



ALL APPLICATIONS MUST BE SUBMITTED VIA THE INTERNET

OHIO DEPARTMENT OF HEALTH

DIVISION OF
Prevention

BUREAU OF
HIV/AIDS, STD and TB

HIV Testing in Ohio Emergency Departments
REQUEST FOR PROPOSALS (RFP)
FOR
FISCAL YEAR 2011
(08/01/11 – 09/29/12)

Non-Profit Applicants
Ohio Emergency Room Departments

COMPETITIVE GRANT APPLICATION INFORMATION

Application Due Date: July 11, 2011
Notice of Intent to Apply/GMIS Training Form
Due Date: June 9, 2010

Table of Contents

I. APPLICATION SUMMARY and GUIDANCE

A. Policy and Procedure	4
B. Application Name	4
C. Purpose.....	4
D. Qualified Applicants	4
E. Service Area.....	4
F. Number of Grants and Funds Available	4
G. Due Date	5
H. Authorization	5
I. Goals	5
J. Program Period and Budget Period.....	5
K. Local Health Districts Improvement Standards.....	6
L. Public Health Impact Statement.....	6
M. Statement of Intent to Pursue Health Equity Strategies.....	7
N. Appropriation Contingency	8
O. Programmatic, Technical Assistance and Authorization for Internet Submission	8
P. Acknowledgment	8
Q. Late Applications	8
R. Successful Applicants	9
S. Unsuccessful Applicants	9
T. Review Criteria	9
U. Freedom of Information Act	9
V. Ownership Copyright.....	10
W. Reporting Requirements	10
X. Special Condition(s).....	11
Y. Unallowable Costs	12
Z. Audit	12
AA. Submission of Application.....	14

II. APPLICATION REQUIREMENTS AND FORMAT

A. Application Information.....	16
B. Budget.....	16
C. Assurances Certification	17
D. Project Narrative	17
E. Civil Rights Review Questionnaire – EEO Survey	19
F. Attachments	19
G. Electronic Funds Transfer (EFT) Form	20
H. Internal Revenue Service (IRS) W-9 Form and Vendor Forms	20
I. Public Health Impact Statement Summary	20
J. Public Health Impact/Response & Intent to pursue Health Equity Statement.....	20
K. Liability Coverage	20
L. Non-Profit Organization Status.....	21
M. Declaration Regarding Material Assistance/Non-Assistance to a Terrorist Organization (DMA) Questionnaire	21
N. Federal Funding Accountability and Transparency Act (FFATA) Requirement	21
O. Attachments as Required by Program.....	22
Attachment A: Ohio Department of Health Sub-Awardee Federal	23
Funding Accountability & Transparency Act (FFATA) Reporting Form	

III. APPENDICES

A. GMIS 2.0 Training Form 25
B. Notice of Intent to Apply 26
C. Grant Application Review Rating Form 27
D. Grant Required Positions 28
E. Ohio Expanded and Routine HIV Testing Protocol

I. APPLICATION SUMMARY and GUIDANCE

An application for an Ohio Department of Health (ODH) grant consists of a number of required parts – an electronic component submitted via the Internet Website: ODH Application Gateway – GMIS 2.0 which includes various paper forms and attachments. All the required parts of a specific application must be completed and submitted by the application due date. **Any required part that is not submitted on time will result in the entire application not being considered for review.**

The application summary information is provided to assist your agency in identifying funding criteria:

- A. Policy and Procedure:** Uniform administration of all the ODH grants is governed by the ODH Grants Administration Policies and Procedures (GAPP) Manual. This manual must be followed to ensure adherence to the rules, regulations and procedures for preparation of all subgrantee applications. The GAPP Manual is available on the ODH Website <http://www.odh.ohio.gov>. (Click on “Funding Opportunities” [located under At a Glance]; click on “About ODH”, click on “ODH Grants” and then click on “GAPP Manual.”)
- B. Application Name:** Expanded HIV Testing in Ohio Emergency Departments (EDs).
- C. Purpose:** In accordance with the Centers for Disease Control and Prevention’s (CDC) Expanded HIV Testing for Disproportionately Affected Populations grant and the Ohio HIV Prevention Plan, the purpose of this program is to increase HIV testing opportunities for populations disproportionately affected by HIV, primarily, African American and Hispanic men and women, men who have sex with men (MSM), and injection drug users (IDUs). Additionally, this award is intended to increase the proportion of HIV-infected persons in these populations who are aware of their infection and are linked to appropriate services.
- D. Qualified Applicants:** All applicants must be a local public or non-profit hospital. Applicant agencies must attend or document in writing prior attendance at Grants Management Information System 2.0 (GMIS) training and must have the capacity to accept an electronic funds transfer (EFT).
- E. Service Area:** All counties within the state of Ohio. Although, awards will be prioritized by the HIV incidence per the Ohio HIV/AIDS Epidemiological Profile for Ohio, which can be located at <http://www.odh.ohio.gov/healthStats/disease/hivdata/pf1.aspx>.
- F. Number of Grants and Funds Available:** Funds supporting this RFP coming from the CDC. Up to five grants may be awarded for a total of \$400,000. Eligible agencies may apply for up to \$80,000. All funds are contingent upon continued level funding from the CDC. No grant award will be issued for less than 30,000. Applications

- submitted for less than the minimum amount will not be considered for review.
- G. Due Date:** Applications including any required forms and required attachments mailed or electronically submitted via GMIS 2.0 are due by 4:00 pm, Monday, **July 11, 2011**. Attachments and/or forms sent electronically must be transmitted by the application due date. Attachments and/or forms mailed that are non-Internet compatible must be postmarked or received on or before the application due date.
- H. Authorization:** Authorization of funds for this purpose is contained in Amended Substitute House Bill 119 and the Catalog of Federal Domestic Assistance (CFDA) Number 93.940.
- I. Goals:** The goal of this program is to reduce the transmission of HIV by building the capacity of public health agencies, community-based organizations (CBOs), and other public health based organizations to:
- i. Among populations disproportionately affected by HIV – primarily (1) African American and Hispanic men and women, and (2) MSM, and IDUs, regardless of race or ethnicity – increase the number of persons who receive HIV testing, and the number and proportion of HIV-infected persons who are aware of their infection, through routine HIV screening within Ohio emergency room departments.
 - ii. Ensure that persons testing positive for HIV infection (new positives and previously diagnosed positives not in care) receive prevention counseling and are linked to medical care, partner services, and HIV prevention services.
 - iii. Promote adoption of sustainable, routine HIV screening programs in Ohio emergency room departments, consistent with CDC’s 2006 *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*.
 - iv. Support integration of HIV testing with testing and prevention services for other infections, such as hepatitis C virus (HCV), hepatitis B virus (HBV), other sexually transmitted diseases (STDs), and tuberculosis (TB).
- J. Program Period and Budget Period:** The program period will begin **August 1, 2011**, and end on **September 29, 2013**. The budget period for this application is **August 1, 2011** through **September 29, 2012**. A subsequent continuation grant will be available for grantees with a budget period of **September 30, 2012 – September 29, 2013**.

Measurable outcomes of the program will be in alignment with the following performance goals for the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP):

1. Decrease the annual HIV incidence rate;
2. Decrease the rate of HIV transmission by HIV-infected persons;
3. Increase the proportion of HIV-infected persons in Ohio who know they are infected; and,
4. Increase the proportion of HIV-infected persons who are linked to

prevention and care services.

- K. Local Health Districts Improvement Standards:** This grant program will address the following Local Health District Improvement Goals and Standard.

Goal 3701-36-04: Protect People from Disease and Injury:

Standard 3701-36-04-01: A surveillance and reporting system exists that identifies health threats. Standard 3701-36-04-03: Communicable disease investigation and control procedures are in place and actions documented.

Goal 3701-36-05: Monitor Health Status:

Standard 3701-36-05-01: Public health assessment processes and tools are in place and are continuously maintained and enhanced. Standard 3701-36-05-03: A community health plan based on an assessment (Standard 3701-36-05-02) is developed, implemented and evaluated.

Goal 3701-36-07: Promote Healthy Lifestyles:

Standard 3701-36-07-01: Health promotion services are targeted to identify health risks in the community. Standard 3701-36-07-02: Community members are actively involved in addressing prevention priorities. Standard 3701-36-07-03: Prevention, health promotion, early intervention, and outreach services are provided directly or through contracts or partnerships.

Goal 3701-36-08: Address the Need for Personal Health Services:

Standard 3701-36-08-02: Information is available that describes the local health system, including resources critical for public health protection and information about health care providers, facilities, and support services. Standard 3701-36-08-03: Information is collected, monitored, and disseminated regarding trends, which over time, affect access to critical health services.

- L. Public Health Impact Statement:** All applicant agencies that are not local health districts must communicate with local health districts regarding the impact of the proposed grant activities on the Local Health Districts Improvement Standards.

1. Public Health Impact Statement Summary - Applicant agencies are required to submit a summary of the program to local health districts prior to submitting the grant application to ODH. The program summary, not to exceed one page, must include:

- a) The Local Health District Improvement Standard(s) to be addressed by grant activities:
 - A description of the demographic characteristics (e.g., age, race, gender, ethnicity) of the target population and the geographical area in which they live (e.g. census tracts, census blocks, block groups);
 - A summary of the services to be provided or activities to be conducted; and,
 - A plan to coordinate and share information with appropriate local health

districts.

The applicant must submit the above summary as part of their grant application to ODH. This will document that a written summary of the proposed activities was provided to the local health districts with a request for their support and/or comment about the activities as they relate to the Local Health Districts Improvement Standards

2. Public Health Impact Statement of Support - Include within the grant application a statement that you have contacted and informed the local health districts Regional AIDS Coordinator and Disease Intervention Services (DIS) Supervisor about the applicant agencies intent to apply for the HIV Testing in Ohio Emergency Departments RFP, (See Contact List attached to this RFP). Discussion points critical to this application must include that the applicant agency has an understanding of the importance of, and procedures to contact the local DIS within the applicants service area. DIS will be responsible for conducting partner services (PS) in the event of a positive HIV test result identified at your facility. If an applicant agency has a multiple region and/or statewide focus, a statement indicating that the applicant agency has contacted all Regional AIDS Coordinators and DIS Supervisors within the applicant's service area. (See Methodology section of this RFP)

M. Statement of Intent to Pursue Health Equity Strategies

The ODH is committed to the elimination of health inequities. All applicant agencies must submit a statement which outlines the intent of this application to address health disparities. This statement should not exceed 1 ½ pages and must: (1) explain the extent in which health disparities are manifested within the health status (e.g., morbidity and/or mortality) or health system (e.g., accessibility, availability, affordability, appropriateness of health services) focus of this application; (2) identify specific group(s) who experience a disproportionate burden for the disease or health condition addressed by this application; and (3) identify specific social and environmental conditions which lead to health disparities (social determinants). This statement must be supported by data. The following section will provide a basic framework and links to information to understand health equity concepts. This information will also help in the preparation of this statement as well as respond to other portions of this application.

