the other party. This HIPAA business associate provision survives termination of this Agreement.

**L. Official Representatives**

- (1) For the Department:

|                         |   |
|-------------------------|---|
| <u>Name:</u>            | Chris Haubenestel   |
| <u>Title:</u>           | Contract Manager  |
| <u>Organization:</u>    | State of Florida, Department of Health, Orange County Health Department |
| <u>Mailing Address:</u> | 6101 Lake Ellenor Drive, Orlando, FL 32809                              |
| <u>Telephone/Fax:</u>   | (407) 723-5068  |
| <u>E-mail:</u>          | William.Haubenestel@flhealth.gov  |

- (2) For the Provider:

|                         |   |
|-------------------------|---|
| <u>Name:</u>            | John Goodrich                           |
| <u>Title:</u>           | Deputy Director                         |
| <u>Organization:</u>    | Orange County Board of Commissioners    |
| <u>Mailing Address:</u> | 2002A E. Michigan St. Orlando, FL 32806 |
| <u>Service Address:</u> | 2002A E. Michigan St. Orlando, FL 32806 |
| <u>Telephone/Fax:</u>   | 407-836-7689                            |
| <u>E-mail:</u>          | john.goodrich@ocfl.net                  |

**M. Venue.** This Memorandum of Agreement is executed and entered into in the State of Florida, and shall be construed, performed, and enforced in all respects in accordance with the laws, rules, and regulations of the State of Florida.

**N. Waiver of Breach.** The failure on the part of either party to enforce any material provision of this Agreement on any single occasion shall not constitute a waiver of the right to enforce any and all material provisions of this Agreement.



- O. Notices. Except as otherwise provided herein, any notice, acceptance, request, or approval from either party to the other party shall be in writing and sent by certified mail, return receipt requested, and shall be deemed to have been received when either deposited in a United States Postal Service mailbox, or personally delivered with signed proof of delivery.
- P. Cooperation with the Inspector General: The parties acknowledge and understand that they have a duty to and will cooperate with the Inspector General in any investigation, audit, inspection, review, or hearing, pursuant to Section 20.055 (5), Florida Statutes.
- Q. All Terms and Conditions Included

This Agreement and its attachments as referenced, Attachment I, Attachment II, Attachment III, and Attachment IV, Attachment V, Attachment VI, and Attachment VII contain all the terms and conditions agreed upon by the parties. There are no provisions, terms, conditions, or obligations other than those contained herein, and the Agreement shall supersede all previous communications, representations, or agreements, either verbal or written between the parties. If any term or provision of the Agreement is found to be illegal or unenforceable, the remainder of the Agreement shall remain in full force and effect and such term or provision shall be stricken.

**IN WITNESS THEREOF**, the parties hereto have caused this 39-page Agreement to be executed by their undersigned officials as duly authorized.

|   |  |
|---|--|
| PROVIDER:<br>Orange County, Florida on behalf of its Health Services Department | DEPARTMENT:<br>State of Florida, Department of Health, Orange County Health Department |
| SIGNED<br>BY:   | SIGNED<br>BY:  |
| NAME:<br>Jerry L. Demings   | NAME:<br>Robert D. Karch, MD, MPH, FAAP  |
| TITLE:<br>Mayor   | TITLE:<br>Director   |
| DATE:   | DATE:  |



## Model Protocol for HIV Counseling and Testing in Health Care Settings

Florida law carefully structures how health care providers and other registered test sites may conduct HIV testing. The Model Protocol provides guidelines for performing HIV testing and counseling in accordance with statutory requirements and established public health policy.

In Florida, HIV testing is established and governed by section 381.004, Florida Statutes, Florida Administrative Code rule 64D-2.004, Internal Operating Procedures, and Model Protocols, all of which are in line with the HIV testing guidelines issued by the Centers for Disease Control and Prevention.

"Health care setting" means any setting devoted to both the diagnosis and care of people. Examples include 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, anonymous and repeat testing, and the special provisions for testing pregnant women. Section 3 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
- Availability, benefits, and confidentiality of partner notification services
- Need to eliminate high-risk behavior

#### 2. Notification

No person shall perform an HIV test without first notifying the person to be tested that the test is planned and that he or she has the right to refuse. Limited exceptions can be found in section 381.004(2)(h), Florida Statutes, and in Florida Administrative Code Rule 64D-2.004(1). Notification may be oral or in writing. Refusal to test shall be documented in the medical record.

### 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 high risk behavior
- Post-test counseling for positive test results must also include information on the availability of medical and support services; the importance of notifying partners including spouses and former spouses, from the past 10 years of their potential exposure; and preventing HIV transmission

## Section 2. HIV Testing in Other Health Care Settings

### 1. Pre-test counseling is not required

### 2. Notification

No person shall perform an HIV test without first notifying the person to be tested that the test is planned and that he or she has the right to refuse. Limited exceptions can be found in section 381.004(2)(h), Florida Statutes, and in Florida Administrative Code Rule 64D-2.004(1). Notification may be oral or in writing. Refusal to test shall be documented in the medical record. Special provisions for hospitals are listed in section 381.004(2)(g), Florida Statutes.

### 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 local county health department to notify the test subject fulfills this responsibility. When test subjects are given their test result, Florida law requires that, at a minimum, the following information is provided:

- **For positives:** Information on preventing transmission of HIV; the availability of medical and support services; the importance of notifying sex and/or needle sharing partners, including spouses and former spouses, from the past 10 years of their potential exposure; 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 their designee must report positive HIV test results to the Department of Health in accordance with section 384.25, Florida Statutes, and Florida Administrative Code rule 64D-3.030.

## Section 3. Additional Testing Guidelines

### 1. Release of Preliminary HIV Test Results

- Pursuant to section 381.004(2)(d), Florida Statutes, 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.

### 2. Anonymous Testing

Information regarding the availability and location of anonymous test sites is maintained and available through the local CHD or at [www.floridaaids.org](http://www.floridaaids.org).

### 3. Special Testing Requirements for Pregnant Women

Section 384.31, Florida Statutes, and Florida Administrative Code rule 64D-2.004 require a health care provider who attends a pregnant woman for conditions relating to her pregnancy to test for HIV and other sexually transmitted diseases (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 Florida Administrative Code rule 64D-3.042.

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 woman, which shall be placed in her medical record.

Emergency departments of hospitals licensed under Chapter 395, Florida Statutes, may satisfy the testing requirements under this rule by referring any woman identified as not receiving prenatal care after the twelfth 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.

### 4. 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
- Sex for drugs/money

Testing should also be based on local HIV prevalence. Men who have sex with men should be tested at least twice annually.



## Model Protocol for HIV Counseling and Testing in Non-Health Care Settings

Florida law carefully structures how health care providers and other registered test sites may conduct HIV testing. The Model Protocol provides guidelines for performing HIV testing and counseling in accordance with statutory requirements and established public health policy.

In Florida, HIV testing is established and governed by section 381.004, Florida Statutes, Florida Administrative Code rule 64D-2.004, Internal Operating Procedures, and Model Protocols, all of which are in line with the HIV testing guidelines issued by the Centers for Disease Control and Prevention.

"Non-health care setting" means any site that conducts HIV testing for the sole purpose of identifying HIV infection. These settings do not provide any type of medical treatment and include community-based organizations, outreach settings, county health department HIV testing programs, and mobile vans.

### 1. Pre-Test Counseling

All county health department HIV testing programs, community-based organizations, outreach settings, and mobile vans must provide 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
- Availability, benefits, and confidentiality of partner notification services
- Need to eliminate high-risk behavior

### 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. Informed consent to perform a test for HIV need not be in writing if there is documentation in the medical record that the test has been explained and consent has been obtained. Exceptions can be found in Florida Administrative Code rule 64D-2.004(3)(a)(b)(c). The limited exceptions to obtaining informed consent can be found in section 381.004(2)(h), Florida Statutes, and in Florida Administrative Code rule 64D-2.004(1). 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 local county health department for surveillance and follow-up purposes.
- A list of anonymous test sites, including the locations, phone numbers, and hours of operation, is available at the local county health department or at [www.floridaaids.org](http://www.floridaaids.org).

### **3. Post-test Counseling**

All county health department HIV testing programs, community-based organizations, outreach settings, and mobile vans must provide face-to-face 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. Post-test counseling should include the following:

- The meaning of the test result
- The possible need for additional testing
- The need to eliminate high risk behavior
- Post-test counseling for negative test results for those at high risk should include the availability of Pre-Exposure Prophylaxis
- Post-test counseling for positive test results must also include information on the availability of medical and support services; the importance of notifying partners including spouses and former spouses from the past 10 years of their potential exposure; and preventing HIV transmission

### **4. Release of Preliminary HIV Test Results**

Pursuant to section 381.004(2)(d), Florida Statutes, preliminary test results may be released to the person tested and to health care providers 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.

