

# Creating Readiness for Rapid HIV Testing: SAMHSA's Rapid HIV Testing Initiative



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U.S. Department of Health and Human Services

# **SAMHSA's Rapid HIV Testing Initiative (RHTI)**

## **Goals:**

- 1. To incorporate rapid HIV testing methodology in SAMHSA's qualified program sites as a strategic intervention**
- 2. To provide effective pre- and post-test counseling**

# SAMHSA's RHTI, continued

## **Target Population:**

**Persons with a substance use and/or mental health disorders, men who have sex with men (MSM), transgender, sex workers, at-risk pregnant women, and reentry populations.**

# **SAMHSA's RHTI, continued**

## **Eligibility Criteria:**

- 1. Located in metropolitan and rural areas with high prevalence of HIV, which are currently interested in providing traditional HIV/AIDS counseling, testing, and referrals**
- 2. Serving high-risk clients**

# SAMHSA's RHTI, continued

## **Eligibility Criteria** (continued):

- 3. Have a rapid testing infrastructure that will expedite Clinical Laboratory Improvement Amendments (CLIA) Waiver certification, and have a few state or local barriers to rapid testing;**
- 4. Have established linkages to HIV/AIDS treatment, counseling, and other supportive services.**

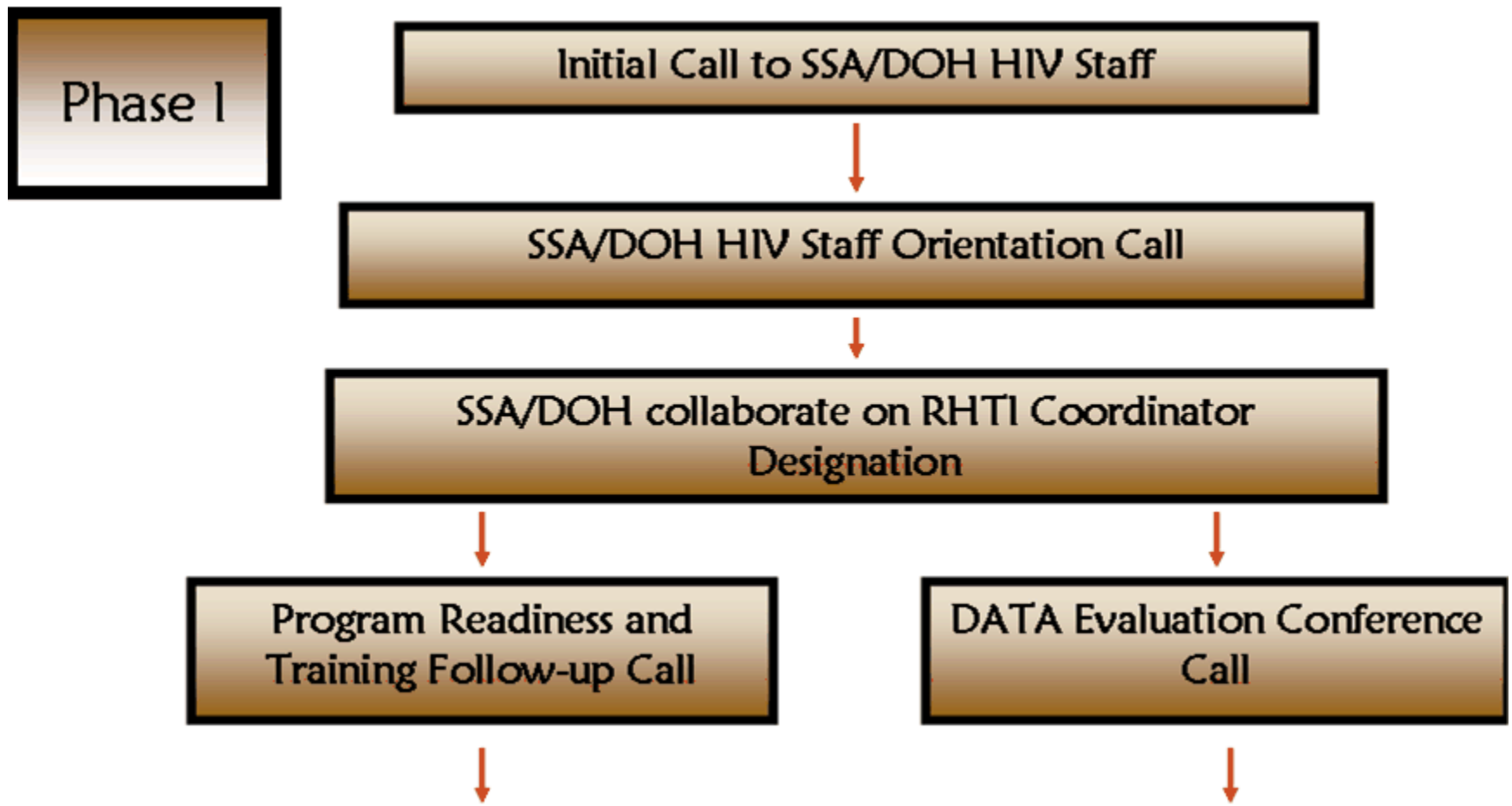
# RHTI Partners

- **Centers for Disease Control and Prevention (CDC)**
- **National Association of State Alcohol and Drug Abuse Directors (NASADAD)**
- **National Association of State Mental Health Program Directors (NASMHPD)**
- **National Alliance of State AIDS Directors (NASTAD)**
- **Health Resources and Services Administration (HRSA)**
- **Department of Justice (DOJ)**
- **National Institute on Drug Abuse (NIDA)**
- **Indian Health Service (IHS)**

# RHTI Planning Model Framework

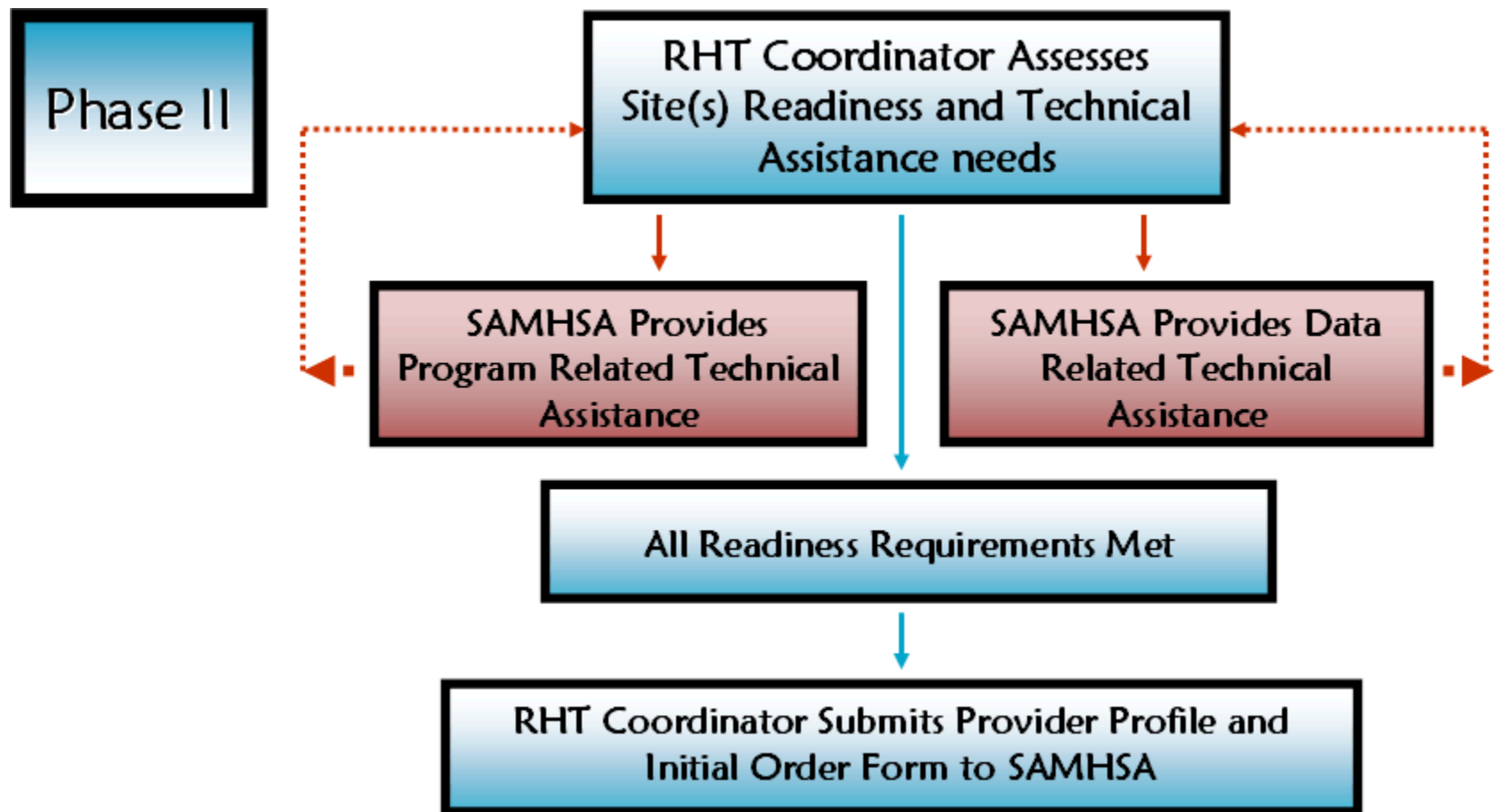
- **Program Orientation Process**
- Site Selection
- **Readiness Requirements**
- Training & Technical Assistance
- Data Collection and Evaluation