- Basic Health Equity Concepts:

Certain groups in Ohio experience a disproportionate burden with regard to the incidence, prevalence and mortality of certain diseases or health conditions. These are commonly referred to as health disparities. Health disparities are not mutually exclusive to one disease or health condition and are measurable through the use of various public health data. Most health disparities affect groups marginalized because of socioeconomic status, race/ethnicity, sexual orientation, gender, disability status, geographic location or some combination of these factors. People in such groups also tend to have less access to resources like

healthy food, good housing, good education, safe neighborhoods, freedom from racism and other forms of discrimination. These are referred to as **social determinants**. Social determinants are necessary to support optimal health. The systematic and unjust distribution of social determinants among these groups is referred to as **health inequities**. As long as health inequities persist, marginalized groups will not achieve their best possible health. The ability of marginalized groups to achieve optimal health (like those with access to social determinants) is referred to as **health equity**. Public health interventions that incorporate social determinants into the planning and implementation of programs will contribute to the elimination of health disparities. For more resources on health equity, please visit the ODH website at:

<http://www.healthyohioprogram.org/healthequity/equity.aspx>.

- N. Appropriation Contingency:** Any award made through this program is contingent upon the availability of funds for this purpose. **In view of this, the subgrantee agency must be prepared to cover the costs of operating the program in the event of a delay in grant payments.**
- O. Programmatic, Technical Assistance and Authorization for Internet Submission:** Initial authorization for Internet submission will be distributed at your GMIS 2.0 Training Session (new agencies). Applicant must attend or must document, in writing, prior attendance at GMIS 2.0 training in order to receive authorization for Internet submission. All other agencies will receive their authorization upon submission of the Notice of Internet to Apply (NOIAF). Programmatic and Technical Assistance inquiries can be submitted to **Nicole Brennan, HIV Prevention Program Manager via email at nicole.brennan@odh.ohio.gov**. All questions regarding this RFP must be submitted via e-mail no later than **5:00 pm July 1, 2011**, questions submitted after the deadline will not be answered. Answers will be circulated to all applicants who submit an Intent to Apply.
- There will be a technical assistance/bidders conference call on Monday June 9, 2011 from 10:00 am to 12:00 pm to provide guidance and answer questions related to the RFP. To participate in this call, please dial 1-800-510-7500 and enter participant code 2528489#.**
- P. Acknowledgment:** An ‘Application Submitted’ status will appear in GMIS 2.0 that acknowledges ODH system receipt of the application submission.
- Q. Late Applications:** Applications are dated the time of actual submission via the Internet utilizing GMIS 2.0. Required attachments and/or forms sent electronically must be transmitted by the application due date. Required attachments and/or forms mailed that are non-Internet compatible must be postmarked or received on or before the application due date of **July 11, 2011**.

Applicants should request a legibly dated postmark, or obtain a legibly dated receipt from the U.S. Postal Service, or a commercial carrier. Private metered postmarks shall **not** be acceptable as proof of timely mailing. Applicants can hand-deliver attachments to ODH, Grants Administration, Central Master Files; but they must be delivered by 4:00 p.m. on the application due date. FAX attachments will not be accepted. **GMIS 2.0 applications and required application attachments received late will not be considered for review.**

- R. Successful Applicants:** Successful applicants will receive official notification in the form of a “Notice of Award” (NOA). The NOA, issued under the signature of the Director of Health, allows for expenditure of grant funds.
- S. Unsuccessful Applicants:** Within 30 days after a decision to disapprove or not fund a grant application for a given program period, written notification, issued under the signature of the Director of Health, or his designee shall be sent to the unsuccessful applicant.
- T. Review Criteria:** All proposals will be judged on the quality, clarity and completeness of the application. Applications will be judged according to the extent to which the proposal:
1. Contributes to the advancement and/or improvement of the health of Ohioans;
 2. Is responsive to policy concerns and program objectives of the initiative/program/activity for which grant dollars are being made available;
 3. Is well executed and is capable of attaining program objectives;
 4. Describe specific objectives, activities, milestones and outcomes with respect to time-lines and resources;
 5. Estimates reasonable cost to the ODH, considering the anticipated results;
 6. Indicates that program personnel are well qualified by training and/or experience for their roles in the program and the applicant organization has adequate facilities and personnel;
 7. Provides an evaluation plan, including a design for determining program success;
 8. Is responsive to the special concerns and program priorities specified in the request for proposal;
 9. Has demonstrated acceptable past performance in areas related to programmatic and financial stewardship of grant funds; and
 10. Has demonstrated compliance to Grants Administration Policies and Procedures GAPP, Chapter 100, and
 11. Explicitly identifies specific groups in the service area who experience a disproportionate burden of the diseases or health condition(s) and explains the root causes of health disparities.

See Appendix C- Rating Form for the scoring sheet that will be used to evaluate this application.

The ODH will make the final determination and selection of successful/unsuccessful applicants and reserves the right to reject any or all applications for any given request for proposals. **There will be no appeal of the Department's decision.**

- U. **Freedom of Information Act:** The Freedom of Information Act and the associated Public Information Regulations (45 CFR Part 5) of the U. S. Department of Health and Human Services require the release of certain information regarding grants requested by any member of the public. The intended use of the information will not be a criterion for release. Grant applications and grant-related reports are generally available for inspection and copying except that information considered to be an unwarranted invasion of personal privacy will not be disclosed. For specific guidance on the availability of information, refer to 45 CFR Part 5.

- V. **Ownership Copyright:** Any work produced under this grant will be the property of the Ohio Department of Health/Federal Government. The department's ownership will include copyright. The content of any material developed under this grant **must** be approved in advance by the awarding office of the ODH. All material(s) must clearly state:

Funded by Ohio Department of Health/Federal Government
 Bureau: HIV/AIDS, STD and TB
 Program: HIV Prevention

- W. **Reporting Requirements:** Successful applicants are required to submit subgrantee program and expenditure reports. Reports must adhere to the ODH, GAPP manual. Reports must be received before the department will release any additional funds.

Note: Failure to assure quality of reporting such as submitting incomplete and/or late program or expenditure reports will jeopardize the receipt of agency flexibility status and/or further payments.

Reports shall be submitted as follows:

- 1. **Program Reports:** Subgrantee Program Reports **must** be completed and submitted via the Grants Monitoring and Evaluation System (GMIS) by the following dates listed below. Any paper non-Internet compatible report attachments must be submitted to Central Master Files by the specific report due date.

Submission of Subgrantee Program Reports via the ODH's SPES indicates acceptance of the ODH GAPP.

Due Date	Report	Submitted Via
December 15, 2011	Progress Report	GMIS
March 15, 2012	Progress Report	GMIS

October 15, 2012	Annual Progress Report	GMIS
Monthly	Test kit tracking forms	Email
Monthly	Client Level Testing Data	Email/Mail

2. **Subgrantee Program Expenditure Reports:** Subgrantee Program Expenditure Reports **must** be completed and submitted **via GMIS 2.0** by the following dates:

Due Date	Quarter
December 15, 2011	August 1, 2011 – October 31, 2011
March 15, 2012	October 31, 2011 – January 31, 2012
June 15, 2012	February 1, 2012 – May 31, 2012
October 15, 2012	June 1, 2012 – September 29, 2012

Submission of Subgrantee Program Expenditure Reports via the ODH’s GMIS 2.0 system indicates acceptance of ODH GAPP. Clicking the “Approve” button signifies your authorization of the submission as an agency official and constitutes your electronic acknowledgment and acceptance of GAPP rules and regulations.

3. **Final Expenditure Reports:** A Subgrantee Final Expenditure Report reflecting total expenditures for the fiscal year must be completed and submitted **via GMIS 2.0** on or before **4:00 PM, November 15, 2012**. The information contained in this report must reflect the program’s accounting records and supportive documentation. Any cash balances must be returned with the Subgrantee Final Expense Report. The Subgrantee Final Expense Report serves as an invoice to return unused funds.

Submission of the Subgrantee Final Expenditure Report via the GMIS 2.0 system indicates acceptance of ODH GAPP. Clicking the “Approve” button signifies authorization of the submission by an agency official and constitutes electronic acknowledgment and acceptance of GAPP rules and regulations.

4. **Inventory Report:** A listing of all equipment purchased in whole or in part with **current** grant funds (Equipment Section of the approved budget) must be submitted via GMIS 2.0 as part of the Subgrantee Final Expenditure Report. At least once every two years, inventory must be physically inspected by the subgrantee. Equipment purchased with ODH grant funds must be tagged as property of ODH for inventory control. Such equipment may be required to be returned to ODH at the end of the grant program period.

- X. **Special Condition(s):** Responses to all special conditions **must be submitted via GMIS 2.0 within 30 days of receipt of the first quarter payment**. A Special Conditions link is available for viewing and responding to special conditions. This link is viewable only after the issuance of the subgrantee’s first payment. The 30 day

time period, in which the subgrantee must respond to special conditions, will begin when the link is viewable. Failure to submit satisfactory responses to the special conditions or a plan describing how those special conditions will be satisfied will result in the withholding of any further payments until satisfied.

Submission of response to grant special conditions via the ODH's GMIS 2.0 system indicates acceptance of ODH GAPP. Checking the "selection" box and clicking the "approve" button signifies authorization of the submission by an agency official and constitutes electronic acknowledgment and acceptance of GAPP rules and regulations.

Y. Unallowable Costs: Funds **may not** be used for the following:

1. To advance political or religious points of view or for fund raising or lobbying; but must be used solely for the purpose as specified in this announcement;
2. To disseminate factually incorrect or deceitful information;
3. Consulting fees for salaried program personnel to perform activities related to grant objectives;
4. Bad debts of any kind;
5. Lump sum indirect or administrative costs;
6. Contributions to a contingency fund;
7. Entertainment;
8. Fines and penalties;
9. Membership fees -- unless related to the program and approved by ODH;
10. Interest or other financial payments;
11. Contributions made by program personnel;
12. Costs to rent equipment or space owned by the funded agency;
13. Inpatient services;
14. The purchase or improvement of land; the purchase, construction, or permanent improvement of any building;
15. Satisfying any requirement for the expenditure of non-federal funds as a condition for the receipt of federal funds;
16. Travel and meals over the current state rates (see OBM Website: <http://obm.ohio.gov/MiscPages/TravelRule> Then click on OBM Travel Rule.
17. Costs related to out-of-state travel, unless otherwise approved by ODH, and described in the budget narrative;
18. Training longer than one week in duration, unless otherwise approved by ODH;
19. Contracts for compensation with advisory board members;
20. Grant-related equipment costs greater than \$300, unless justified and approved by ODH;
21. Payments to any person for influencing or attempting to influence members of Congress or the Ohio General Assembly in connection with awarding of grants;

Use of grant funds for prohibited purposes will result in the loss and/or recovery of those funds.