### **5. Repeat Testing**

All persons likely to be at high risk for HIV should be offered testing 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
- Sex for drugs/money

Testing should also be based on local HIV prevalence. Men who have sex with men should be tested at least twice annually.



| Quarterly HIV Testing Site Summary-Clinical  |                             |                         |  |        |
|--|-----------------------------|-------------------------|--|--------|
| <i>Agency Name</i>   |                             | <i>Report Quarter</i>   |  |        |
| <i>Staff Completing Report</i>   |                             | <i>Date Submitted</i>   |  |        |
| <i>Email Address</i>   |                             | <i>Contract Manager</i> | Chris Haubenestel  |        |
| Section II.R: Submit the Quarterly HIV Testing Site Summary (Attachment III) to the contract manager every quarter starting from date of execution.          |                             |                         |  |        |
| Task to be Completed   | To be completed by Provider |                         | To be completed by Contract Manager                      |        |
|  | Quarterly Activity          |                         | Deliverable Met?   | Notes: |
|  | Required                    | Actual                  |  |        |
| <b>Due-Annually</b><br><br>Provide, at a minimum, one hundred and twenty rapid HIV tests annually to continue an active status as an HIV testing site        | 120                         | 0                       | <input type="checkbox"/> YES <input type="checkbox"/> NO |        |
| <b>Due-Annually</b><br><br>Provide a screening for PrEP and nPEP eligibility to all clients who receive a rapid test for HIV                                 | 120                         | 0                       | <input type="checkbox"/> YES <input type="checkbox"/> NO |        |
| <b>Due Quarterly</b><br><br>Ensure that clients who are found to be eligible for PrEP and/or nPEP services, are initiated into PrEP and/or nPEP medical care | As Needed                   | 0                       | <input type="checkbox"/> YES <input type="checkbox"/> NO |        |
| <b>Due Quarterly</b><br><br>Provide medical treatment for clients who receive a positive diagnosis for HIV   | As Needed                   | 0                       | <input type="checkbox"/> YES <input type="checkbox"/> NO |        |
| <b>Due Quarterly</b><br><br>Provide screening for Sexually Transmitted Infections (STI)  | As Needed                   | 0                       | <input type="checkbox"/> YES <input type="checkbox"/> NO |        |
| <b>Due Quarterly</b><br><br>Ensure that clients who receive a positive diagnoses for a STI receive medical treatment   | As Needed                   | 0                       | <input type="checkbox"/> YES <input type="checkbox"/> NO |        |

|   |           |            |  |  |
|---|-----------|------------|--|--|
| <p><b>Due Quarterly</b></p> <p>Participate in the Area 7 Rapid Start Treatment Network. Rapid start shall be defined as the initiation of Antiretroviral Treatment (ART) no later than seven days of the initial HIV diagnosis or if previously diagnosed with HIV, the initial interaction with the client.</p> <p>Document the number of clients linked to HIV medical care through Rapid Start Treatment Program Network</p> | As Needed | 0          | <input type="checkbox"/> YES <input type="checkbox"/> NO |  |
| Date:   |           |            |  |  |
| Contract Manager Name:  |           | Signature: |  |  |

| Testing   |           |  |  |
|---|-----------|--|--|
| Routine HIV Testing   |           | Prioritized HIV Testing                                    |  |
|   |           | # of Test:   |  |
| # of Clients Eligible:  |           | # of Results Given:  |  |
| # of Clients Tested:  |           | # of Positive Results:                                     |  |
| # of Clients Opted Out:   |           |  |  |
| # of Positive Result:   |           |  |  |
| Integrated STI Screening  |           |  |  |
| Type:   | # Tested: | # STD Positive:  | # Co-infected with HIV at Time of Diagnosis: |
| Gonorrhea   |           |  |  |
| Chlamydia   |           |  |  |
| Syphilis  |           |  |  |
| Viral Hep.  |           |  |  |
| TB  |           |  |  |
| Total # of STI tests:   |           |  | 0  |
| # Clients Treated for STIs:   |           |  | 0  |
| Narrative   |           |  |  |
| Please discuss any best practices/challenges you had this month when conducting HIV testing and/or STI screenings. Also include any request for technical assistance. |           |  |  |
|   |           |  |  |
| Essential Support Services  |           |  |  |
| # Screened:   |           | # Referred:  | 0  |
| # Followed up on Referral:  |           | # Linked:  |  |
| # Not needing Referral:   |           | # Opt. out of Referral:                                    |  |
| # of Referrals by Referral Type   |           |  |  |
| Education Continuation/Completion Services  |           | Educational Services for Hormone Replacement Therapy (HRT) |  |
| Employment Services   |           | Substance Abuse Treatment & Services                       |  |
| Health Insurance/Medical  |           | Transportation Services                                    |  |
| Housing   |           | Violence Prevention Services                               |  |
| Mental Health Counseling & Services   |           | TOPWA/Pernatal Corrdinator                                 |  |
| Narrative   |           |  |  |
| Please discuss any best practices/challenges you had this month providing essential support services. Also include any request for technical assistance.              |           |  |  |
|   |           |  |  |

| Category                                    | Number of HIV-Positive Persons cannot exceed Number of Persons Tested |   | The Sum of columns C - E cannot exceed the Number of HIV-Positive Persons |   |   | Test Results Unknown cannot exceed Number of Persons Tested |
|---|---|---|---|---|---|---|
|   | (A)   | (B)   | (C)   | (D)   | (E)   | (F)   |
| Category                                    | Number of Persons Tested <sup>1,2</sup>                               | Number of HIV-Positive Persons <sup>3</sup> | Previously Diagnosed HIV-Positive Persons                                 | Newly Diagnosed HIV-Positive Persons Confirmed in Surveillance <sup>4</sup> | Newly Diagnosed HIV-Positive Persons Identified by Self-Report <sup>5</sup> | Test Results Unknown  |
| <b>Age Group</b>                            |   |   |   |   |   |   |
| <15 Years                                   |   |   |   |   |   |   |
| 15-19 Years                                 |   |   |   |   |   |   |
| 20-29 Years                                 |   |   |   |   |   |   |
| 30-65 Years                                 |   |   |   |   |   |   |
| ≥ 66 Years                                  |   |   |   |   |   |   |
| Unknown Age                                 |   |   |   |   |   |   |
| <b>Total</b>                                | <b>0</b>  | <b>0</b>                                    | <b>0</b>  | <b>0</b>  | <b>0</b>  | <b>0</b>  |
| <b>Gender</b>                               |   |   |   |   |   |   |
| Male  |   |   |   |   |   |   |
| Female                                      |   |   |   |   |   |   |
| Transgender <sup>6</sup>                    |   |   |   |   |   |   |
| Unknown Gender                              |   |   |   |   |   |   |
| <b>Total</b>                                | <b>0</b>  | <b>0</b>                                    | <b>0</b>  | <b>0</b>  | <b>0</b>  | <b>0</b>  |
| <b>Race and Hispanic Origin<sup>7</sup></b> |   |   |   |   |   |   |
| Hispanic or Latino                          |   |   |   |   |   |   |
| American Indian/Alaska Native alone         |   |   |   |   |   |   |
| Asian alone                                 |   |   |   |   |   |   |
| Black/African American alone                |   |   |   |   |   |   |
| Native Hawaiian/Pacific Islander alone      |   |   |   |   |   |   |
| White alone                                 |   |   |   |   |   |   |
| Two or more races                           |   |   |   |   |   |   |
| Unknown Race                                |   |   |   |   |   |   |
| <b>Total</b>                                | <b>0</b>  | <b>0</b>                                    | <b>0</b>  | <b>0</b>  | <b>0</b>  | <b>0</b>  |
| <b>Test Setting</b>                         |   |   |   |   |   |   |
| Health Care Setting                         |   |   |   |   |   |   |
| Non-Health Care Setting                     |   |   |   |   |   |   |
| Unknown Test Setting                        |   |   |   |   |   |   |
| <b>Total</b>                                | <b>0</b>  | <b>0</b>                                    | <b>0</b>  | <b>0</b>  | <b>0</b>  | <b>0</b>  |
| <b>Testing History</b>                      |   |   |   |   |   |   |
| First-Time Tester                           |   |   |   |   |   |   |
| Repeat Tester                               |   |   |   |   |   |   |
| Unknown Test history                        |   |   |   |   |   |   |
| <b>Total</b>                                | <b>0</b>  | <b>0</b>                                    | <b>0</b>  | <b>0</b>  | <b>0</b>  | <b>0</b>  |

<sup>1</sup> Includes tests that are supported by all funding sources

<sup>2</sup> Includes persons who had a positive or negative test result

<sup>3</sup> Includes newly and previously diagnosed infections and those with unknown prior history

<sup>4</sup> Includes newly identified HIV diagnosis that have been confirmed in surveillance. For persons included in this column, the HIV surveillance system is checked and 1) no prior report of HIV diagnosis is found and 2) there is no indication of a previous diagnosis by either client self-report (if the client was asked) or review of other data sources (if other data sources were checked).

<sup>5</sup> Includes self-report and provider report of new HIV diagnosis.

<sup>6</sup> Transgender includes all persons whose gender identity or expression is different from their sex assigned at birth. Transgender persons may self-identify as transgender female or transgender woman, transgender male or transgender man, or other gender non-binary person.

<sup>7</sup> Race and ethnicity are to be collected at the local level in accordance with OMB standards (<https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf>) and reported to CDC in the aggregate using these categories. Hispanic or Latino persons can be of any race.

| HIV Medical Treatment   |  |
|---|--|
| Total # Positive HIV Diagnosis:   |  |
| Total # of Clients Referred to HIV Medical Care                                 |  |
| Total # of Clients Linked to Medical Care                                       |  |
|   |  |
| Total # Clients referred to Medical Care through Rapid Start Treatment Program: |  |
| Total # Clients linked to Medical Care through Rapid Start Treatment Program:   |  |

| HIV Medical Care Provision          |              |        |     |           |           |                   |
|-------------------------------------|--------------|--------|-----|-----------|-----------|-------------------|
| HIV Medical Care (New Clients Only) |              |        |     |           |           |                   |
| Ethnicity/Race                      | Heterosexual |        | MSM | Trans-MtF | Trans-FtM | Trans-Unspecified |
|                                     | Male         | Female |     |           |           |                   |
| Hispanic/Latino                     |              |        |     |           |           |                   |
| Black/African American              |              |        |     |           |           |                   |
| White                               |              |        |     |           |           |                   |
| American Indian/Alaska Native       |              |        |     |           |           |                   |
| Asian                               |              |        |     |           |           |                   |
| Native American/Pacific Islander    |              |        |     |           |           |                   |
| Other                               |              |        |     |           |           |                   |
| Total # of New Clients on ART:      |              |        |     |           | 0         |                   |
| Total # of Clients Retained ART:    |              |        |     |           | 0         |                   |

| Rapid Strat Treatment Program Provision Demographics                                     |        |        |     |           |           |             |
|--|--------|--------|-----|-----------|-----------|-------------|
| Ethnicity/Race   | Hetero |        | MSM | Trans-MtF | Trans-FtM | Trans-Unsp. |
|  | Male   | Female |     |           |           |             |
| Hispanic/Latino  |        |        |     |           |           |             |
| Black/African American   |        |        |     |           |           |             |
| White  |        |        |     |           |           |             |
| American Indian/Alaska Native  |        |        |     |           |           |             |
| Asian  |        |        |     |           |           |             |
| Native American/Pacific Islander   |        |        |     |           |           |             |
| Other  |        |        |     |           |           |             |
| Total # of New Clients Linked to HIV Medical Care through Rapid Start Treatment Program: |        |        |     |           | 0         |             |

**Narrative**

Please discuss any successes/challenges/barriers with linking clients in HIV medical care through Rapid Start Treatment Program.