# State Program Orientation Process





# State Program Orientation Process



# Readiness Requirements

1. Required Training
2. CLIA Certificate of Waiver
3. State Regulations
4. Linkages to Care
5. Rapid HIV Testing Quality Assurance Plan
6. Policies and Procedures
7. Data Collection

# Required Training

- Basic fundamentals of HIV/AIDS training, as recognized by the State.
- State-certified HIV counseling and testing reporting (CTR) Services.
- “Fundamentals of Rapid HIV Testing and Prevention Counseling with OraQuick<sup>®</sup> Rapid HIV-1 Antibody Test” (provided by SAMHSA or CDC, and States, as required).

# CLIA Certificate of Waiver

- Complete Centers for Medicare & Medicaid Services (CMS) form CMS-116
- CMS-116 can be obtained from CMS Web site: <http://www.cms.gov/cliaapp.asp> or from your state health department.
- The completed Certificate of Waiver application should be forwarded to the address of the local state agency of the state in which the testing will be performed. CMS has a list of these agencies by state at <http://cms.hhs.gov/clia/ssa-map.asp>

# CLIA Certificate of Waiver, continued

- Many states have additional regulations that apply to laboratory testing, and some require separate application to the state agency.
- Before applying, you should consider these application requirements and the best method for receiving the authority for testing, including contacting your state health department and local CMS inspector for guidance.

# CLIA Certificate of Waiver, continued

- You can contact your local state agency for assistance in filling out the application.
- You will need to submit the \$150.00 fee with your application.
- The Certificate of Wavier is valid for two years. A renewal application will need to be completed and sent to the state agency not less nine months before the certificate's expiration date.

# Linkages to Care

Linkages to care must consist of, but are not limited to, partnership(s) with

- Local health departments, Indian Health Service and AIDS service organizations to secure appropriate HIV/AIDS support resources, including laboratory services;
- HIV/AIDS primary and behavioral health care services;
- Hepatitis services, and
- Other necessary support services (e.g., insurance, housing, food, transportation).

# RHT Quality Assurance Plan

- Quality assurance (QA) refers to planned, step-by-step activities to ensure that testing is being carried out correctly, results are accurate, and mistakes are found and corrected to avoid adverse outcomes.
- Quality assurance is an ongoing set of activities that helps to ensure that the test results provided are accurate and reliable as possible for all persons being tested.
- Quality assurance activities should be in place during the entire testing process.



# RHT Quality Assurance Plan, continued

- **Basic elements of QA Program:**
  1. Organization of the QA program
  2. Testing personnel
  3. Process control
    - Before testing
    - During testing
    - After testing
  4. Documents and records
  5. Troubleshooting

# Organization of the QA Program

- Identify the person(s) responsible for managing the QA program
- Write procedures (step-by-step instruction) and make them available to all staff involved in testing
- Ensure staff know how to perform processes and procedures
- Create system for communication so that those who need to know are informed about QA issues, as well as all staff, when appropriate
- Develop and implement systems to ensure site meets all applicable Federal, State, and other regulatory requirements

# Organization of the QA Program, continued

- Before offering the test to clients or patients verify that testing process works as planned
- Provide written procedures
  - Step-by-step written instructions that are made available to all staff performing testing to ensure that all personnel know how to perform specific task and testing success is not left to chance.