Z. Audit: Subgrantees currently receiving funding from the ODH are responsible for submitting an independent audit report that meets OMB Circular A-133 requirements, a copy of the auditor's management letter, a corrective action plan (if applicable) and a data collection form (for single audits) within 30 days of the receipt of the auditor's report, but not later than 9 months after the end of the subgrantee's fiscal year.

Subgrantees that have an agency fiscal year that ends on or after January 1, 2004 (and expend \$500,000 or more in federal awards per fiscal year) are required to have a single audit. The fair share of the cost of the single audit is an allowable cost to federal awards provided that the audit was conducted in accordance with the requirements of OMB Circular A-133.

Subgrantees that have an agency fiscal year that ends on or after January 1, 2004 which expend less than the \$500,000 threshold require a financial audit conducted in accordance with Generally Accepted Government Auditing Standards. The financial audit is not an allowable cost to the program.

Once an audit is completed, **a copy must be sent to the ODH, Grants Administration, Central Master Files address within 30 days.** Reference: *GAPP Chapter 100, Section 108 and OMB Circular A-133, Audits of States, Local Governments, and Non-Profit Organizations for additional audit requirements.*

Subgrantee audit reports (finalized and published, and including the audit Management Letters, if applicable) **which include internal control findings, questioned costs or any other serious findings, must include a cover letter which:**

- Lists and highlights the applicable findings;
- Discloses the potential connection or effect (direct or indirect) of the findings on subgrants passed-through the ODH;
- Summarizes a Corrective Action Plan (CAP) to address the findings. A copy of the CAP should be attached to the cover letter.

AA. Submission of Application:

The GMIS 2.0 application submission must consist of the following:

**Complete
& Submit
Via Internet**

1. Application Information
2. Project Narrative
3. Project Contacts
4. Budget
 - Primary Reason
 - Funding
 - Cash Needs
 - Justification
 - Personnel
 - Other Direct Costs
 - Equipment
 - Contracts
 - Compliance Section D
 - Summary
5. Civil Rights Review Questionnaire (EEO Survey)
6. Assurances Certification
7. Federal Funding Accountability and Transparency Act (FFATA) reporting form (Attachment A).
8. Attachments as required by Program:
 - Public Health Impact Statement
 - Statement of Support from the Local Health Districts
 - Statement of Intent to Pursue Health Equity Strategies
 - Liability Coverage (non-governmental agencies only)
 - Evidence of Non-Profit Status

**Copy &
Mail to ODH**

An original and one copy of the following forms, available on GMIS 2.0, must be completed, printed, signed in blue ink with original signature by the Agency Head or Agency Financial Head and mailed to the address listed below:

**Complete, Sign &
Mail to ODH**

1. Electronic Funds Transfer (EFT) Form (**Required if new agency, thereafter only if banking information has changed.**)
2. IRS W-9 Form (**Required if new agency, thereafter only when tax identification number or agency address information has changed.**) **One of the following forms must accompany the IRS W-9 Form:**
 - a. Vendor Information Form (**New Agency Only**)
 - b. Vendor Information Change Form (**Existing Agency with tax identification number, name and/or address change(s).**)
 - c. Change request in writing on Agency letterhead (**Existing Agency with tax identification number, name and/or address change(s).**)

One copy of the following documents must be mailed to the address listed below:

**Complete
Copy & Mail
to ODH**

1. Current Independent Audit (latest completed organizational fiscal period; **only if not previously submitted**)
2. Declaration Regarding Material Assistance/Non Assistance to a Terrorist Organization (DMA) Questionnaire (**Required by ALL Non-Governmental Applicant Agencies**)
3. An original of attachments and one copy of non-Internet compatible documents are required.

**Ohio Department of Health
Grants Administration
Central Master Files, 4th Floor
246 N. High Street
Columbus, Ohio 43215**

II. APPLICATION REQUIREMENTS AND FORMAT

Access to the on-line GMIS 2.0, will be provided after GMIS 2.0 training for those agencies requiring training. All others will receive access after receipt of the Submission of the Notice of Intent to Apply for Funding (NOIAF).

All applications must be submitted via GMIS 2.0. Submission of all parts of the grant application via the ODH's GMIS 2.0 system indicates acceptance of ODH GAPP. Submission of the Application signifies authorization by an agency official and constitutes electronic acknowledgment and acceptance of GAPP rules and regulations in lieu of an executed Signature Page document.

- A. **Application Information:** Information on the applicant agency and its administrative staff must be accurately completed. This information will serve as the basis for necessary communication between the agency and the ODH.
- B. **Budget:** Prior to completion of the budget section, please review page nine of the RFP for unallowable costs. Match or Applicant Share is not required by this program. Do not include match or Applicant Share in the budget and/or the Applicant Share column of the Budget Summary. Only the narrative may be used to identify additional funding information from other resources.
 - 1. **Primary Reason and Justification Pages:** Provide a detailed budget justification narrative that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs. Describe the specific functions of the personnel, consultants and collaborators. Explain and justify equipment, travel, (including any plans for out-of-state travel), supplies and training costs. If you have joint costs refer to GAPP Chapter 100, Section 103 and the Compliance Section D (9) of the application for additional information.
 - 2. **Personnel, Other Direct Costs, Equipment and Contracts):** Submit a budget with these sections and form(s) completed as necessary to support costs for the period August 1, 2011 – September 29, 2012.

Funds may be used to support personnel, their training, travel (see OBM Web site <http://obm.ohio.gov/MiscPages/TravelRule> and supplies directly related to planning, organizing and conducting the Initiative/program activity described in this announcement. Fringe rates for support personnel cannot exceed 35 percent; fringe rates submitted that exceed 35 percent are subject to special conditions and may be denied.

When appropriate, retain all contracts on file. The contracts should not be sent to ODH. A completed "Confirmation of Contractual Agreement" (CCA) form must be submitted via GMIS 2.0 for each contract once it has been signed by both

parties. The submitted CCA must be approved by ODH before contractual expenditures are authorized.

Submission of the “Confirmation of Contractual Agreement” (CCA) via the ODH’s GMIS 2.0 system indicates acceptance of ODH GAPP. Clicking the “Approve” button signifies authorization of the submission by an agency official and constitutes electronic acknowledgement and acceptance of GAPP rules and regulations. CCAs cannot be submitted until after the 1st quarter grant payment has been issued.

Where appropriate, itemize all equipment (**minimum \$300 unit cost value**) to be purchased with grant funds in the Equipment Section.

- 3. Compliance Section D:** Answer each question on this form as accurately as possible. Completion of the form ensures your agency’s compliance with the administrative standards of ODH and federal grants.
 - 4. Funding, Cash Needs and Budget Summary Sections:** Enter information about the funding sources and forecasted cash needs for the program. Distribution should reflect the best estimate of need by quarter. Failure to complete and balance this section will cause delays in receipt of grant funds.
- C. Assurances Certification:** Each subgrantee must submit the Assurances (Federal and State Assurances for Subgrantees) form. This form is submitted as a part of each application via GMIS 2.0. The Assurances Certification sets forth standards of financial conduct relevant to receipt of grant funds and is provided for informational purposes. The listing is not all-inclusive and any omission of other statutes does not mean such statutes are not assimilated under this certification. Review the form and then press the “Complete” button. By submission of an application, the subgrantee agency agrees by electronic acknowledgment to the financial standards of conduct as stated therein.
- D. Project Narrative:**
- 1. Executive Summary:** Identify the community and target population(s) to be served. Describe services and programs to be offered and what agency or agencies will provide those services. Describe the public health problem(s) within your region that the program will address. (1 page maximum)
 - 2. Description of Applicant Agency/Documentation of Eligibility/Personnel:**
 - Briefly discuss the applicant agency's eligibility to apply.
 - Summarize the agency's structure as it relates to this program and, as the lead agency, how the program will be managed. Each agency should have at least a portion of a medical administrator and a portion of an expanded HIV testing

coordinator funded through this project. See Appendix D for required duties of these positions.

- Describe the capacity of your organization, its personnel or contractors to communicate effectively and convey information in a manner that is easily understood by diverse audiences. This includes persons of limited English proficiency, those who are not literate, have low literacy skills, and individuals with disabilities.
- Note any personnel or equipment deficiencies that will need to be addressed in order to carry out this grant.
- Describe plans for hiring and training, as necessary.
- Delineate all personnel who will be directly involved in program activities; include qualifications of medical administrator and program coordinator.

3. **Problem/Need:** Identify and describe the local health status concern that will be addressed by the program. Do not restate national and state data. The specific health status concerns that the program intends to address may be stated in terms of health status (e.g., morbidity and/or mortality) or health system (e.g., accessibility, availability, affordability, appropriateness of health services) indicators. The indicators should be measurable in order to serve as baseline data upon which the evaluation will be based. Clearly identify the target population.

Explicitly describe segments of the target population who experience a disproportionate burden of the local health status concern (this information must correlate with the Statement of Intent to Pursue Health Equity Strategies.)

Include a description of other agencies/organizations also addressing this problem/need.

4. **Methodology:** By answering the following section questions in narrative form, applicants should identify the program goals, **Specific, Measureable, Attainable, Realistic & Time-Phased (SMART)** process, impact, or outcome objectives and activities. Indicate each SMART objective will be evaluated to determine the level of success of the program. *In addition, please describe how program activities will address health disparities.*

- 4a. Approximately how many patients visit the ED in a calendar year?
- 4b. Approximately what proportion of that population meets the disproportionately affected population(s) targeted by this RFP?
- 4c. Does the ED currently conduct HIV testing? If so how many test were conducted in 2010? What test technology was used? How many positives were identified?
- 4d. What type of HIV test technology will the ED utilize to conduct expanded HIV testing?
- 4e. How will the ED identify individuals for HIV testing within the first 12 months of this grant? For example, diagnostic testing, targeted testing,

screening or universal testing?

- 4f. What HIV testing staffing model will be used within the ED? For example, indigenous staff (integrated model), supplemental counseling staff (parallel model), testing teams, laboratory staff.
- 4g. Describe how the applicant agency will ensure that data is collected, checked for quality and reported to ODH monthly.
- 4h. What barriers currently exist to implementing HIV testing within the ED?
- 4i. Indicate that the applicant agency is willing to comply with ODH's Expanded and Routine HIV Testing Protocol.
- 4ia. Discuss that the applicant agencies understanding of DIS and the importance of contacting DIS in the event of a HIV positive test result. Discuss that the applicant agency has made contact with the local AIDS Coordinator and or DIS Supervisor and will follow the procedures to initiate partner services in the service area.

Complete the following tables:

Table A:

Date: by	# Patients will be Tested	% Positive	% Patients who receive test result	% Patients linked to care
September 2011				
March 2012				
September 2012				
September 2013				

Table B:

Note: Dates can span from September 1, 2011 – September 29, 2013

Protocol	Date Completed:
1st Draft ED HIV Testing Protocol	
Final ED HIV Testing Protocol	
1 st Draft ED Linkage to Care and Referral Protocol	
Final Draft ED Linkage to Care and Referral Protocol	
1 st Draft ED HIV Testing Sustainability Plan	
Final Draft ED HIV Testing Sustainability Plan	

- E. Civil Rights Review Questionnaire - EEO Survey:** The Civil Rights Review Questionnaire (EEO) Survey is a part of the Application Section of GMIS 2.0. Subgrantees must complete the questionnaire as part of the application process. This

questionnaire is submitted automatically with each application via the Internet.