| Category                               | Number of HIV-Positive Persons cannot exceed Number of HIV-Positive Persons |  | The Sum of columns C - E cannot exceed the Number of HIV-Positive Persons Referred to Medical Care |   |  | Test Results Unknown cannot exceed Number of Persons Linked to HIV Medical Care                        |
|--|---|--|--|---|--|--|
|  | (A)<br>Number of HIV-Positive Persons                                       | (B)<br>Number of HIV-Positive Persons referred to Medical Care | (C)<br>Newly Diagnosed HIV-Positive Persons Linked to Medical Care                                 | (D)<br>Previously Diagnosed HIV-Positive Persons Linked to Medical Care | (E)<br>Newly or Previously Diagnosed HIV-Positive Persons co-infected with a STI | (F)<br>Number of Diagnosed Person Linked to HIV Medical Care through The Rapid Start Treatment Program |
| <b>Age Group</b>                       |   |  |  |   |  |  |
| <15 Years                              |   |  |  |   |  |  |
| 15-19 Years                            |   |  |  |   |  |  |
| 20-29 Years                            |   |  |  |   |  |  |
| 30-65 Years                            |   |  |  |   |  |  |
| ≥ 66 Years                             |   |  |  |   |  |  |
| Unknown Age                            |   |  |  |   |  |  |
| <b>Total</b>                           | <b>0</b>  | <b>0</b>   | <b>0</b>   | <b>0</b>  | <b>0</b>   | <b>0</b>   |
| <b>Gender</b>                          |   |  |  |   |  |  |
| Male                                   |   |  |  |   |  |  |
| Female                                 |   |  |  |   |  |  |
| Transgender                            |   |  |  |   |  |  |
| Unknown Gender                         |   |  |  |   |  |  |
| <b>Total</b>                           | <b>0</b>  | <b>0</b>   | <b>0</b>   | <b>0</b>  | <b>0</b>   | <b>0</b>   |
| <b>Race and Hispanic Origin</b>        |   |  |  |   |  |  |
| Hispanic or Latino                     |   |  |  |   |  |  |
| American Indian/Alaska Native alone    |   |  |  |   |  |  |
| Asian alone                            |   |  |  |   |  |  |
| Black/African American alone           |   |  |  |   |  |  |
| Native Hawaiian/Pacific Islander alone |   |  |  |   |  |  |
| White alone                            |   |  |  |   |  |  |
| Two or more races                      |   |  |  |   |  |  |
| Unknown Race                           |   |  |  |   |  |  |
| <b>Total</b>                           | <b>0</b>  | <b>0</b>   | <b>0</b>   | <b>0</b>  | <b>0</b>   | <b>0</b>   |
| <b>Test Setting</b>                    |   |  |  |   |  |  |
| Health Care Setting                    |   |  |  |   |  |  |
| Non-Health Care Setting                |   |  |  |   |  |  |
| Unknown Test Setting                   |   |  |  |   |  |  |
| <b>Total</b>                           | <b>0</b>  | <b>0</b>   | <b>0</b>   | <b>0</b>  | <b>0</b>   | <b>0</b>   |
| <b>Testing History</b>                 |   |  |  |   |  |  |
| First-Time Tester                      |   |  |  |   |  |  |
| Repeat Tester                          |   |  |  |   |  |  |
| Unknown Test history                   |   |  |  |   |  |  |
| <b>Total</b>                           | <b>0</b>  | <b>0</b>   | <b>0</b>   | <b>0</b>  | <b>0</b>   | <b>0</b>   |

**Rapid Start Treatment Program  
Quarterly Report Log**

| Agency Specific<br>Client ID | Initial Client<br>Interaction Date | Test Date<br>(If Known) | HIV Diagnosis Date | ART Initiation Date | Medication<br>Prescribed | Linkage to HIV Medical<br>Care Completion Date | Comments<br>(i.e. Where referred, linked, status pending etc...) |
|------------------------------|------------------------------------|-------------------------|--------------------|---------------------|--------------------------|--|--|
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |
|                              |                                    |                         |                    |                     |                          |  |  |

| PrEP & nPEP Services                         |  |
|--|--|
| Total # of Clients Screened for PrEP & nPEP: |  |
| Total # of Clients Eligible for PrEP:        |  |
| Total # of Clients Eligible for nPEP:        |  |
|  |  |
| Total # of PrEP Referrals:                   |  |
| Total # of nPEP Referrals:                   |  |

| PrEP & PEP Provision                           |              |        |     |           |           |                   |
|--|--------------|--------|-----|-----------|-----------|-------------------|
| PrEP Provision Demographics (New Clients Only) |              |        |     |           |           |                   |
| Ethnicity/Race                                 | Heterosexual |        | MSM | Trans-MtF | Trans-FtM | Trans-Unspecified |
|  | Male         | Female |     |           |           |                   |
| Hispanic/Latino                                |              |        |     |           |           |                   |
| Black/African American                         |              |        |     |           |           |                   |
| White  |              |        |     |           |           |                   |
| American Indian/Alaska Native                  |              |        |     |           |           |                   |
| Asian  |              |        |     |           |           |                   |
| Native American/Pacific Islander               |              |        |     |           |           |                   |
| Other  |              |        |     |           |           |                   |
| Total # of New Clients on PrEP:                |              |        |     |           |           | 0                 |
| Total # of Clients Retained PrEP:              |              |        |     |           |           | 0                 |

| nPEP Provision Demographics      |              |        |     |           |           |             |
|----------------------------------|--------------|--------|-----|-----------|-----------|-------------|
| Ethnicity/Race                   | Heterosexual |        | MSM | Trans-MtF | Trans-FtM | Trans-Unsp. |
|                                  | Male         | Female |     |           |           |             |
| Hispanic/Latino                  |              |        |     |           |           |             |
| Black/African American           |              |        |     |           |           |             |
| White                            |              |        |     |           |           |             |
| American Indian/Alaska Native    |              |        |     |           |           |             |
| Asian                            |              |        |     |           |           |             |
| Native American/Pacific Islander |              |        |     |           |           |             |
| Other                            |              |        |     |           |           |             |
| Total # of New Clients on nPEP:  |              |        |     |           |           | 0           |

**Narrative**

Please discuss any successes/challenges/barriers with PrEP & nPEP services (screenings, eligibility, referrals and/or provision). Also include any request for technical assistance.



**PrEP Activities Report**

**Provider Name:**

**Quarter:**

| Category   | Number of Persons Tested for HIV | Number of Persons Receiving PrEP Education | Number of Persons Screened for PrEP Need | Number of Persons Referred to PrEP Provider | Number of Persons Linked to a PrEP Provider | Number of Persons Prescribed PrEP |
|--|----------------------------------|--|--|---|---|-----------------------------------|
| <b>Age Group</b>   |                                  |  |  |   |   |                                   |
| Less than 15 Years                                       |                                  |  |  |   |   |                                   |
| 15-19 Years  |                                  |  |  |   |   |                                   |
| 20-29 Years  |                                  |  |  |   |   |                                   |
| 30-65 Years  |                                  |  |  |   |   |                                   |
| ≥ 66 Years   |                                  |  |  |   |   |                                   |
| Unknown Age  |                                  |  |  |   |   |                                   |
| <b>Total</b>   | <b>0</b>                         | <b>0</b>                                   | <b>0</b>                                 | <b>0</b>                                    | <b>0</b>                                    | <b>0</b>                          |
| <b>Gender</b>  |                                  |  |  |   |   |                                   |
| Male   |                                  |  |  |   |   |                                   |
| Female   |                                  |  |  |   |   |                                   |
| Transgender <sup>1</sup>                                 |                                  |  |  |   |   |                                   |
| Unknown Gender   |                                  |  |  |   |   |                                   |
| <b>Total</b>   | <b>0</b>                         | <b>0</b>                                   | <b>0</b>                                 | <b>0</b>                                    | <b>0</b>                                    | <b>0</b>                          |
| <b>Race and Hispanic Origin<sup>2</sup></b>              |                                  |  |  |   |   |                                   |
| Hispanic or Latino                                       |                                  |  |  |   |   |                                   |
| American Indian/Alaska Native alone                      |                                  |  |  |   |   |                                   |
| Asian alone  |                                  |  |  |   |   |                                   |
| Black/African American alone                             |                                  |  |  |   |   |                                   |
| Native Hawaiian/Pacific Islander alone                   |                                  |  |  |   |   |                                   |
| White alone  |                                  |  |  |   |   |                                   |
| Two or more races  |                                  |  |  |   |   |                                   |
| Unknown Race   |                                  |  |  |   |   |                                   |
| <b>Total</b>   | <b>0</b>                         | <b>0</b>                                   | <b>0</b>                                 | <b>0</b>                                    | <b>0</b>                                    | <b>0</b>                          |
| <b>Population Groups</b>                                 |                                  |  |  |   |   |                                   |
| Men who have sex with men (MSM)/Injection Drug Use (IDU) |                                  |  |  |   |   |                                   |
| MSM  |                                  |  |  |   |   |                                   |
| Person who injects drugs (PWID)                          |                                  |  |  |   |   |                                   |
| Heterosexual males                                       |                                  |  |  |   |   |                                   |
| Heterosexual females                                     |                                  |  |  |   |   |                                   |
| Other  |                                  |  |  |   |   |                                   |
| Unknown Population Group                                 |                                  |  |  |   |   |                                   |
| <b>Total</b>   | <b>0</b>                         | <b>0</b>                                   | <b>0</b>                                 | <b>0</b>                                    | <b>0</b>                                    | <b>0</b>                          |

<sup>1</sup> Transgender includes all persons whose gender identity or expression is different from their sex assigned at birth. Transgender persons may self-identify as transgender female or transgender woman, transgender male or transgender man, or other gender non-binary person.