# Testing Personnel

Having qualified trained staff to perform and supervise OraQuick testing and the various activities in the QA program is one of the most important factors for ensuring accurate results.

Key elements include:

- Qualifications
- Training
- Competency assessment

# Qualifications

OraQuick test is waived under CLIA, there are no specific Federal requirements on who can perform the test; however, the site should find out if there are any State or other requirements.

# Qualifications, continued

It is recommended that certain qualities be considered when selecting personnel:

- Sincerity and commitment
- Literacy
- Organizational skills
- Decision-making skills
- Communication skills

# Training

The key components to include in a personnel training program are:

- How to perform the test, including procedures performed before, during and after testing.
- How testing is integrated into the overall counseling and testing program
- The importance of QA and the elements of the site's QA program.
- The use and importance of Universal (or Standard) Precautions/biohazard safety.

# Competency Assessment

Before a trainee is permitted to perform testing alone for the first time, their ability to conduct the test should be demonstrated and documented. This assessment should be carried out at periodic intervals after training, such as every six months.



# Process Control

- Activities and techniques that are carried out to ensure that the testing procedures are performed correctly, the environment is suitable, and the kit works as expected.
- Steps in the testing process follow the path of workflow beginning with task before, during and after testing.

## Steps in the testing process



Before Testing	During Testing	After Testing
<ul style="list-style-type: none"> <li>• Check storage and room temperatures daily</li> <li>• Check inventory and test kits lots as needed</li> <li>• Receive request for testing</li> <li>• Provide HIV/AIDS information to the test subject</li> <li>• Set-up test area, label test device</li> <li>• Perform external quality control according to the manufacturer's and the site instructions</li> </ul>	<ul style="list-style-type: none"> <li>• Follow biohazard safety precautions</li> <li>• Collect the finger-stick specimen</li> <li>• Perform the test</li> <li>• Interpret test results</li> </ul>	<ul style="list-style-type: none"> <li>• Clean up and dispose of biohazardous waste</li> <li>• Report results to client</li> <li>• Document results</li> <li>• Collect, process and transport confirmatory test specimens</li> <li>• Manage confirmatory test results</li> <li>• Participate in external quality assessment (periodically)</li> </ul>

# Documentation and Records

- One of the hallmarks of a QA program is comprehensive documentation. QA records should include:
  - Training documentation
  - Temperature logs
  - External control result logs
  - Test results logs
  - Specimen transfer logs

# Troubleshooting

- Each site should have a method to detect and resolve problems that occur at any point in the testing process, especially those that may affect the accuracy of test results. Significant problems should be immediately reported to the appropriate supervisory personnel.

# Troubleshooting Procedures

- When to discontinue testing
- How to take corrective action
- How to document problems and action taken
- How to verify the corrective actions taken to address the problem

# RHTI in Minnesota

- 5/20/06 Received 3,950 free RHT Kits and 158 control kits
- 9/27/06 Received 100 free RHT Kits and 1 control kit

# RHTI in Minnesota

Minnesota Department of Health contact:

Sarah Gordon

HIV Testing, Counseling & Referral Coordination

612-676-5103

*or*

David Rompa

615-634-2296

# RHT Site

- **Indigenous Peoples Task Force**  
**1433 Franklin Avenue South, Ste. 18A**  
**Minneapolis, MN 55404**
- Provides outreach and HIV testing by the OraSure method to gay/bi men of color or injection drug users. For more information, contact: (612) 870-1723 extension 18



# SAMHSA's RHTI?

<b>Fact Sheet</b>	<a href="http://www.samhsa.gov/">http://www.samhsa.gov/</a>
<b>Email</b>	<a href="mailto:rhti@samhsa.hhs.gov">rhti@samhsa.hhs.gov</a>
<b>RHTI Helpline</b>	<b>1-877-219-6953</b>