- F. Attachment(s):** Attachments are documents deemed necessary to the application that are not a part of the GMIS 2.0 system. Attachments that are non-Internet compatible must be postmarked or received on or before the application due date. An original and the required number of copies of non-Internet compatible attachments must be mailed to the ODH, Grants Administration Central Master Files address on or before **July 11, 2011**. All attachments must clearly identify the authorized program name and program number. A minimum of an original and one copy of non-Internet attachments are required.
- G. Electronic Funds Transfer (EFT) Form:** Print in PDF format and mail to ODH, Grants Administration, Central Master Files address. The completed EFT form **must be dated and signed, in blue ink, with original signatures**. Submit the original and one copy. **(Required only if new agency, thereafter only when banking information has changed.)**
- H. Internal Revenue Service (IRS) W-9 and Vendor Forms:** Print in PDF format and mail to ODH, Grants Administration, Central Master Files address. The completed IRS W-9 form **must be dated and signed, in blue ink, with original signatures**. Submit the original and one copy. **(Required if new agency, thereafter only when tax identification number or agency address information has changed.) One of the following forms must accompany the IRS, W-9:**
- 1. Vendor Information Form (New Agency Only), or**
 - 2. Vendor Information Change Form (Existing Agency with tax identification number, name and/or address change(s).)**
 - 3. Change request in writing on Agency letterhead (Existing Agency with tax identification number, name and/or address change(s).)**

Print in PDF format and mail to ODH, Grants Administration, Central Master Files address. The completed appropriate Vendor Form **must be dated and signed, in blue ink, with original signatures**. Submit the original and one copy of each.

- I. Public Health Impact Statement Summary:** Submit two copies of a one-page program summary regarding the impact to proposed grant activities on the Local Health Districts Improvement Standards **(for competitive cycle only; for continuation, only if changed)**.
- J. Public Health Impact & Intent to Pursue Health Equity Statements:** Submit two copies of the response/statement(s) of support from the local health district(s) to your agency's communication regarding the impact of the proposed grant activities on the Local Health Districts Improvement Standards and Intent to Pursue Health Equity Statements. If a statement of support from the local health district is not available, indicate that and submit a copy of the program summary your agency forwarded to

the local health district(s) **(for competitive cycle only; for continuation, only if changed).**

- K. Liability Coverage:** Liability coverage is required for all non-profit agencies. Non-profit organizations **must** submit documentation validating current liability coverage. Submit two copies of the Certificate of Insurance Liability **(Non-Profit Organizations only; current liability coverage and thereafter at each renewal period.)**
- L. Non-Profit Organization Status:** Non-profit organizations **must** submit documentation validating current status. Submit two copies of the Internal Revenue Services (IRS) letter approving non-tax exempt status **(Non-Profit Organizations only; for competitive cycle only; for continuation, only if changed.)**
- M. Declaration Regarding Material Assistance/Non-Assistance to a Terrorist Organization (DMA) Questionnaire:** The DMA is a questionnaire that must be completed by all non-governmental grant applicant agencies to certify that they have not provided “material assistance” to a terrorist organization (Sections 2909.32, 2909.33 and 2909.34 of the Ohio Revised Code). The completed DMA Questionnaire **must be** dated and signed, in blue ink, with the Agency Head’s signature. The DMA Questionnaire (in PDF format. [Adobe Acrobat](#) is required) is located at the Ohio Department of Public Safety /Ohio Homeland Security website:

<http://www.publicsafety.ohio.gov/links/HLS0038.pdf>

- Print a hard copy of the form once it has been downloaded. The form must be completed in its entirety and your responses must be truthful to the best of your knowledge. **(Required by all Non-Governmental Applicant Agencies.)**
- N. Federal Funding Accountability and Transparency Act (FFATA) Requirements:** The Federal Funding Accountability and Transparency Act (FFATA) was signed on September 26, 2006. The intent is to empower every American with the ability to hold the government accountable for each spending decision. ODH is required to report all subgrants receiving \$25,000 or more of federal funds. All applicants applying for ODH grant funds required to complete the FFATA Reporting Form. A sample of the FFATA Reporting Form is attached to this RFP.

All applicants for ODH grants are required to obtain a Data Universal Number System (DUNS) and a Central Contractor Registration Number (CCR) and submit the information in the grant application, Attachment B. For information about the DUNS, go to <http://fedgov.dnb.com/webform>. For information about CCR go to www.ccr.gov.

Information on Federal Spending Transparency can be located at www.USAspending.gov or the Office of Management and Budget's website for Federal Spending Transparency at www.whitehouse.gov/omb/open.

(Required by all applicants, Attachment B is located on the GMIS Bulletin Board. It must be completed and attached to the GMIS Application/Project Comment Section.)

O. Attachments as Required by Program:

ATTACHMENT A - Ohio Department of Health Sub-Awardee Federal Funding Accountability and Transparency Act (FFATA) Reporting Form

IV. APPENDICES

- A.** GMIS 2.0 Training Form
- B.** Notice of Intent to Apply
- C.** Application Review form
- D.** Grant Required Positions
- E.** Ohio Expanded and Routine HIV Testing Protocol

ATTACHMENT A

**Ohio Department of Health Sub-Awardee
Federal Funding Accountability and Transparency Act (FFATA) Reporting Form**

Submission Date

____/____/____

Sub-Awardee Data

1	DUNS #	
2	DUNS # plus 4	
3	Name	
4	DBA Name	
5	Address - Street # 1	
6	Address - Street # 2	
7	Address - Street # 3	
8	City	
9	State	
10	County (select from list of Ohio counties)	
11	Zip plus 4	
12	Congressional District	
13	Sub-awardee - Parent DUNS #	
14	Amount of Sub-award/Contract	Completed by ODH
15	Sub-award Obligation/Action Date (i.e., date the NOA and/or Contract is signed/approved)	Completed by ODH
16	CFDA and Program Title	Completed by ODH
17	Federal Agency Name	Completed by ODH
18	Principal Place of Performance (PPP)- City (or County if as a whole)	
19	PPP - State	
20	PPP - County	
21	PPP - Zip + 4	
22	PPP - Congressional District	
23	Sub-award/Contract # (i.e., the project ID for sub-grants)	
24	Q1. In organization's previous FY did it receive 80% or more from federal contracts and \$25,000,000 or more from federal contracts? If yes, please see Q2.	
25	Q2. Does the public have access to compensation of senior executives via the section 6104 of the IRS Code of 1986? If "yes", then the project is not required to report the compensation information. If "no" please enter the compensation information.	
26	1 of 5 highest compensated officials - Name	

27	1 of 5 highest compensated officials - Amount	
28	2 of 5 highest compensated officials - Name	
29	2 of 5 highest compensated officials - Amount	
30	3 of 5 highest compensated officials - Name	
31	3 of 5 highest compensated officials - Amount	
32	4 of 5 highest compensated officials - Name	
33	4 of 5 highest compensated officials - Amount	
34	5 of 5 highest compensated officials - Name	
35	5 of 5 highest compensated officials - Amount	
36	Project Description	Completed by ODH
37	Agency Director/President	
38	Agency Program/Project Director	
39	Agency Phone Number	
40	Program Source/Treasury Account Symbol	Completed by ODH
41	CCR # (of Parent Agency if applicable)	

Complete section below if Agency is not in the State of Ohio

42	If 'Other' County Selected, name of county outside of Ohio	
43	If 'Out of State' Congressional District Selected, provide State and Congressional District	
44	If 'Out of State' PPP - County	
45	If 'Out of State' PPP - Congressional District	

Ohio Department of Health
GMIS 2.0 TRAINING

ALL INFORMATION REQUESTED MUST BE COMPLETED for EACH EMPLOYEE FROM YOUR AGENCY WHO WILL ATTEND A GMIS 2.0 TRAINING SESSION.

(Please Print Clearly or Type)

Grant Program _____ RFP Due Date _____

County of Applicant Agency _____

Federal Tax Identification Number _____

NOTE: The applicant agency/organization name must be the same as that on the IRS letter. This is the legal name by which the tax identification number is assigned and as listed, if applicable, currently in GMIS.

Applicant Agency/Organization _____

Applicant Agency Address _____

Agency Employee to attend training _____

Telephone Number _____

E-mail Address _____

GMIS 2.0 Training Authorized by: _____

(Signature of Agency Head or Agency Fiscal Head)

Required:

Please check one: _____ Yes – I ALREADY have access to the ODH GATEWAY (SPES, ODRS, LHis, etc.)

_____ No – I DO NOT have access to the ODH

GATEWAY

Please indicate your training date choices: 1st choice _____, 2nd choice _____ 3rd choice _____

Mail, E-mail or Fax To: **GAIL BYERS**
Grants Administration Unit
Ohio Department of Health
246 N. High Street
Columbus, Ohio 43215
E-mail: gail.byers@odh.ohio.gov

Fax: 614-752-9783

CONFIRMATION OF YOUR GMIS 2.0 TRAINING SESSION WILL BE E-MAILED TO YOU
Request for Training must be received by 5:00PM, June 9, 2011

APPENDIX B

**OHIO DEPARTMENT OF HEALTH
Notice of Intent to Apply for Funding /GMIS 2.0 Training Request form**

*ALL INFORMATION REQUESTED BELOW MUST BE COMPLETED
(Please Print Clearly or Type)*

This form must be received by 5:00 pm, June 9, 2011

For Competitive Grant Cycle ONLY:

RFP Due Date: _____

County of Applicant Agency: _____

Federal Tax Identification Number: _____

NOTE: The applicant agency/organization name must be the same as that on the IRS letter. This is the legal name by which the tax identification number is assigned and as listed, if applicable, currently in GMIS.

Agency/Organization Name: _____

Agency Address: _____

Agency Contact: _____

Telephone Number: _____

Contact E-mail Address (Required): _____

Agency Fax # (Required): _____

GMIS 2.0 Training Authorized by: _____

(Signature of Agency Head or Agency Fiscal Head)

Required:

(Check all that apply)

- Our agency will apply for this funding opportunity
- Our agency has not previously applied for an ODH grant
- Our agency has access to ODH Gateway (e.g. GMIS, SPES, ODRS, LHIS)
- Our agency **does not** need GMIS 2.0 training
- Our agency **does** need GMIS 2.0 training

Name of Employee(s) to attend GMIS training: _____

Confirmation of receipt and notice of GMIS training dates will be sent to agency within 5 days of receipt at ODH.