<sup>2</sup> Race and ethnicity are to be collected at the local level in accordance with OMB standards (<https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf>) and reported to CDC in the aggregate using these categories. Hispanic or Latino persons can be of any race.

| Community Outreach |           |          |                     |               | Narrative   |
|--------------------|-----------|----------|---------------------|---------------|---|
| Date               | Site Name | Zip Code | Priority Population | # of Tests    | Please discuss any best practices/challenges you had this month providing outreach services. Also include any request for technical assistance. |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     |               |   |
|                    |           |          |                     | <b>Total:</b> |   |

| CDC Indicators   |       |     |
|--|-------|-----|
|  | Month | YTD |
| Number of newly diagnosed HIV-positive clients linked to HIV medical care this month<br><i>Client attends a initial HIV medical care visit within 30 days of HIV diagnosis</i>   |       |     |
| Number of HIV-diagnosed clients who were linked to treatment adherence services this month<br><i>ART adherence services may include patient counseling and education, medication cues and reminders, and social and peer support interventions designed to improve ART use.</i>  |       |     |
| Number of HIV-diagnosed clients who were linked to a Disease Intervention Specialist.  |       |     |
| Number of out of care HIV-diagnosed re-engaged with HIV medical care and treatment services this month<br><i>A previously diagnosed person, who is not in HIV medical care, is said to be re-engaged in care when he/she re-enters care after lapse in care and begins attending scheduled follow-up medical appointments.</i> |       |     |
| Number of HIV-infected pregnant women linked to TOPWA and/or perinatal coordinator this month  |       |     |

**I. Patient Identification (record all dates as mm/dd/yyyy)**

|   |  |              |             |                          |              |                   |                                |           |  |
|---|--|--------------|-------------|--------------------------|--------------|-------------------|--------------------------------|-----------|--|
| *First Name   |  | *Middle Name |             | *Last Name               |              | Last Name Soundex |                                |           |  |
| Alternate Name Type (ex: Alias, Married)  |  |              | *First Name |                          | *Middle Name |                   | *Last Name                     |           |  |
| Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility<br><input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other<br><input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary |  |              |             | *Current Address, Street |              |                   | Address Date<br>____/____/____ |           |  |
| *Phone<br>( )   |  | City         |             | County                   |              | State/Country     |                                | *ZIP Code |  |
| *Medical Record Number  |  |              |             | *Other ID Type           |              |                   | *Number                        |           |  |

U.S. Department of Health  
and Human Services

## Adult HIV Confidential Case Report Form

(Patients  $\geq$ 13 years of age at time of diagnosis) \*Information NOT transmitted to CDC

Centers for Disease Control  
and Prevention (CDC)**II. Health Department Use Only (record all dates as mm/dd/yyyy)**

Form approved OMB no. 0920-0573 Exp. 02/28/2026

|   |  |   |  |                    |              |  |
|---|--|---|--|--------------------|--------------|--|
| Date Received at Health Department<br>____/____/____  |  | eHARS Document UID  |  |                    | State Number |  |
| Reporting Health Dept—City/County   |  |   |  | City/County Number |              |  |
| Document Source   |  | Surveillance Method <input type="checkbox"/> Active <input type="checkbox"/> Passive <input type="checkbox"/> Follow up <input type="checkbox"/> Reabstraction <input type="checkbox"/> Unknown   |  |                    |              |  |
| Did this report initiate a new case investigation?<br><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |  | Report Medium<br><input type="checkbox"/> 1-Field visit <input type="checkbox"/> 2-Mailed <input type="checkbox"/> 3-Faxed <input type="checkbox"/> 4-Phone <input type="checkbox"/> 5-Electronic transfer <input type="checkbox"/> 6-CD/disk |  |                    |              |  |

**III. Facility Providing Information (record all dates as mm/dd/yyyy)**

|                                       |  |  |                         |   |  |  |  |   |  |
|---------------------------------------|--|--|-------------------------|---|--|--|--|---|--|
| Facility Name                         |  |  |                         | *Phone<br>( )   |  |  |  |   |  |
| *Street Address                       |  |  |                         |   |  |  |  |   |  |
| City                                  |  | County   |                         | State/Country   |  | *ZIP Code  |  |   |  |
| Facility Type                         |  | Inpatient: <input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____ |                         | Outpatient: <input type="checkbox"/> Private physician's office <input type="checkbox"/> Adult HIV clinic <input type="checkbox"/> Other, specify _____ |  | Screening, Diagnostic, Referral Agency: <input type="checkbox"/> CTS <input type="checkbox"/> STD clinic <input type="checkbox"/> Other, specify _____ |  | Other Facility: <input type="checkbox"/> Emergency room <input type="checkbox"/> Laboratory <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____ |  |
| Date Form Completed<br>____/____/____ |  |  | *Person Completing Form |   |  | *Phone<br>( )  |  |   |  |

**IV. Patient Demographics (record all dates as mm/dd/yyyy)**

|  |  |   |                                    |                    |  |
|--|--|---|------------------------------------|--------------------|--|
| Sex Assigned at Birth <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown   |  | Country of Birth <input type="checkbox"/> US <input type="checkbox"/> Other/US dependency (specify) _____ |                                    |                    |  |
| Date of Birth ____/____/____   |  |   | Alias Date of Birth ____/____/____ |                    |  |
| Vital Status <input type="checkbox"/> 1-Alive <input type="checkbox"/> 2-Dead  |  | Date of Death ____/____/____  |                                    | State of Death     |  |
| Gender Identity <input type="checkbox"/> Man <input type="checkbox"/> Woman <input type="checkbox"/> Transgender man <input type="checkbox"/> Transgender woman<br><input type="checkbox"/> Additional gender identity (specify) _____<br><input type="checkbox"/> Declined to answer <input type="checkbox"/> Unknown |  |   |                                    |                    |  |
| Date Identified ____/____/____   |  |   |                                    |                    |  |
| Sexual Orientation <input type="checkbox"/> Straight or heterosexual <input type="checkbox"/> Lesbian or gay <input type="checkbox"/> Bisexual<br><input type="checkbox"/> Additional sexual orientation (specify) _____<br><input type="checkbox"/> Declined to answer <input type="checkbox"/> Unknown               |  |   |                                    |                    |  |
| Date Identified ____/____/____   |  |   |                                    |                    |  |
| Ethnicity <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino <input type="checkbox"/> Unknown   |  |   |                                    | Expanded Ethnicity |  |
| Race (check all that apply) <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black/African American<br><input type="checkbox"/> Native Hawaiian/Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Unknown                   |  |   |                                    | Expanded Race      |  |

**V. Residence at Diagnosis (add additional addresses in Comments) (record all dates as mm/dd/yyyy)**

|   |  |        |  |               |  |           |  |
|---|--|--------|--|---------------|--|-----------|--|
| Address Event Type<br>(check all that apply to address below) <input type="checkbox"/> Residence at HIV diagnosis <input type="checkbox"/> Residence at stage 3 (AIDS) diagnosis <input type="checkbox"/> Check if <u>SAME</u> as current address   |  |        |  |               |  |           |  |
| Address Type <input type="checkbox"/> Residential <input type="checkbox"/> Bad address <input type="checkbox"/> Correctional facility <input type="checkbox"/> Foster home <input type="checkbox"/> Homeless <input type="checkbox"/> Military <input type="checkbox"/> Other <input type="checkbox"/> Postal <input type="checkbox"/> Shelter <input type="checkbox"/> Temporary |  |        |  |               |  |           |  |
| *Street Address   |  |        |  |               |  |           |  |
| City  |  | County |  | State/Country |  | *ZIP Code |  |

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0573). **Do not send the completed form to this address.**

**VI. Facility of Diagnosis (add additional facilities in Comments)**

|   |  |  |  |
|---|--|--|--|
| <b>Diagnosis Type</b> (check all that apply to facility below) <input type="checkbox"/> HIV <input type="checkbox"/> Stage 3 (AIDS) <input type="checkbox"/> Check if <u>SAME</u> as facility providing information |  |  |  |
| <b>Facility Name</b> _____  |  |  | <b>*Phone</b> (    ) _____   |
| <b>*Street Address</b> _____  |  |  |  |
| <b>City</b> _____   | <b>County</b> _____  | <b>State/Country</b> _____   | <b>*ZIP Code</b> _____   |
| <b>Facility Type</b> <u>Inpatient:</u> <input type="checkbox"/> Hospital<br><input type="checkbox"/> Other, specify _____   | <u>Outpatient:</u> <input type="checkbox"/> Private physician's office<br><input type="checkbox"/> Adult HIV clinic<br><input type="checkbox"/> Other, specify _____ | <u>Screening, Diagnostic, Referral Agency:</u> <input type="checkbox"/> CTS <input type="checkbox"/> STD clinic<br><input type="checkbox"/> Other, specify _____ | <u>Other Facility:</u> <input type="checkbox"/> Emergency room<br><input type="checkbox"/> Laboratory <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown<br><input type="checkbox"/> Other, specify _____ |
| <b>*Provider Name</b> _____   |  | <b>*Provider Phone</b> (    ) _____  | <b>Specialty</b> _____   |

**VII. Patient History (respond to all questions) (record all dates as mm/dd/yyyy)     Pediatric Risk (enter in Comments)**

|   |   |
|---|---|
| <b>After 1977 and before the earliest known diagnosis of HIV infection, this patient had:</b>                                   |   |
| Sex with male   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Sex with female   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Injected nonprescription drugs  | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Received clotting factor for hemophilia/coagulation disorder<br>Specify clotting factor: _____ Date received ____/____/____     | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| <b>HETEROSEXUAL relations with any of the following:</b>  |   |
| HETEROSEXUAL contact with person who injected drugs   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| HETEROSEXUAL contact with bisexual male   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| HETEROSEXUAL contact with person with hemophilia/coagulation disorder with documented HIV infection                             | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| HETEROSEXUAL contact with transfusion recipient with documented HIV infection   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| HETEROSEXUAL contact with transplant recipient with documented HIV infection  | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| HETEROSEXUAL contact with person with documented HIV infection, risk not specified  | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Received transfusion of blood/blood components (other than clotting factor) (document reason in Comments)                       | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| First date received ____/____/____    Last date received ____/____/____   |   |
| Received transplant of tissue/organs or artificial insemination   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Worked in a healthcare or clinical laboratory setting   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| If occupational exposure is being investigated or considered as primary mode of exposure, specify occupation and setting: _____ |   |
| Other documented risk (include detail in Comments) _____  | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |

**VIII. Clinical: Acute HIV Infection and Opportunistic Illnesses (record all dates as mm/dd/yyyy)**

|  |   |
|--|---|
| <b>Suspect acute HIV infection?</b> <i>If YES, complete the two items below; enter documented negative HIV test result data in Laboratory Data section, and enter patient or provider report of previous negative HIV test result in HIV Testing History section</i> | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Clinical signs/symptoms consistent with acute retroviral syndrome (e.g., fever, malaise/fatigue, myalgia, pharyngitis, rash, lymphadenopathy)?    Date of sign/symptom onset ____/____/____  | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |
| Other evidence suggestive of acute HIV infection? <i>If YES, describe:</i> _____<br>Date of evidence ____/____/____  | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown |

| Opportunistic Illnesses   |         |   |         |  |         |
|---|---------|---|---------|--|---------|
| Diagnosis   | Dx Date | Diagnosis   | Dx Date | Diagnosis  | Dx Date |
| Candidiasis, bronchi, trachea, or lungs                         |         | Herpes simplex: chronic ulcers (>1 mo. duration), bronchitis, pneumonitis, or esophagitis |         | M. tuberculosis, pulmonary <sup>1</sup>                                      |         |
| Candidiasis, esophageal   |         | Histoplasmosis, disseminated or extrapulmonary  |         | M. tuberculosis, disseminated or extrapulmonary <sup>1</sup>                 |         |
| Carcinoma, invasive cervical                                    |         | Isosporiasis, chronic intestinal (>1 mo. duration)  |         | Mycobacterium, of other/unidentified species, disseminated or extrapulmonary |         |
| Coccidioidomycosis, disseminated or extrapulmonary              |         | Kaposi's sarcoma  |         | Pneumocystis pneumonia   |         |
| Cryptococcosis, extrapulmonary                                  |         | Lymphoma, Burkitt's (or equivalent)   |         | Pneumonia, recurrent, in 12 mo. period                                       |         |
| Cryptosporidiosis, chronic intestinal (>1 mo. duration)         |         | Lymphoma, immunoblastic (or equivalent)   |         | Progressive multifocal leukoencephalopathy                                   |         |
| Cytomegalovirus disease (other than in liver, spleen, or nodes) |         | Lymphoma, primary in brain  |         | Salmonella septicemia, recurrent   |         |
| Cytomegalovirus retinitis (with loss of vision)                 |         | Mycobacterium avium complex or M. kansasii, disseminated or extrapulmonary                |         | Toxoplasmosis of brain, onset at >1 mo. of age                               |         |
| HIV encephalopathy  |         |   |         | Wasting syndrome due to HIV  |         |

<sup>1</sup>If a diagnosis date is entered for either tuberculosis diagnosis above, provide RVCT Case Number:

**IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy)**

|  |                                       |
|--|---------------------------------------|
| <b>HIV Immunoassays</b>  |                                       |
| <b>TEST</b> <input type="checkbox"/> HIV-1 IA <input type="checkbox"/> HIV-1/2 IA <input type="checkbox"/> HIV-1/2 Ag/Ab <input type="checkbox"/> HIV-2 IA   |                                       |
| <b>Test Brand Name/Manufacturer</b> _____  | <b>Lab Name</b> _____                 |
| <b>Facility Name</b> _____   | <b>Provider Name</b> _____            |
| <b>Result</b> <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Indeterminate   | <b>Collection Date</b> ____/____/____ |
| <b>Testing Option</b> (if applicable) <input type="checkbox"/> Point-of-care test by provider <input type="checkbox"/> Self-test, result directly observed by a provider <sup>2</sup> <input type="checkbox"/> Lab test, self-collected sample |                                       |

**IX. Laboratory Data (record additional tests and tests not specified below in Comments) (record all dates as mm/dd/yyyy) (cont)**

**TEST**  HIV-1/2 Ag/Ab differentiating immunoassay (differentiates between HIV Ag and HIV Ab)  
**Test Brand Name/Manufacturer** \_\_\_\_\_ **Lab Name** \_\_\_\_\_  
**Facility Name** \_\_\_\_\_ **Provider Name** \_\_\_\_\_  
**Result** **Overall:**  Reactive  Nonreactive **Collection Date** \_\_\_\_/\_\_\_\_/\_\_\_\_  
**Analyte results:** HIV-1 Ag:  Reactive  Nonreactive HIV-1/2 Ab:  Reactive  Nonreactive  
**Testing Option** (if applicable)  Point-of-care test by provider  Self-test, result directly observed by a provider<sup>2</sup>  Lab test, self-collected sample

**TEST**  HIV-1/2 Ag/Ab and type-differentiating immunoassay (differentiates among HIV-1 Ag, HIV-1 Ab, and HIV-2 Ab)  
**Test Brand Name/Manufacturer** \_\_\_\_\_ **Lab Name** \_\_\_\_\_  
**Facility Name** \_\_\_\_\_ **Provider Name** \_\_\_\_\_  
**Result**<sup>3</sup> **Overall interpretation:**  Reactive  Nonreactive  Index Value \_\_\_\_\_ **Collection Date** \_\_\_\_/\_\_\_\_/\_\_\_\_  
**Analyte results:** HIV-1 Ag:  Reactive  Nonreactive  Not reportable due to high Ab level **Index Value** \_\_\_\_\_  
HIV-1 Ab:  Reactive  Nonreactive  Reactive undifferentiated **Index Value** \_\_\_\_\_  
HIV-2 Ab:  Reactive  Nonreactive  Reactive undifferentiated **Index Value** \_\_\_\_\_  
**Testing Option** (if applicable)  Point-of-care test by provider  Self-test, result directly observed by a provider<sup>2</sup>  Lab test, self-collected sample

**TEST**  HIV-1/2 type-differentiating immunoassay (supplemental) (differentiates between HIV-1 Ab and HIV-2 Ab)  
**Test Brand Name/Manufacturer** \_\_\_\_\_ **Lab Name** \_\_\_\_\_  
**Facility Name** \_\_\_\_\_ **Provider Name** \_\_\_\_\_  
**Result**<sup>4</sup> **Overall interpretation:**  HIV positive, untypable  HIV-1 positive with HIV-2 cross-reactivity  HIV-2 positive with HIV-1 cross-reactivity  
 HIV negative  HIV indeterminate  HIV-1 indeterminate  HIV-2 indeterminate  HIV-1 positive  HIV-2 positive  
**Analyte results:** HIV-1 Ab:  Positive  Negative  Indeterminate **Collection Date** \_\_\_\_/\_\_\_\_/\_\_\_\_  
HIV-2 Ab:  Positive  Negative  Indeterminate  
**Testing Option** (if applicable)  Point-of-care test by provider  Self-test, result directly observed by a provider<sup>2</sup>  Lab test, self-collected sample

**TEST**  HIV-1 WB  HIV-1 IFA  HIV-2 WB  
**Test Brand Name/Manufacturer** \_\_\_\_\_ **Lab Name** \_\_\_\_\_  
**Facility Name** \_\_\_\_\_ **Provider Name** \_\_\_\_\_  
**Result**  Positive  Negative  Indeterminate **Collection Date** \_\_\_\_/\_\_\_\_/\_\_\_\_  
**Testing Option** (if applicable)  Point-of-care test by provider  Self-test, result directly observed by a provider<sup>2</sup>  Lab test, self-collected sample

**HIV Detection Tests**

**TEST**  HIV-1/2 RNA NAAT (Qualitative) **Lab Name** \_\_\_\_\_  
**Test Brand Name/Manufacturer** \_\_\_\_\_ **Provider Name** \_\_\_\_\_  
**Facility Name** \_\_\_\_\_ **Collection Date** \_\_\_\_/\_\_\_\_/\_\_\_\_  
**Result**  HIV-1  HIV-2  Both (HIV-1 and HIV-2)  HIV, not differentiated (HIV-1 or HIV-2)  Neither (negative)  
**Testing Option** (if applicable)  Point-of-care test by provider  Self-test, result directly observed by a provider<sup>2</sup>  Lab test, self-collected sample

**TEST**  HIV-1 RNA NAAT (Qualitative and Quantitative)  
**Test Brand Name/Manufacturer** \_\_\_\_\_ **Lab Name** \_\_\_\_\_  
**Facility Name** \_\_\_\_\_ **Provider Name** \_\_\_\_\_  
**Result** **Qualitative:**  Reactive  Nonreactive **Collection Date** \_\_\_\_/\_\_\_\_/\_\_\_\_  
**Analyte results:** HIV-1 Quantitative:  Detectable above limit  Detectable within limits  Detectable below limit  
**Copies/mL** \_\_\_\_\_ **Log** \_\_\_\_\_  
**Testing Option** (if applicable)  Point-of-care test by provider  Self-test, result directly observed by a provider<sup>2</sup>  Lab test, self-collected sample

**TEST**  HIV-1 RNA/DNA NAAT (Qualitative)  HIV-1 culture  HIV-2 RNA/DNA NAAT (Qualitative)  HIV-2 culture  
**Test Brand Name/Manufacturer** \_\_\_\_\_ **Lab Name** \_\_\_\_\_  
**Facility Name** \_\_\_\_\_ **Provider Name** \_\_\_\_\_  
**Result**  Positive  Negative  Indeterminate **Collection Date** \_\_\_\_/\_\_\_\_/\_\_\_\_  
**Testing Option** (if applicable)  Point-of-care test by provider  Self-test, result directly observed by a provider<sup>2</sup>  Lab test, self-collected sample

**TEST**  HIV-1 RNA/DNA NAAT (Quantitative)  HIV-2 RNA/DNA NAAT (Quantitative)  
**Test Brand Name/Manufacturer** \_\_\_\_\_ **Lab Name** \_\_\_\_\_  
**Facility Name** \_\_\_\_\_ **Provider Name** \_\_\_\_\_  
**Result**  Detectable above limit  Detectable within limits  Detectable below limit  Not detected **Copies/mL** \_\_\_\_\_ **Log** \_\_\_\_\_  
**Collection Date** \_\_\_\_/\_\_\_\_/\_\_\_\_  
**Testing Option** (if applicable)  Point-of-care test by provider  Self-test, result directly observed by a provider<sup>2</sup>  Lab test, self-collected sample

**Drug Resistance Tests (Genotypic)**

**TEST**  HIV-1 Genotype (Unspecified) **Test Brand Name/Manufacturer** \_\_\_\_\_  
**Lab Name** \_\_\_\_\_ **Facility Name** \_\_\_\_\_  
**Provider Name** \_\_\_\_\_ **Collection Date** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Immunologic Tests (CD4 count and percentage)**

**CD4 count** \_\_\_\_\_ cells/ $\mu$ L **CD4 percentage** \_\_\_\_\_% **Collection Date** \_\_\_\_/\_\_\_\_/\_\_\_\_  
**Test Brand Name/Manufacturer** \_\_\_\_\_ **Lab Name** \_\_\_\_\_  
**Facility Name** \_\_\_\_\_ **Provider Name** \_\_\_\_\_

**Documentation of Tests**

**Did documented laboratory test results meet approved HIV diagnostic algorithm criteria?**  Yes  No  Unknown  
**If YES, provide specimen collection date of earliest positive test result for this algorithm** \_\_\_\_/\_\_\_\_/\_\_\_\_  
*Complete the above only if none of the following were positive for HIV-1: Western blot, IFA, culture, quantitative NAAT (RNA or DNA), qualitative NAAT (RNA or DNA), HIV-1/2 type-differentiating immunoassay (supplemental test), stand-alone p24 antigen, or nucleotide sequence.*  
**Is earliest evidence of HIV infection diagnosis documented by a physician rather than by laboratory test results?**  Yes  No  Unknown  
**If YES, provide date of diagnosis by physician** \_\_\_\_/\_\_\_\_/\_\_\_\_  
**Date of last documented negative HIV test result** (before HIV diagnosis date) \_\_\_\_/\_\_\_\_/\_\_\_\_  
**Specify type of test:** \_\_\_\_\_  
**Testing Option** (if applicable)  Point-of-care test by provider  Self-test, result directly observed by a provider<sup>2</sup>  Lab test, self-collected sample

<sup>2</sup>Results not directly observed by a provider should be recorded in HIV Testing History.