Fax or E-mail Intent to Apply to: Nicole Brennan, HIV Prevention Program Manager
Fax Number: 614-644-1878
E-Mail Address: nicole.brennan@odh.ohio.gov

**HIV PREVENTION
OHIO EMERGENCY DEPARTMENT
EXPANDED HIV TESTING
GRANT APPLICATION REVIEW-RATING FORM**

Agency: _____ Date: _____

Reviewer: _____ Total Score: _____

Recommended Funding Level: _____

SCORE TABLE:

Use the following table as a guide in completing the review sheet.

Point Value	Criterion Unmet	Criterion Partially Met	Criterion met
1	0		1
2	0	1	2
3	0	1, 2	3
4	0, 1	2, 3	4
5	0, 1	2, 3	4, 5

Criterion Unmet – Does not answer the question nor address any of the required issues.

Criterion Partially Met - Attempts to answer the question, but does not offer specific information. Answers the question and offers some concrete information.

Criterion Met - Offers substantive information; a complete answer in a clear manner. An exemplary answer, uses quantitative measure for example; is concise and to the point.

NOTE: The maximum point value is shown in each section. Please score each section using the score table as a guide. Your comments are important and provide clarification when necessary.

TOTAL MAXIMUM SCORE: 100 points

MINIMUM SCORE TO BE ELIGIBLE FOR FUNDING: 70 points

COMPONENT OF PROPOSAL	Max points possible	SCORE	STRENGTHS / WEAKNESS
<i>1. PROGRAM NARRATIVE</i>	80 points total		
1. EXECUTIVE SUMMARY A one page summary of the proposal-should include target population, services and programs to be offered and what agency (ies) will provide those services.	2		
A description of the public health problems that the project will address.	3		
Total:	5		
2. Description of Applicant Agency/ Documentation of Eligibility Demonstrate the applicant agency's eligibility to apply.	3		
Summarize the agency's structure as it relates to this program	4		
Each agency should have at least a portion of a medical administrator and a portion of an expanded HIV testing coordinator funded through this project.	2		
Describe the capacity of your organization, its personnel or contractors to communicate effectively	2		
Note any personnel or equipment deficiencies	2		
Describe plans for hiring and training personnel to assure clients will receive culturally appropriate care.	3		
Note any personnel or equipment deficiencies; Describe plans for hiring and training, as necessary	4		

COMPONENT OF PROPOSAL	Max points possible	SCORE	STRENGTHS / WEAKNESS
Delineate all personnel who will be directly involved in program activities; include qualifications of medical administrator and program coordinator.	5		
Total:	25		
3. Problem/Need Identify and describe the local health status concern(s) that will be addressed by the program. Specific health status concerns that the program intends to address may be stated in terms of health status (e.g., morbidity and/or mortality) or health system (e.g., accessibility, availability, affordability, appropriateness of health services) indicators. The indicators should be measurable in order to serve as baseline data upon which the evaluation will be based.	4		
Clearly identify the target population.	4		
Include a description of other agencies/organizations also addressing this problem/need.	2		
Total:	10		
1D. Health Disparities Statement Applicant submitted a 1 1/2 page summary that included program activities and strategies to address health disparities.	5		
Total:	5		
4. METHODOLOGY a. Approximately how many patients visit the ED in a calendar year?	2		

COMPONENT OF PROPOSAL	Max points possible	SCORE	STRENGTHS / WEAKNESS
b. Approximately what proportion of that population meets the disproportionately affected population(s) targeted by this RFP?	2		
c. Does the ED currently conduct HIV testing? If so, how many tests were conducted in 2010? What model of testing is used? What test technology was used? How many positives were identified?	5		
d. What type of HIV test technology will the ED utilize to conduct expanded HIV testing?	2		
e. How will the ED identify individuals for HIV testing within the first 18 months of this grant? For example, diagnostic testing, targeted testing, screening or universal testing?	2		
f. What HIV testing staffing model will be used within the ED? For example, indigenous staff (integrated model), supplemental counseling staff (parallel model), testing teams, laboratory staff.	2		
h. Describe how the applicant agency will ensure that data is collected, checked for quality and reported to ODH monthly.	5		
i. Indicate that the applicant agency is willing to comply with ODH's Expanded and Routine HIV Testing Protocol. In addition to activities related to section L 2.	5		

COMPONENT OF PROPOSAL	Max points possible	SCORE	STRENGTHS / WEAKNESS
Completed Table A	5		
Completed Table B	5		
Total:	35		
3. BUDGET	10 Points Total		
3A. Budget Narrative A detailed narrative budget justification which describes how the categorical costs are derived should be provided. This should discuss the necessity, reasonableness and ability to allocate the proposed costs. Budget narrative matches the budget submitted in GMIS 2.0.	5		
All personnel, contractors, other direct costs (e.g. supplies, travel and training) should be explained and justified.	5		
Total:	10		
6. OVERALL QUALITY	10 Points Total		
Clarity / completeness	5		
Adherence to RFP guidelines	5		
Total:	10		
CUMULATIVE TOTAL	100		

Recommendation of Reviewer:

Approval (funding) of proposal as submitted (no conditions)

Approval (funding) of proposal with conditions (please list conditions below)

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

Disapproval of project. State reason(s) below:

1. _____

2. _____

3. _____

Signature of Reviewer

Date

Grant Required Positions

Each funded agency is required to fund at least a portion of two positions with this grant, an administrator and a grant coordinator. Below are the minimum required tasks of these positions.

- **Emergency Department (ED) Expanded Testing Administrator**

ED expanded testing administrators are clinical and administrative directors within the ED. These include medical chiefs, formal and informal physician and nurse leaders, administrative directors, and residency and fellowship directors. Expanded testing administrators are expected to create a supportive environment for HIV testing. They should champion the effort among other hospital administrators and ED staff.

- Act as a champion for HIV testing within the ED, promoting routine integrated HIV testing within the ED.
- Participate in quarterly conference calls, facilitated by ODH, with other ED administrators to discuss testing models, best practices, challenges and concerns.
- Set yearly goals for ED HIV testing.
- Develop an ED HIV testing protocol.
- Develop an ED linkage to care and referral protocol.
- Develop an HIV testing sustainability plan.

- **Project Coordinator**

- Conduct, compile, and evaluate a survey of staff attitudes regarding HIV testing within the ED.
- Order test kits from ODH.
- Manage test kit usage, preventing expiration or wastage of test kits.
- Submit test kit tracking report to ODH monthly.
- Perform quality assurance on data collection forms.
- Assure that data collection includes all required testing indicators.
- Assure that ODH receives testing data on a monthly basis.
- Assist with the training and technical assistance of ED staff to perform HIV testing.
- Assure that local health department has been notified of every HIV positive case.
- Participate in quarterly conference calls with ED administrator.
- Assist with the development of an ED HIV testing protocol.
- Assist with the development of an ED linkage to care and referral protocol.
- Assist with the development of an HIV testing sustainability plan.

APPENDIX E

Ohio Department of Health HIV Prevention Program

EXPANDED AND ROUTINE HIV TESTING INITIATIVE PROTOCOL

2011

TABLE OF CONTENTS

<u>Introduction</u>	3
Goals of Ohio’s HIV Expanded Testing Initiative	4
<u>ETI Guidelines</u>	5
<u>ETI Standards</u>	6
<u>Ohio Testing Law</u>	7
Definitions	7
Quick Reference	8
Reference links	9
<u>Partner Notification Services</u>	10
<u>ETI Health Care Testing Models</u>	11
Provider Initiated	11
Tester Initiated	12
In-house CTR	12
<u>ETI Outreach</u>	13
<u>Rapid HIV Testing</u>	14
<u>HIV Test Results</u>	15
Negative	15
Positive	16
Indeterminate	16
<u>Lab Submission</u>	18
<u>ETI Data</u>	19
<u>HIV Referral</u>	21
<u>Appendix</u>	23
<u>Acronyms</u>	24
Important Phone Numbers	25
Examples of Closed-Ended vs. Open-Ended Questions	28
Examples of Global vs. Specific Risk Reduction Steps	29
Risk Reduction Plan	30
Consent Form (English)	31
Consent Form (Spanish)	32
HIV Sampling Submission Form	33
Single Session Counseling Flowchart	34
Refrigerator Temperature Log	35
External Control Log	37
Test Result Log	39
Confirmatory Specimen Transfer Log	41
HIV Rapid Test False Positive Report	43
Monthly Test Kit Report	44
Content of a Referral Resource Guide	47
HIV Test Form Manual	49

INTRODUCTION

This protocol will serve as the standard and required guidelines for operating an HIV testing site funded through the Ohio HIV Expanded Testing Initiative (ETI) grant administered by the Ohio Department of Health's HIV Prevention Program.

Background

Approximately 25 percent of people living with HIV/AIDS (PLWHA) in the United States do not know their HIV status.¹ The National HIV/AIDS Strategy (NHAS) released in July 13, 2010, outlines the commitment to reduce HIV incidence in the United States by 25 percent by 2015.² In congruence with the 2006, Centers for Disease Control and Prevention's (CDC) "*Revised Recommendations for HIV Testing for Adults, Adolescents, and Pregnant Women in Health-Care Settings*"³ The Ohio Department of Health's (ODH) HIV Prevention Program has developed this protocol to assist healthcare, clinical and non-clinical settings develop and implement strategies for the expanded and routine offering of HIV testing to patients.

The HIV/AIDS epidemic impacts persons regardless of sex, age, race/ethnic group and/or geographic region in Ohio, but the impact is not the same for all population groups.⁴

- In 2009, there were 1,129 new diagnoses of HIV infection in Ohio. Among the cases: 21 percent were female, 27 percent were 25-34 years old, 49 percent were black and 44 percent were white.
- The number of persons living with a diagnosis of HIV infection in Ohio continues to increase each year. As of 2008, 15,442 persons were known to be living with an HIV infection, of which 49 percent were living with AIDS.
- Blacks and Hispanics are disproportionately impacted by HIV/AIDS. The rate of persons living with an HIV infection per 100,000 population in Ohio in 2008 was nearly six times higher among blacks compared to whites.
- In 2008, 36 percent of persons living with a diagnosis of HIV infection in Ohio were in the 45-54 year-old age group: 79 percent were male, 30 percent were 25-34 years old, 49 percent were black and 44 percent were white.
- The 2009 risk estimates indicate male-to-male sexual contact was the leading mode of transmission for HIV among males in Ohio, followed by heterosexual contact and injection drug use. Among females in Ohio, heterosexual contact was the leading mode of transmission, followed by injection drug use.
- According to ODH's Office of Vital Statistics, HIV infection was the sixth leading cause of death among persons 25-44 years of age in Ohio in 2007.