<sup>3</sup>Complete the overall interpretation and the analyte results.

<sup>4</sup>Always complete the overall interpretation. Complete the analyte results when available.

**X. Treatment/Services Referrals (record all dates as mm/dd/yyyy)**

|  |              |  |  |
|--|--------------|--|--|
| Has this patient been informed of his/her HIV infection?<br><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown  |              | This patient's partners will be notified about their HIV exposure and counseled by<br><input type="checkbox"/> 1-Health dept <input type="checkbox"/> 2-Physician/Provider <input type="checkbox"/> 3-Patient <input type="checkbox"/> 9-Unknown |  |
| Evidence of receipt of HIV medical care other than laboratory test result (select one; record additional evidence in Comments)<br><input type="checkbox"/> 1-Yes, documented <input type="checkbox"/> 2-Yes, client self-report, only Date of medical visit or prescription ____/____/____ |              |  |  |
| <b>For Female Patient</b>  |              |  |  |
| This patient is receiving or has been referred for gynecological or obstetrical services <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown   |              | Is this patient currently pregnant? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown  |  |
| Has this patient delivered live-born infants? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown  |              |  |  |
| <b>For Children of Patient (record most recent birth in these boxes; record additional or multiple births in Comments)</b>   |              |  |  |
| *Child's Name _____  |              | Child's Date of Birth ____/____/____   |  |
| Child's Last Name Soundex _____  |              | Child's State Number _____   |  |
| Facility Name of Birth (if child was born at home, enter "home birth") _____   |              | *Phone (____) _____  |  |
| Facility Type <i>Inpatient:</i><br><input type="checkbox"/> Hospital <input type="checkbox"/> Other, specify _____   |              | <i>Outpatient:</i><br><input type="checkbox"/> Other, specify _____  |  |
| <i>Other Facility:</i> <input type="checkbox"/> Emergency room <input type="checkbox"/> Corrections <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____   |              |  |  |
| *Street Address _____  |              | *ZIP Code _____  |  |
| City _____   | County _____ | State/Country _____  |  |

**XI. Antiretroviral Use History (record all dates as mm/dd/yyyy)**

|  |                       |                           |   |
|--|-----------------------|---------------------------|---|
| Main source of antiretroviral (ARV) use information (select one)<br><input type="checkbox"/> Patient interview <input type="checkbox"/> Medical record review <input type="checkbox"/> Provider report <input type="checkbox"/> NHM&E <input type="checkbox"/> Other |                       |                           | Date patient reported information<br>____/____/____ |
| Ever taken any ARVs? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown   |                       |                           |   |
| If yes, reason for ARV use (select all that apply)   |                       |                           |   |
| <input type="checkbox"/> HIV Tx  | ARV medications _____ | Date began ____/____/____ | Date of last use ____/____/____                     |
| <input type="checkbox"/> PrEP  | ARV medications _____ | Date began ____/____/____ | Date of last use ____/____/____                     |
| <input type="checkbox"/> PEP   | ARV medications _____ | Date began ____/____/____ | Date of last use ____/____/____                     |
| <input type="checkbox"/> PMTCT   | ARV medications _____ | Date began ____/____/____ | Date of last use ____/____/____                     |
| <input type="checkbox"/> HBV Tx  | ARV medications _____ | Date began ____/____/____ | Date of last use ____/____/____                     |
| <input type="checkbox"/> Other (specify reason) _____  | ARV medications _____ | Date began ____/____/____ | Date of last use ____/____/____                     |

**XII. HIV Testing History (record all dates as mm/dd/yyyy)**

|   |  |  |   |
|---|--|--|---|
| Main source of testing history information (select one)<br><input type="checkbox"/> Patient interview <input type="checkbox"/> Medical record review <input type="checkbox"/> Provider report <input type="checkbox"/> NHM&E <input type="checkbox"/> Other |  |  | Date patient reported information<br>____/____/____   |
| Ever had previous positive HIV test result? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Date of first positive HIV test result ____/____/____   |  |  |   |
| Was the first positive test result from a self-test performed by the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown   |  |  |   |
| Ever had a negative HIV test result? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown  |  |  | Date of last negative HIV test result (if date is from a lab test with test type, enter in Lab Data section) ____/____/____ |
| Was the last negative test result from a self-test performed by the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown  |  |  |   |
| Number of negative HIV test results within the 24 months before the first positive test result _____ <input type="checkbox"/> Unknown   |  |  |   |
| How many of these negative test results were from self-tests performed by the patient? _____ <input type="checkbox"/> Unknown   |  |  |   |

**XIII. Comments**

|   |  |
|---|--|
| <input type="checkbox"/> CHECK OOS STATE: _____ | If pregnant, list EDD (due date): ____/____/____ |
| <input type="checkbox"/> DOC# _____             |  |
|   |  |
|   |  |
|   |  |
| Link with e-HARS stateno(s): _____              |  |

**XIV. \*Local/Optional Fields**

|  |  |
|--|--|
| STARS# _____   | NIR OP <input type="checkbox"/> Date: ____/____/____ |
| Other Risks: A <input type="checkbox"/> B/C <input type="checkbox"/> D <input type="checkbox"/> F <input type="checkbox"/> M <input type="checkbox"/> V <input type="checkbox"/> J <input type="checkbox"/> O <input type="checkbox"/> | NIR CL <input type="checkbox"/> Date: ____/____/____ |
| Hepatitis: A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> Other <input type="checkbox"/> UNKnown <input type="checkbox"/>  | NIR RE <input type="checkbox"/> Date: ____/____/____ |
| Test & Treat (Yes/No) _____  | Initials(3) _____ Source code: _____                 |

This report to CDC is authorized by law (Sections 304 and 306 of the Public Health Service Act, 42 USC 242b and 242k). Response in this case is voluntary for federal government purposes but may be mandatory under state and local statutes. Your cooperation is necessary for the understanding and control of HIV. Information in CDC's National HIV Surveillance System that would permit identification of any individual on whom a record is maintained is collected with a guarantee that it will be held in confidence, will be used only for the purposes stated in the assurance, and will not otherwise be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 USC 242m).



**STD Surveillance**  
Orange, Osceola, Brevard,  
Seminole Counties

Rodney Jones  
Phone: 407 665-3384  
Cell: 407-608-9133  
Fax: 407-845-6134

**FLORIDA CONFIDENTIAL REPORT OF  
SEXUALLY TRANSMITTED DISEASES**

*"Protecting Your Health...It's what we do"*

**Sex assigned at birth: FEMALE / MALE**  
**Pregnant? YES / NO**  
**Pregnancy EDD** \_\_\_\_\_

**Patient Name:** \_\_\_\_\_  
**DOB:** \_\_\_\_\_ **SSN:** \_\_\_\_\_  
**Address:** \_\_\_\_\_  
**Phone:** \_\_\_\_\_  
**Email:** \_\_\_\_\_  
**Please print legibly OR use a label.**

**RACE:** WHITE BLACK OTHER AM INDIAN/ALASKAN ASIAN/PAC ISLANDER  
**ETHNICITY:** Hispanic / Non-Hispanic

**Provider Name:** \_\_\_\_\_ **Provider Phone:** \_\_\_\_\_

**Provider Address:** \_\_\_\_\_

**CASES OF SYPHILIS MUST BE REPORTED TO DOH STD WITH TREATMENT BY THE NEXT BUSINESS DAY**

| CHLAMYDIA  | GONORRHEA  | OTHER  |
|--|--|--|
| <input type="checkbox"/> Uncomplicated<br><input type="checkbox"/> Ophthalmia<br><input type="checkbox"/> Pelvic Inflammatory Disease (PID)<br><input type="checkbox"/> Pneumonia  | <input type="checkbox"/> Uncomplicated<br><input type="checkbox"/> Disseminated Gonococcal<br><input type="checkbox"/> Ophthalmia<br><input type="checkbox"/> Oral/Pharyngeal<br><input type="checkbox"/> Other resistant strain<br><input type="checkbox"/> Pelvic Inflammatory Disease<br><input type="checkbox"/> Penicillinase-Producing<br>Neisseria Gonorrhoea (PPNG)<br><input type="checkbox"/> Rectal   | <input type="checkbox"/> Cancroid<br><input type="checkbox"/> Granuloma Inguinal<br><br><input type="checkbox"/> Herpes Simplex*<br><input type="checkbox"/> Human Papillomavirus**<br><br><input type="checkbox"/> Lymphogranuloma<br>Venereal<br><input type="checkbox"/> Other (specify)  |
| Collection date  | Collection date  | Collection date  |
| Reporting laboratory   | Reporting laboratory   | Reporting laboratory   |
| Treatment date _____<br><b>* CDC Recommended Regimen</b><br><br><input type="checkbox"/> Azithromycin 1 gm*<br><input type="checkbox"/> Doxycycline 100 mg BID x 7d*<br><input type="checkbox"/> Levofloxacin 500 mg x 7d<br><input type="checkbox"/> Ofloxacin 300 mg BID x 7d<br><input type="checkbox"/> Amoxicillin 500 mg TID x 7d<br><input type="checkbox"/> Erythromycin base 500 QID x 7d<br><br><b>IF PREGNANT</b><br><input type="checkbox"/> Azithromycin 1 gm*<br><input type="checkbox"/> Erythromycin base 500 QID x 7d<br><input type="checkbox"/> Amoxicillin 500 TID x 7d<br><br><b>NOTE:</b> Any treatment used other than recommended treatment will need a Test of Cure 3 weeks after completion of therapy. Test of Cure less than 3 weeks could yield false positive results. | Treatment date _____<br><b>* CDC Recommended Regimen</b><br><br><b>Uncomplicated gonococcal infections of the cervix, urethra, rectum, pharynx, and pregnant patients:</b><br><br>---- Ceftriaxone 500 mg ****<br><br><b>ONLY IF</b><br><i>The patient has severe cephalosporin allergy:</i><br><br><input type="checkbox"/> AZ 2 gm in a single oral dose<br>AND Gentamicin 240 mg in a single dose.<br><br>TOC in 1 week<br><br>----- Other (Please Specify) | * In infants up to 60 days old with disseminated infection with involvement of liver, encephalitis and infections limited to skin, eyes and mouth; anogenital in children < 12 yrs. Old.<br><br>** HPV associated with laryngeal papilloma's or recurrent respiratory papillomatosis in children < 6 yrs. old; anogenital in children < 12 yrs. old. |