¹ Centers for Disease Control and Prevention (CDC). *Estimates of new HIV infection in the United States*. 2008. Available at: <http://www.cdc.gov/hiv/topics/surveillance/resources/factsheets/pdf/incidence.pdf>

² *The National HIV/AIDS Strategy for the United States* Available at <http://www.whitehouse.gov/ONAP>

³ <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>

⁴ Ohio Department of Health, HIV/AIDS Surveillance. *Ohio HIV/AIDS Integrated Epidemiological Profile*. 2010. Available at: <http://www.odh.ohio.gov/healthStats/disease/hivdata/pf1.aspx>

Goals of Ohio's HIV Expanded Testing Initiative

- Increase HIV testing opportunities for populations disproportionately affected by HIV-primarily:
 - African American and Hispanic men and women,
 - Men who have sex with men (MSM)
 - injection drug users (IDUs)
- Increase the proportion of HIV-infected persons who are aware of their infection and are linked to appropriate services.
- Identify strategies for leveraging resources to maximize the yield and sustainability of routine HIV screening programs in healthcare settings.
- Promote early knowledge of HIV status through HIV testing and ensure that all persons either recommended for or receiving HIV testing are provided information regarding transmission, prevention, and the meaning of HIV test results.

Key Recommendations⁵:

For patients in all health-care settings

- HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Persons at high risk for HIV infection should be screened for HIV at least annually.
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.

For pregnant women

- In addition to the above listed recommendations, HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women.
- Repeat screening in the third trimester is recommended in certain jurisdictions with elevated rates of HIV infection among pregnant women.

Integration of Services

- All patients initiating treatment for TB should be screened routinely for HIV infection.
- All patients seeking treatment for STDs, including all patients attending STD clinics, should be screened routinely for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavior risks for HIV infection.

⁵ Centers for Disease Control and Prevention (CDC). *Estimates of new HIV infection in the United States*. 2008. Available at: <http://www.cdc.gov/hiv/topics/surveillance/resources/factsheets/pdf/incidence.pdf>

ETI GUIDELINES

To participate in the HIV ETI and receive federally procured HIV rapid testing kits and laboratory support ETI testing sites shall agree to the following guidelines:

- Understand that per the provider contract and ETI protocol, ODH will provide, as federal and state funds allow HIV testing kits and ODH Laboratory support at no cost.
- Understand that ODH is the point of contact for all expanded HIV testing protocol and technical assistance requests.
- Will comply with the Ohio Revised Code (3701.242) and Ohio Administrative Code (3701-3-11) in conjunction with the established ODH HIV ETI Protocol.
- Will submit all confirmatory samples for preliminary positive rapid test results to the ODH Laboratory, or a laboratory as prescribed by ODH.
- Will contact a disease investigation specialist supervisor upon receipt of a preliminary and/or confirmatory positive HIV test result.
- Will maintain all records related to the HIV testing in a confidential manner.
- Will provide HIV testing at no charge to the patient when using HIV test kits provided by ODH.
- Will comply with the requirements for test kit ordering, accountability, and management. Will maintain proper storage and handling standards for HIV testing kits recommended in the most recent addition of the Clinical Laboratory Improvement Amendments (CLIA) certificate/waiver requirements.
- Will submit to ODH the HIV Test Kit Tracking form by the 7th day of each month. Will assure these forms are reviewed for quality assurance.
- Will submit to ODH HIV testing forms, which have been reviewed for quality assurance, on a monthly basis.
- Understand and agree that the ODH HIV Prevention Program will conduct annual site visits. Site visits will consist of protocol, storage and handling compliance, as well as quality assurance checks.
- Will provide the ODH HIV Prevention Program with the names of individuals designated as program contacts. Will advise ODH of any personnel changes, in writing, within thirty (30) days of a staff member's first and/or final day of employment.
- ODH or the ETI testing site may terminate this agreement, in writing, at any time for personal reasons or failure to comply with these requirements. Upon termination, the testing site will properly return any unused ODH supplied test kits.

ETI STANDARDS

- **The testing site must have a written HIV testing protocol in place.** The protocol should address, but not be limited to the following issues: testing procedures, issues of confidentiality and record keeping, test kit maintenance, and procedures for quality assurance of testing data.
 - ETI testing sites that are also Ohio counseling, testing and referral (CTR) sites must describe in writing to ODH how the ETI and CTR program will be implemented separately and follow two different testing guidelines.
- **All personnel who will be conducting HIV tests must be trained to administer the test.**
- **Maintain a list of anonymous testing locations.** Sites must provide a list of testing locations that are able to administer anonymous HIV testing for clients unwilling to have a confidential test.
- **Test results must be given in person, and the medical personnel/counselor and client must be in a private space.** After receiving the results, the client may bring in a supportive friend, partner or family member. The following situations are exempted: when the client requires an interpreter, when the HIV counselor is being audited, or when an HIV counselor is being trained or supervised.
- **When a site receives the faxed HIV positive lab result, the testing location should call the Disease Intervention Specialist (DIS) Supervisor to notify them of the positive result, and advise them as to when the client will return for their confirmatory results.** If present, DIS will offer partner services to the client during this session. If an HIV-positive client fails to return for the confirmatory results, the DIS Supervisor will be notified the day the client fails to return.
 - **HIV positive clients should be linked to medical care and an HIV case manager as soon as possible.**
 - **HIV positive clients and individuals at high risk for HIV infection should receive other medical and HIV prevention referrals as necessary.** Integration of STD, hepatitis, TB and immunization screening services should be utilized whenever possible.
- **Clinical Laboratory Improvement Amendments:** The Clinical Laboratory Improvement Amendments of 1988 (CLIA) establish quality standards for laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results. CLIA requires that any facility examining human specimens for diagnosis, prevention or treatment of a disease, or for assessment of health, must register with the federal Centers for Medicare & Medicaid Services (CMS) and obtain CLIA certification. For more information go to www.cdc.gov.

OHIO TESTING LAW

Definitions

- **Anonymous Testing** – Patient’s name is not recorded with test result.
- **Confidential** – Patient’s name is recorded with test result. HIPPA standards and requirements are maintained.
- **HIV Prevention Counseling** – Refers to an interactive process of assessing risk, recognizing specific behaviors that increase the risk for acquiring or transmitting HIV and developing a plan to take specific steps to reduce risk.
 - **Pre-test Counseling** can include: (1) discussing HIV, risk factors and preventive methods; (2) explaining the meaning of positive and negative test results and their implications; (3) assessing the patient’s personal and social supports; (4) determining the patient’s readiness to cope with test results; (5) discussing disclosure of test results to others; and (6) advising the patient if reporting positive test results to health authorities is required.
 - **Post-test Counseling** can include: (1) informing the patient of the results and meaning of the test results; (2) providing education and avoiding risks of sexual and injection drug exposures; and, for patients who test positive, (3) assessing the impact of test results for the patient family; (4) explaining treatment options; (5) discussing partner counseling and disclosure of test results to others; (6) making referrals to HIV Prevention services; and (7) initiating treatment plan.
- **General Consent** – Consent for HIV screening is included in the general medical consent.
- **Informed Consent** – A process of communication between patient and provider through which an informed patient can choose whether to undergo HIV testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding HIV, the risks and benefits of testing, the implications of HIV testing results, how test results will be communicated, and the opportunity to ask questions.
- **Name-based reporting** – Cases are reported by patient name (required in Ohio).
- **Opt-in** – Patients typically are provided pre-HIV test counseling and must consent specifically to an HIV antibody test, either orally or in writing.
- **Opt-out** – Performing HIV screening after notifying the patient that: the test will be performed; and the patient may elect to decline or defer testing. Assent is inferred unless the patient declines testing (Ohio is an opt-out state).
- **Routing Testing** – HIV screening that is performed routinely during health care encounters.

- **Rapid Testing** – Testing with any of the FDA approved rapid HIV tests that provide results in 30 minutes or less.

Ohio Law Quick Reference

Informed Consent: An HIV test may be performed by or on the order of a health care provider who, in the exercise of the provider’s professional judgment, determines the test to be necessary for providing diagnosis and treatment to the individual to be tested.

Anonymous Testing: If the individual or the individual’s parent or guardian has given consent to the provider for medical or other health care treatment. The health care provider shall inform the individual of the individual’s right to an anonymous test. A health care facility or health care provider that does not provide anonymous testing shall refer an individual requesting an anonymous test to a site where it is available.

Minor/Adolescent Testing: A minor may consent to be given an HIV test. The consent is not subject to disaffirmance because of minority. The parents or guardian of a minor giving consent under this division are not liable for payment and shall not be charged for an HIV test given to the minor without the consent of a parent or the guardian.

Post-Test Counseling: The health care provider ordering an HIV test shall provide post-test counseling for an individual who receives an HIV-positive test result.

Reporting: Testing locations shall report promptly every case of AIDS, every AIDS-related condition, and every confirmed positive HIV test to the department of health on forms and in a manner prescribed by the director of health. In each county the director shall designate the health commissioner of a health district in the county to receive the reports.

Ohio HIV Testing Law References (3/1/2011)

	Policy Category	Type	Section Code(s)
PRE-TESTING	Introduction to HIV testing Law	Definitions	ORC 3701.24
	Who may perform an HIV Test	Health care provider within provider's scope of practice	ORC 3701.242 OAC 3701-3-11
	Informed Consent	Consent for medical care required – written or verbal	ORC 3701.242 OAC 3701-3-11
		Minors can give consent (age 13)	ORC 3701.242 OAC 3701-3-11
	Counseling requirements	Pre-test counseling not-required	ORC 3701.242 OAC 3701-3-11
	Anonymous testing	State Department of Health must support counseling and testing programs that offer anonymous testing	ORC 3701.241
		Any individual seeking an HIV test has the right, on the individual's request, to an anonymous test.	ORC 3701.242 OAC 3701-3-11
POST-TESTING	Post test counseling	The health care provider ordering an HIV test shall provide post-test counseling for an individual who receives an HIV-positive test result.	ORC 3701.242
	Disclosure/confidentiality	Exceptions to confidentiality	ORC 3701.243
		Sexual partner notification	ORC 3701.241
		Court orders may allow access to confidential test results	ORC 3701.243
Reporting	HIV diagnoses must be reported to designated local health department	ORC 3701.24	
OTHER	Testing of minors/adolescents	Minors may consent to HIV testing	ORC 3701.242 OAC 3701-3-11

Recommended Resources

129th Ohio General Assembly
<http://www.legislature.state.oh.us/>

Ohio Revised and Administrative Code
<http://codes.ohio.gov/>

State HIV Testing Laws Compendium – 2011
<http://www.nccc.ucsf.edu/docs/Ohio.pdf>

Infectious Disease Control Manual
<http://www.odh.ohio.gov/healthresources/infectiousdiseasemanual.aspx>

PARTNER NOTIFICATION SERVICES

Partner notification services are defined as voluntary and confidential services that assist persons living with HIV to tell their partner(s) about possible exposure, and to facilitate linkages to services. Partner notification services are provided by specifically trained health professionals called Disease Intervention Specialists (DIS).

- **When a site receives the faxed HIV positive lab result, the HIV test site must call the DIS Supervisor to notify them of the positive result, and advise them as to when the client will return for their results.** The DIS will offer partner notification services to the client during this session. (Please refer to Appendix B for the supervisor in your region).
- **Partner notification services will be offered to all clients testing HIV-positive who return for their confirmatory test results.**
- **If a client tests confidentially and is HIV-positive, but fails to return for their result, a DIS will discretely contact the client to give them their result.**
- **The DIS will explain partner notification services to the client and together they will decide if it is a good time to discuss partners.**
- **If the client and DIS decide that the result-giving session is not a good time to discuss partners, the DIS will arrange to meet with the client at another time to conduct partner notification services.**
- **The DIS takes responsibility for confidentially contacting partners and notifying them of their possible exposure.** At the time of notification, the DIS offers risk reduction counseling and HIV testing, or makes referrals for counseling/testing. Stringent confidentiality procedures are followed and information concerning the identity of the original client is never disclosed.

ETI HEALTH CARE TESTING MODELS

This protocol describes three models for implementing the routine offer of HIV testing in clinical settings. The three models described in this section are:

- Provider-initiated testing (integrated)
- Tester-initiated testing (parallel)
- In-house counseling & testing program referral

Please note that there are many other models, and variations on these models that may effectively offer HIV testing in a health care setting. Providers are advised to develop and implement a model that best fits their existing clinical framework, resources and patient base. These three models are broadly described to elicit thought and conversation as to which strategy best suits the clinical setting in question. In all models, it is preferred that rapid HIV testing and phlebotomy are available.

Models may be modified based on available resources and specific clinical settings. For example, if funding and/or staffing for the routine testing of all patients within a clinical setting during all hours of operation is not available or feasible, then an implementation model may be modified so that patients are prioritized based on the presentation of symptoms and disclosed risk indicators for HIV acquisition. Therefore, patients that present with symptoms of infection (e.g. fever or rash) or with a history of high risk behavior that may place them at risk for HIV infection (e.g. injection drug use, unprotected sex) may be pre-screened and offered an HIV test. Alternatively, a health care provider may elect to routinely screen all patients seen during certain hours or on certain days.

When considering the implementation of routine screening in clinical settings, health care providers are encouraged to:

- Assess their current clinical environment and patient flow
- Ascertain available resources (e.g. staff, rapid HIV testing technology, marketing tools, reimbursement mechanisms)
- Select a model for the implementation of routine testing
- Select a strategy for approaching patients regarding HIV testing
- Select tools to support the marketing and implementation of this initiative

Provider-Initiated Model:

In this model, the health care provider routinely offers patients an HIV test and recommends testing as a standard component of medical care. There are many variations of this model given available staffing and resources. The term “health care provider” is used broadly in this model and may include individuals such as the patient’s physician, nurse, practitioner, physicians assistant, intake nurse, medical assistant, phlebotomist/laboratorian and clinic receptionist.

This model, also known as an integrated medical model, may use a team approach to introduce and provide the HIV test. During triage the nurse may obtain the specimen for rapid HIV testing or inform the physician to order an HIV test through the clinic laboratory. Or, the physician may

be the individual who initiates the testing process during evaluation.

Determining which medical personnel will obtain the specimen to be tested may depend on the staff, time and HIV test technology (rapid test versus conventional test) available.

Test results should be delivered in person. In the case of a reactive rapid test or positive conventional test result, physicians (or a clinical provider designated by the physician) should ensure that the patient receives the test result and an explanation of the results of the test and is referred to care for his/her HIV infection.

Development of the testing model should consider how to:

- Maintain patient confidentiality
- Assess patient's capacity to understand the test
- Obtain informed written consent to test (if not included in general medical consent)
- Perform the test (rapid HIV test preferred when possible)
- Deliver the test result in person
- Establish post-test counseling components for positive results
- Link to medical, preventive and supportive services as needed

Tester-Initiated Model:

In this model, also called a parallel model, a dedicated HIV tester routinely offers patients an HIV test and recommends testing as a standard component of medical care during the patient's clinical visit.

Again, there are variations of this model depending on the clinical space and environment. For instance, a dedicated HIV tester would be available at the clinic to routinely screen patients (days and hours may vary). Brochures and posters advertising HIV testing and hours of availability could be posted in the waiting room. The tester might choose to approach patients as they wait for their appointment, let them know HIV testing is available and offer to test. If it is preferred that clients in the waiting room not be approached by testers, physicians could refer the patient to the tester after the visit.

This model differs from the provider-initiated model because it is a dedicated HIV tester that:

- Offers the patient an HIV test
- Reviews testing information with the patient
- Obtains informed written consent to test (if not included in general medical consent)
- Procures a specimen to be tested and conducts the rapid HIV test (if available)
- Delivers the test result to the patient in person
- Shares the test results with the patient's physician so the patient may be connected to care as needed.

Unless the facility intends to pay the salary of an HIV tester for the long term, this model is not as sustainable as the integrated model.

In-House Counseling & Testing Referral Model

In this model, the patient's health care provider routinely offers patients a referral to an existing in-house or onsite HIV counseling and testing program for testing services.

The clinical facility may have access to an HIV counseling and testing program within the center, and once the collaborative relationship is formalized between the clinical setting and the HIV testing program, counselors from the existing in-house HIV testing program would conduct the counseling and testing process. The physician in the clinical setting would routinely offer HIV testing to all patients and then refer patients that accept testing to the in-house HIV program.

In this model, the counselor from the in-house HIV testing program must assume the following components in the counseling and testing session:

- Maintain patient confidentiality
- Assess patient's capacity to understand the test
- Obtain informed written consent to test (if not included in general medical consent)
- Perform the test (rapid HIV test preferred when possible)
- Deliver the test result in person
- Establish post-test counseling components for positive results
- Link to medical, preventive and supportive services as needed

When test results are made available to the counselor and physician, the counselor or the patient's physician may deliver the test result to the patient and engage him/her into HIV care and support services as needed. When initially discussing this collaborative arrangement, the clinical practice and HIV testing program should decide who delivers the result to the patient—the testing counselor or the patient's physician.

ETI Outreach (community-based organizations)

Outreach HIV testing is defined as testing that takes place outside an agency or testing site. This includes, but is not limited to, street outreach, crack houses, churches, bars, festivals, gay pride events, bathhouses, parks, college dormitories, migrant labor camps and public sex environments.

- **HIV testing in these settings must include plans to give the client her or his results.** If a rapid test is being used, the client needs to be assessed for readiness to receive the results on the same day. If client is unable to receive results during the outreach event, a time should be scheduled for the client to receive their HIV test result.
- **HIV prevention counseling in an outreach venue must be done in a confidential setting.** Creativity and flexibility is required to achieve a confidential setting in the field, where there is often little privacy and a lot of people. Using another room of the house or

building, moving to a secluded part of the park or street, are all examples of providing a more secure and confidential environment.

RAPID HIV TESTING

Rapid HIV tests are simple to use and require little or no specialized equipment. They make it possible to provide test results at the time the test is done. Rapid HIV testing can:

- Increase the number of persons at high risk for HIV who obtain a test.
- Increase the number of persons testing for HIV who receive their test results.
- Increase the early identification of new HIV infections and subsequent referral to care, prevention, and case management services.
- Increase the number of routine tests conducted in busy Emergency Departments, Urgent Cares, etc.
- Decrease the need for follow-up activities for clients who do not return for their HIV test results and associated prevention counseling.

Testing Technology

In Ohio, there are multiple types of HIV rapid test technologies that are used. The most common types are OraQuick®, Uni-Gold®, and Clearview®. The testing site is required to follow the instructions and protocols included in the package insert for the type of technology that is being used. The package inserts can be found on the respective websites listed below:

- OraQuick® - OraSure - www.orasure.com
- Uni-Gold® - Trinity Biotech - www.unigoldhiv.com
- Clearview® - Inverness Medical - www.invernessmedicalpd.com

Rapid HIV Testing Logs

The following logs (located in the Appendix) should be used to maintain proper quality assurance procedures:

- Refrigerator Temperature Log
- Ambient Temperature Log
- External Control Log
- Test Result Log
- Confirmatory Specimen Transfer Log

HIV TEST RESULTS

Negative Test Results

A negative HIV test result usually indicates that a person is not infected. Because a negative test result likely indicates absence of HIV infection, a negative test need not be repeated in clients with any new exposure in settings with low HIV prevalence. For clients with a recent history (less than 3 months prior to the test) of known or possible exposure to HIV who are tested before they could develop detectable antibodies, the possibility of HIV infection cannot be excluded without follow-up testing.

The average time between infection and HIV antibody detection is 25 days with the majority of infected clients developing detectable antibodies within 3-6 months after infection. Delayed HIV seroconversion more than 6 months after exposure is rare. False negative tests are highly unlikely.

Causes for false negative ELISA tests:

- Immune system has not developed antibodies because infection is too new
- Malignancy
- Long-term immunosuppressive therapy
- Bone marrow transplantation
- B-cell dysfunction

Causes for false negative Western Blots:

- End-stage HIV disease/AIDS

Suggested Language

- **Negative Test Result (no risk behavior within the last 3 months):**
“The test indicates you do not have HIV. This means that you were not infected as of 3 months ago.”
- **Negative Test Result (risk behavior within the last 3 months):**
“Your test results are negative. This means that you were not infected as of 3 months ago. The last risk behavior you said you engaged in, on (date), may not show up on this test. You need another test a full 3 months from (date) to be sure that you are not infected.”

Reactive (Preliminary Positive) Test Results

Further testing is always required to confirm a reactive (preliminary positive) screening test result.

Providing reactive (preliminary positive) results to clients without the benefit of a same-day confirmatory test can be a challenge. However, for all clients with a reactive rapid HIV test result, it is essential to:

- Explain the meaning of the reactive test result in simple terms, avoiding technical jargon.
- Emphasize the importance of confirmatory testing and schedule a return visit for the confirmatory test results.

- Underscore the importance of taking precautions to avoid the possibility of transmitting HIV to others while awaiting results of confirmatory testing.

A simple message to convey this information could be: *“Your preliminary test result is positive, but we won’t know for sure if you have HIV until we get the results from your confirmatory test. In the meantime, you should take precautions to avoid transmitting the virus.”*

Positive Test Results

An HIV test should be considered positive only after screening (ELISA) and confirmatory (Western Blot) tests are reactive. A confirmed positive test result indicates that a person has acquired HIV.

False Positive Test Results

False-positive results with both reactive screening and reactive confirmatory tests are rare. However, the possibility of a mislabeled sample or laboratory error must be considered, especially for a client with no identifiable risk for acquiring HIV.