**STD Surveillance**  
Orange, Osceola, Brevard,  
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**FLORIDA CONFIDENTIAL REPORT OF  
SEXUALLY TRANSMITTED DISEASES**

*"Protecting Your Health...It's what we do"*

**Sex assigned at birth: FEMALE / MALE**  
**Pregnant? YES / NO**  
**Pregnancy EDD** \_\_\_\_\_

**Patient Name:** \_\_\_\_\_  
**DOB:** \_\_\_\_\_ **SSN:** \_\_\_\_\_  
**Address:** \_\_\_\_\_  
**Phone:** \_\_\_\_\_  
**Email:** \_\_\_\_\_  
**Please print legibly OR use a label.**

**RACE:** WHITE BLACK OTHER AM INDIAN/ALASKAN ASIAN/PAC ISLANDER  
**ETHNICITY:** Hispanic / Non-Hispanic

**Provider Name:** \_\_\_\_\_ **Provider Phone:** \_\_\_\_\_

**Provider Address:** \_\_\_\_\_

**CASES OF SYPHILIS MUST BE REPORTED TO DOH STD WITH TREATMENT BY THE NEXT BUSINESS DAY**

**SYPHILIS**

|   |  |  |
|---|--|--|
| <b>Reason for visit:</b>  | <b>Symptoms:</b>   | <b>Previous history of syphilis infection?</b><br><br>YES / NO<br><br><b>Previous titer (if known):</b> _____<br><br><b>Date of last negative RPR:</b> _____ |
| Collection date   | Symptom onset date   | <b># of sexual partners (within past year):</b>  |
| Reporting laboratory  | Sexual orientation   |  |
| <b><u>Confirmatory tests</u></b><br>___ TP-PA positive<br>___ FTA-ABS positive<br>___ IgG-EIA positive<br>___ MHA-TP<br>___ TP-AB positive<br><br><b><u>Diagnosis</u></b><br>___ Primary<br>___ Secondary<br>___ Early Latent (< 1 yr)<br>___ Late Latent<br>___ Tertiary<br>___ Congenital | <b><u>Treatment dates:</u></b><br><br>2.4 BIC #1 _____<br>2.4 BIC #2 _____<br>2.4 BIC #3 _____<br><br>___ Doxycycline 100 BID x 14d<br><b>Date</b> _____<br><br>___ Doxycycline 100 BID x 28d<br><b>Date</b> _____<br><br><b><u>IF PREGNANT</u></b><br><br>Was sex partner(s) treated?<br><br>YES / NO<br><br>If NO, was sex partner(s) referred to the Health Department?<br><br>YES / NO | <b><u>Sexual Partner(s) information (if known/given):</u></b>  |

# BUSINESS ASSOCIATES AGREEMENT

## Attachment VII

Combined HIPAA Privacy Business Associate Agreement and Confidentiality Agreement and HIPAA Security Rule Addendum and HI-TECH Act Compliance Agreement and the Florida Information Protection Act of 2014

This Agreement is entered into between the State of Florida, Florida Department of Health (“Covered Entity”), and **Orange County, Florida on behalf of its Health Services Department**, (“Business Associate”). The parties have entered into this Agreement for the purpose of satisfying the Business Associate contract requirements in the regulations at 45 CFR 164.502(e) and 164.504(e), issued under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the Security Rule, codified at 45 Code of Federal Regulations (“C.F.R.”) Part 164, Subparts A and C; Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5 (Feb. 17, 2009) and related regulations. This Agreement corresponds to the following: MOA-A7-306.

### 1.0 Definitions

Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms in 45 CFR 160.103 and 164.501. Notwithstanding the above, "Covered Entity" shall mean the State of Florida Department of Health. "Individual" shall have the same meaning as the term "individual" in 45 CFR 164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g); "Secretary" shall mean the Secretary of the U.S. Department of Health and Human Services or his designee; and "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

### **Part I: Privacy Provisions**

#### 2.0 Obligations and Activities of Business Associate

- (a) Business Associate agrees to not use or further disclose Protected Health Information (“PHI”) other than as permitted or required by Sections 3.0 and 5.0 of this Agreement, or as required by Law.
- (b) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information as provided for by this Agreement.
- (c) Business Associate agrees to take reasonable measures to protect and secure data in electronic form containing personal information as defined by §501.171, Florida Statutes.
- (d) Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use, access, or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.
- (e) Business Associate agrees to report to Covered Entity any use, access, or disclosure of the Protected Health Information not provided for by this Agreement of which it becomes aware.
- (f) Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.
- (g) Business Associate agrees to make available protected health information in a designated record set to the Covered Entity within 10 days of a request, or directly to an Individual or the Individual’s designee in a prompt and reasonable manner consistent with the time frames established in the Covered Entity’s Information Security and Privacy Policy, in order to meet the requirements under 45 CFR 164.524.
- (h) Business Associate agrees to ensure no more than the reasonable cost-based fee, permitted under 42 CFR 164.524, is charged to an individual requesting copies of their protected health information.

# BUSINESS ASSOCIATES AGREEMENT

## Attachment VII

- (i) Business Associate agrees to make any Amendment(s) to Protected Health Information in a designated record set as directed or agreed to by the Covered Entity pursuant to 45 CFR 164.526, in a prompt and reasonable manner consistent with the HIPAA regulations.
- (j) Business Associate agrees to make its internal practices, books, and records, including policies and procedures and Protected Health Information, relating to the use and disclosure of Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity available to the Covered Entity, or at the request of the Covered Entity, to the Secretary in a time and manner designated by the Covered Entity or the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.
- (k) Business Associate agrees to document disclosures of Protected Health Information and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.
- (l) Business Associate agrees to provide to Covered Entity or an Individual an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528, in a prompt and reasonable manner consistent with the HIPAA regulations.
- (m) Business Associate agrees to satisfy all applicable provisions of HIPAA standards for electronic transactions and code sets, also known as the Electronic Data Interchange (EDI) Standards, at 45 CFR Part 162. Business Associate further agrees to ensure that any agent, including a subcontractor, that conducts standard transactions on its behalf, will comply with the EDI Standards.
- (n) Business Associate agrees to determine the Minimum Necessary type and amount of PHI required to perform its services and will comply with 45 CFR 164.502(b) and 514(d).
- (o) Business Associate agrees to comply with all aspects of §501.171, Florida Statutes.

### 3.0 Permitted or Required Uses and Disclosures by Business Associate General Use and Disclosure.

- (a) Except as expressly permitted in writing by Department of Health, Business Associate may use Protected Health Information only as necessary to perform the services set forth in the contract or purchase order, as referenced herein. Business Associate shall not disclose information to any third party without the expressed written consent of the Covered Entity.
- (b) Business Associate may use or disclose protected health information as required by law.
- (c) Business Associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by the Covered Entity.
- (d) Except as otherwise limited in this Agreement, Business Associate may use Protected Health Information to provide data aggregation services relating to health care operations of the Covered Entity as permitted by 45 CFR 164.504(e)(2)(i)(B).
- (e) Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j) (1).

### 4.0 Obligations of Covered Entity to Inform Business Associate of Covered Entity's Privacy Practices, and any Authorization or Restrictions.

- (a) Covered Entity shall provide Business Associate with its notice of privacy practices developed in accordance with 45 CFR 164.520, as well as any changes to such notice.
- (b) Covered Entity shall provide Business Associate with any changes in, or revocation of, Authorization by Individual or his or her personal representative to use or disclose Protected Health Information, if such changes affect Business Associate's uses or disclosures of Protected Health Information.
- (c) Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR

# BUSINESS ASSOCIATES AGREEMENT

## Attachment VII

164.522, if such changes affect Business Associate's uses or disclosures of Protected Health Information.

### 5.0 Confidentiality under State Law.

- (a) In addition to the HIPAA privacy requirements and the data security requirements of §501.171, Florida Statutes, Business Associate agrees to observe the confidentiality requirements of Chapter 381, Florida Statutes and any other Florida Statute relating to the confidentiality of information provided under this agreement.
- (b) Receipt of a Subpoena. If Business Associate is served with subpoena requiring the production of Department of Health records or information, Business Associate shall immediately contact the Department of Health, Office of the General Counsel, (850) 245-4005. A subpoena is an official summons issued by a court or an administrative tribunal, which requires the recipient to do one or more of the following:
  1. Appear at a deposition to give sworn testimony and may also require that certain records be brought to be examined as evidence.
  2. Appear at a hearing or trial to give evidence as a witness and may also require that certain records be brought to be examined as evidence.
  3. Furnish certain records for examination, by mail, or by hand-delivery.
- (c) Employees and Agents. Business Associate acknowledges that the confidentiality requirements herein apply to all its employees, agents and representatives. Business Associate assumes responsibility and liability for any damages or claims, including state and federal administrative proceedings and sanctions, against Department of Health, including costs and attorneys' fees, resulting from the breach of the confidentiality requirements of this Agreement. Nothing in this Agreement shall constitute a waiver of the County's sovereign immunity. Without waiving any of the provisions or protections under Florida law, under no circumstances shall the County be liable to the Agency under any contract, negligence, strict liability, or other legal or equitable theory for any amounts in excess of those limits per claim and per occurrence set forth for tort liability in Section 768.28 of the Florida Statutes, which limits are hereby made applicable to all manner of claims against the County related to this Agreement and are not confined to tort liability.