Causes of false positive ELISA tests:

- Multiple pregnancies
- Multiple transfusions
- Severe alcoholic liver disease
- Hematological malignancies
- Lymphoma
- Acute DNA viral infections
- Renal transplants
- Renal failure
- Hemophilia
- History of injection drug use
- Hepatitis C infection
- Antibodies to other retroviruses
- Stevens-Johnson syndrome
- HIV vaccine trial participants

Causes of false positive Western Blot tests:

- Cross reactions with:
 - Other human retroviruses
 - Antibody to mitochondrial, nuclear, T-cell and leukocyte antigens
 - Antibody to HLA antigens
 - Globulins produced during polyclonal gammopathy

Indeterminate Test Results

Persons with an initial indeterminate Western blot result who have acquired the virus will develop detectable HIV antibodies within one month. Persons with an initial indeterminate Western Blot result should be re-tested for HIV status six weeks after the first indeterminate Western Blot result. Persons with continued indeterminate Western blot results after one month are unlikely to have acquired HIV and should be counseled as though they are HIV negative

unless recent HIV exposure is suspected.

Causes for indeterminate Western Blot test results:

- Blood transfusions
- Prior or current infection with syphilis
- Prior or current infection with malaria parasites
- Autoimmune disease (e.g., diabetes, Grave's disease, etc.)
- Infection with other human retroviruses
- Association with large animals (e.g., animal trainers and veterinarians sometimes pick up animal retroviruses that interfere with HIV antibody tests)
- Second or subsequent pregnancies in women

HIV Test Interpretation at the ODH Laboratory

The two serological tests used to detect antibodies to HIV are the ELISA, which is the enzyme-linked immunosorbent assay, and the Western Blot. When used together, the results from this two-part testing are greater than 99.9% accurate.

There are two species of HIV, HIV-1 and HIV-2. While both HIV-1 and HIV-2 have been identified in the United States, the number of known documented cases of persons with HIV-2 in the United States is very small.

The ELISA and Western Blot tests used at the ODH Lab are used to test for HIV-1 antibodies.

ELISA:

ELISA results are reported as reactive or non-reactive.

- If an ELISA test is non-reactive, the test is interpreted as negative for HIV antibodies.
- If an ELISA test is reactive, a second ELISA is run on the same sample. If two out of three results are reactive, it is interpreted as a positive antibody test result.
- If two out of three ELISA tests are reactive, the serum or oral fluid is then tested by the Western Blot procedure for confirmation.

WESTERN BLOT:

Western Blot results may be reported as reactive, non-reactive, or indeterminate.

- A reactive Western Blot must contain two of the three major bands of diagnostic significance:
 - gp 160 or gp 120
 - gp 41
 - p 24
- If the Western Blot is reactive, the results are interpreted as positive for HIV antibodies.
- A non-reactive Western Blot is one that contains no bands. Even in the presence of two reactive ELISAs, if the Western Blot is non-reactive, the test is considered negative.
- An indeterminate Western Blot is one that shows any band pattern that does not meet the reactive criteria.

LAB SUBMISSION

The following procedures should be followed when submitting specimens to the Ohio Department of Health Lab:

- **Complete the HIV Sampling Submission Form. Instructions for submitting a specimen are on the form.** A copy of the form is in the Appendix.
 1. **Samples will be mailed through UPS.** You may call 1-800-PICK-UPS to schedule a pickup. If you have not received your preprinted labels, you may use Account # **V37209**. Please note this account is valid only for shipping specimens for HIV diagnostic testing to the Ohio Department of Health Laboratories. Shipping charges accrued for unauthorized use will be billed to the shipper.
 2. Please call UPS at 1-800-PICK-UPS to order pre-printed labels.
- **The ODH Lab maintains a list of confidential fax numbers for each site where results can be faxed.** Sites cannot change this number without contacting the ODH Lab.
- **Call the customer service number at the ODH Lab to order mailing tubes.**
- **Contact Information for the ODH Lab:**

Ohio Department of Health
Bureau of Public Health Laboratories
8995 East Main Street
Reynoldsburg, OH 43086
Customer Service: 888-ODH-LABS, option 2

Laboratories (not sponsored by ODH)

Laboratories performing HIV testing for sites not using the ODH Lab will report positive results in the following manner:

- One copy of the result to the agency submitting the specimen
- One copy of the result to the agency submitting to the local health department
- One copy of the result to the ODH HIV/STD Prevention Program in Columbus
- One copy of the result to the ODH HIV/AIDS Surveillance Program in Columbus

ETI DATA

1. The following data must be collected for all patients testing at ETI sites:

a. Agency level variables:

- i. Community plan jurisdiction
- ii. Agency ID
- iii. Form ID
- iv. Intervention ID
- v. Site ID
- vi. Site Type
- vii. Site Zip Code
- viii. Client ID
- ix. Session Date

b. Client Variables

- i. Year of Birth
- ii. Assigned Sex at Birth
- iii. Current Gender Identity
- iv. Race
- v. Ethnicity
- vi. State of Residency
- vii. Previous HIV Test
- viii. Self Reported Previous Test Result
- ix. Behavioral Risk Category

c. HIV Test Variable

- i. Sample Date
- ii. Test Election
- iii. Test Technology Type
- iv. Test Result
- v. Result Provided
- vi. Date Result Provided

d. Referral Variables (HIV Positive Clients Only)

- i. Client referred to HIV Medical Care?
- ii. Client Attended First Appointment within 90 days to test date (DIS to collect)
- iii. Client Referred to Partner Services?
- iv. Client Interviewed within 30 days (DIS to collect)?
- v. Client Referred to HIV Prevention Services?
- vi. Client Accessed HIV Prevention Services?
- vii. Is Female Client Pregnant?
- viii. Is Female Client in Prenatal Care?
- ix. If No, was Client Referred to Prenatal Care
- x. Did Client Attend First Prenatal Appointment?

2. Completed HIV test data should be sent or mailed to the Ohio Department of Health (ODH) when approximately 50 tests are completed or once a month, whichever occurs first.
3. If site is completing op-scan forms they should be sent in a 10"x13" mailing envelope. Forms must not be torn, folded, bent, stapled, taped or twisted. Any form received in damaged condition will be returned to be recopied onto a new form.
4. All test forms should be labeled "10138" in the CD02 field.
5. Send only the top copy of the HIV Test Form. Keep the carbon copy for your records.
6. All HIV testing sites must assign a staff person to check all HIV Test Forms for accuracy and completeness. All forms that are incomplete or have errors will be returned for correction.
7. All forms that are returned to the site for damage, errors or incomplete information must be returned within ten days of receipt.
8. Each site is responsible for maintaining a copy of all completed HIV test files for one calendar year.
9. Instructions for completing the HIV Test Form can be found in the HIV Test Form Manual (see Appendix R).
10. Please mail forms to:

Ohio Department of Health
HIV Prevention
ETI Testing Data Entry
35 E. Chestnut Street, 6th Floor
Columbus, Ohio 43215

HIV REFERRAL

Definition of Referral

In the context of HIV testing, referral is the process by which immediate client needs for care and supportive services are assessed and prioritized and clients are provided with assistance (e.g., setting up appointments, providing transportation) in accessing services. Referral should also include follow-up efforts necessary to facilitate initial contact with care and support service providers.

Typical Referral Needs

Clients should be referred to services that are responsive to their priority needs and appropriate for their culture, language, gender, sexual orientation, age, and developmental level. Examples of these services include:

- **Medical evaluation, care, and treatment.** Following the delivery of a confirmed positive HIV test result, it is imperative that patients are linked to medical care in a timely manner. Appointments with a primary care or infectious disease specialist (physician or nurse practitioner) should be scheduled to occur within one week of a patient receiving the HIV diagnosis. Prompt entry into medical care ensures that patients receive appropriate laboratory tests and disease staging. Fifty-nine percent of AIDS cases were diagnosed less than 12 months after the first reported HIV diagnosis. Individuals testing positive for HIV infection may present with a range of immune suppression and HIV-related symptoms upon diagnosis. In all cases, prompt assessment of health status at baseline is essential to maximize health care outcomes for newly diagnosed individuals.

A prompt connection to care also ensures that patients receive complete and accurate information about HIV disease progression, antiretroviral treatment options, management of co-morbid conditions, and guidance to reduce the risks of HIV transmission to sexual and drug injection partners. Connecting HIV-positive patients to medical care also serves as a point of entry for other health, assessment, and social services programs; including: case management, benefits advocacy, substance use treatment, mental health counseling, risk reduction services, and partner services, among others.

Linkage to HIV primary care also provides a bridge to connect patients with supported referrals to a range of specialty medical care services, including sexually transmitted infection (STI) treatment, viral hepatitis services, nutrition support, family planning, psychiatry, endocrinology, cardiology, and other areas that may directly impact persons living with HIV/AIDS.

- **Comprehensive Risk Counseling and Services (CRCS).** Clients with multiple and complex needs that affect their ability to adopt and sustain behaviors that will reduce their risk for transmitting or acquiring HIV should receive or be referred to CRCS, including ongoing prevention counseling. CRCS can help coordinate diverse referral and follow-up concerns.

- **Partner services.** Persons with HIV-positive test results should receive or be referred to services to help them notify their sex partners, injection-drug-equipment-sharing partners and/or spouses and partners about their exposure to HIV and how to access HIV Prevention Services.
- **Reproductive health services.** Female clients who are pregnant or of childbearing age should receive or be referred to reproductive health services. HIV-positive pregnant women should be referred to providers who can provide prevention counseling and education, initiate medical therapy to prevent perinatal transmission and provide appropriate care based on established treatment guidelines.
- **Drug or alcohol prevention and treatment.** Clients who abuse drugs or alcohol should receive or be referred to substance or alcohol abuse prevention and treatment services.
- **Mental health services.** Clients who have mental health issues or diagnoses, developmental disability, or difficulty coping with an HIV diagnosis or HIV-related conditions should receive or be referred to appropriate mental health services.
- **STD screening and care.** Clients who are HIV-positive or at increased risk for HIV are also at risk for other STDs and should receive or be referred to further STD screening and treatment.
- **TB screening and care.** Clients who are HIV-positive should receive or be referred for TB screening and treatment.
- **Screening and treatment for viral hepatitis.** Many clients who are HIV-positive or at increased risk for HIV are also at increased risk for acquiring viral hepatitis (A, B, and C). Men who have sex with men (MSM) and IDUs should be vaccinated for hepatitis A. All clients without a history of hepatitis B infection or vaccination should be tested for hepatitis B, and if not infected, should receive or be referred for hepatitis B vaccination. In addition, clients who inject drugs should be routinely recommended for testing for hepatitis C. All clients with any hepatitis virus should be referred for appropriate treatment.
- **Other services.** Clients might have multiple needs that can be addressed through other HIV prevention and support services (e.g., assistance with housing, food, employment, transportation, child care, domestic violence, and legal services). Addressing these needs can help clients access and accept medical services and adopt and maintain behaviors to reduce the risks for HIV transmission and acquisition. Clients should receive referrals as appropriate for identified needs.
- **Ryan White Care Program.** HIV-positive clients who have identifiable needs for medical, mental health or social support services, and who indicate that they may be experiencing socioeconomic distress of any kind (e.g., poverty, disability, unemployed, underemployed, uninsured, underinsured, homeless, etc.) should be referred to the local agency funded by the State of Ohio's HIV Care Services Program to determine the client's eligibility to receive HIV case management services through the [Ryan White Care Program](#).