### 6.0 Permissible Requests by Covered Entity.

Covered Entity shall not request Business Associate to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by Covered Entity.

### 7.0 Term and Termination.

- (a) Term.

The Term of this Agreement shall be coterminous with the underlying contract or purchase order, giving rise to this Agreement.
- (b) Termination for Cause.

Business Associate authorizes termination of this Agreement by Covered Entity, if Covered Entity determines Business Associate has violated a material term of the Agreement and Business Associate has not cured the breach or ended the violation within the time specified by the Covered Entity.
- (c) Effect of Termination.
  1. Within sixty (60) days after termination of the Agreement for any reason, or within such other time period as mutually agreed upon in writing by the parties, Business Associate shall return to Covered Entity or destroy all Protected Health Information maintained by Business Associate in any form and shall retain no copies thereof. Business Associate also shall recover, and shall return or destroy with such time period, any Protected Health Information in the possession of its subcontractors or agents.

# BUSINESS ASSOCIATES AGREEMENT

## Attachment VII

2. Within fifteen (15) days after termination of the Agreement for any reason, Business Associate shall notify Covered Entity in writing as to whether Business Associate elects to return or destroy such Protected Health Information. If Business Associate elects to destroy such Protected Health Information, it shall certify to Covered Entity in writing when such Protected Health Information has been destroyed. If any subcontractors or agents of the Business Associate elect to destroy the Protected Health Information, Business Associate will require such subcontractors or agents to certify to Business Associate and to Covered Entity in writing when such Protected Health Information has been destroyed. If it is not feasible for Business Associate to return or destroy any of said Protected Health Information, Business Associate shall notify Covered Entity in writing that Business Associate has determined that it is not feasible to return or destroy the Protected Health Information and the specific reasons for such determination.
3. Business Associate further agrees to extend any and all protections, limitations, and restrictions set forth in this Agreement to Business Associate's use or disclosure of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses or disclosures to the purposes that make the return or destruction of Protected Health Information not feasible.
4. If it is not feasible for Business Associate to obtain, from a subcontractor or agent, any Protected Health Information in the possession of the subcontractor or agent, Business Associate shall provide a written explanation to Covered Entity and require the subcontractors and agents to agree to extend any and all protections, limitations, and restrictions set forth in this Agreement to the subcontractors' or agents' uses or disclosures of any Protected Health Information retained after the termination of this Agreement, and to limit any further uses or disclosures to the purposes that make the return or destruction of the Protected Health Information not feasible.

### **Part II: Breaches and Security Incidents**

#### 8.0 Privacy or Security Breach.

Business Associate will report to Covered Entity's Privacy Officer or the Covered Entity's contract manager within 2 business days after the discovery, any unauthorized access, use, disclosure of Covered Entity's protected health information not permitted by the Business Associates Agreement along with any breach of Covered Entity's unsecured protected health information. Business Associate will treat the breach as being discovered in accordance with 45 CFR §164.410. If a delay is requested by a law enforcement official in accordance with 45 CFR §164.412, Business Associate may delay notifying the Covered Entity for the applicable time period. Business Associates report will at a minimum:

- (a) Identify the nature of the breach or other non-permitted use or disclosure, which will include a brief description of what happened, including the date of any breach and the date of discovery of the breach;
- (b) Identify Covered Entity's Protected Health Information that was subject to the non-permitted use or disclosure or breach (such as whether name, social security number, date of birth, home address, account number or other information was disclosed/accessed) on an individual basis;
- (c) Identify who made the non-permitted use or disclosure and who received it;
- (d) Identify what corrective action or mitigation Business Associate took or will take to prevent further non-permitted uses or disclosures, to mitigate harmful effects and to protect against any further breaches;
- (e) Identify what steps the individuals who were subject to a breach should take to protect themselves;

# BUSINESS ASSOCIATES AGREEMENT

## Attachment VII

- (f) Provide such other information, including a written report, as Covered Entity may reasonably request.

### 8.1 Security of Electronic Protected Health Information.

Business Associate and Department of Health agree to also address herein the applicable requirements of the Security Rule, codified at 45 Code of Federal Regulations (“C.F.R.”) Part 164, Subparts A and C, issued pursuant to the Administrative Simplification provisions of Title II, Subtitle F of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA-AS”), and the Florida Information Protection Act (FIPA) §501.171, Florida Statutes, so that the Covered Entity may meet compliance obligations under HIPAA-AS and FIPA the parties agree:

- (a) Business Associate will develop, implement, maintain, and use administrative, technical, and physical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic Protected Health Information (as defined in 45 C.F.R. § 160.103) and Personal Information (as defined in §501.171, Florida Statutes) that Business Associate creates, receives, maintains, or transmits on behalf of the Covered Entity consistent with the Security Rule.
- (b) Reporting Security Incidents. Business Associate will report to Covered Entity within 48 hours of discovery any successful (A) unauthorized access, use, disclosure, modification, or destruction of Covered Entity’s Electronic Protected Health Information or unauthorized access of data in an electronic form containing Personal Information as defined in §501.171, Florida Statute, or (B) interference with Business Associate’s system operations in Business Associate’s information systems, of which Business Associate becomes aware.

### 8.2 Corrective Action.

- (a) Business Associate agrees to take prompt corrective action and follow all provisions required in state and federal law to notify all individuals reasonably believed to be potentially affected by the breach.
- (b) Cure: Business Associate agrees to take prompt corrective action to cure any security deficiencies.

## **Part III**

### 9.0 Miscellaneous.

- (a) Regulatory References. A reference in this Agreement to a section in the Privacy Rule or the Security Rule means the section as in effect or as amended, and for which compliance is required.
- (b) Amendment. Upon the enactment of any law or regulation affecting the use or disclosure of Protected Health Information, Personal Information, Standard Transactions, the security of Health Information, or other aspects of HIPAA-AS or FIPA applicable or the publication of any decision of a court of the United States or any state relating to any such law or the publication of any interpretive policy or opinion of any governmental agency charged with the enforcement of any such law or regulation, either party may, by written notice to the other party, amend this Agreement in such manner as such party determines necessary to comply with such law or regulation. If the other party disagrees with such Amendment, it shall so notify the first party in writing within thirty (30) days of the notice. If the parties are unable to agree on an Amendment within thirty (30) days thereafter, then either of the parties may terminate the Agreement on thirty (30) days written notice to the other party.
- (c) Survival. The respective rights and obligations of Business Associate under Section 7.0 of this Agreement shall survive the termination of this Agreement.

# BUSINESS ASSOCIATES AGREEMENT

## Attachment VII

- (d) Interpretation. Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy Rule and the confidentiality requirements of the State of Florida.
- (e) No third-party beneficiary. Nothing expressed or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the parties and the respective successors or assignees of the parties, any rights, remedies, obligations, or liabilities whatsoever.
- (f) Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the state of Florida to the extent not preempted by the Privacy Rules or other applicable federal law.
- (g) Venue. The venue of any proceedings shall be the appropriate federal or state court in Leon County, Florida.
- (h) Indemnification and performance guarantees. Business Associate shall indemnify, defend, and save harmless the State of Florida for any financial loss as a result of claims brought by third parties and which are caused by the failure of Business Associate, its officers, directors or agents to comply with the terms of this Agreement or for penalties imposed by the HHS Office of Civil Rights for any violations of the Federal Privacy Rule caused by the Business Associate. Additionally, Business Associate shall indemnify the State of Florida for any time and expenses it may incur from breach notifications that are necessary under either §501.171, Florida Statute or the HIPAA Breach Notification Rule, 45 CFR §§ 164.400-414, which are caused by the failure of Business Associate, its officers, directors or agents to comply with the terms of this Agreement. Nothing in this Agreement shall constitute a waiver of the County's sovereign immunity. Without waiving any of the provisions or protections under Florida law, under no circumstances shall the County be liable to the Agency under any contract, negligence, strict liability, or other legal or equitable theory for any amounts in excess of those limits per claim and per occurrence set forth for tort liability in Section 768.28 of the Florida Statutes, which limits are hereby made applicable to all manner of claims against the County related to this Agreement and are not confined to tort liability.
- (i) Assignment. Business Associate shall not assign either its obligations or benefits under this Agreement without the expressed written consent of the Covered Entity, which shall be at the sole discretion of the Covered Entity. Given the nature of this Agreement, neither subcontracting nor assignment by the Business Associate is anticipated and the use of those terms herein does not indicate that permission to assign or subcontract has been granted.
- (j) E-Verify. Effective January 1, 2021, Business Associate is required to use the U.S. Department of Homeland Security's E-Verify system to verify the employment eligibility of all employees used by the Business Associate under this Agreement, pursuant to section 448.095, Florida Statutes. Also, the Business Associate must include in related subcontracts, if authorized under this Agreement, a requirement that subcontractors performing work or providing services pursuant to this Agreement use the E-Verify system to verify employment eligibility of all employees used by the subcontractor for the performance of services under this Agreement. The subcontractor must provide the Covered Entity with an affidavit stating that the subcontractor does not employ, contract with, or subcontract with an unauthorized alien. The Business Associate must maintain a copy of such affidavit for the duration of the Agreement. If the Department has a good faith belief that a subcontractor knowingly violated section 448.095(1), Florida Statutes, and notifies the Covered Entity of such, but the Business Associate otherwise complied with this statute, the Business Associate must immediately terminate the subcontract with the subcontractor.

SIGNATURES ON THE NEXT PAGE

**BUSINESS ASSOCIATES AGREEMENT**

Attachment VII

Orange County, Florida on behalf of its  
Health Services Department

State of Florida, Department of Health,  
Orange County Health Department

By: \_\_\_\_\_  
Name: Jerry L. Demings  
Title: Mayor  
Date: \_\_\_\_\_

By: \_\_\_\_\_  
Name: Robert D. Karch, MD, MPH, FAAP  
Title: Director  
Date: \_\_\_\_\_