Minority AIDS Initiative Rapid HIV Testing Clinical Information Form

Implementation with Ethnic and Racial Minorities at Risk for Substance Use and HIV/AIDS

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting Office of Management and Budget (OMB) approval for the use of a revised version of the Minority AIDS Initiative (MAI) Rapid HIV Testing Clinical Information Form (OMB No. 0930-0295; see Attachment A) for the Minority AIDS Initiative Targeted Capacity Expansion Program (MAI-TCE). The MAI Rapid Testing Clinical Information Form is currently used to collect data for the Rapid HIV Testing (RHT) Component of SAMHSA's 63 grantee, Targeted Capacity Expansion Program for Substance Abuse Treatment and HIV/AIDS (TCE-HIV) multi-site program. The form will be used to collect data on the additional 11 grantee Minority AIDS Initiative Targeted Capacity Program (MAI-TCE). This data collection is approved under OMB No. 0930-0295, which expires September 30, 2012.

The purpose of the MAI Rapid HIV Testing Clinical Information Form is to collect systematic and critical information when a rapid HIV test is administered to enhance preventive services for those who test HIV-negative and refer to treatment/medical care those who test HIV-positive. Grantees must develop a medical case management plan for all clients who have a preliminary positive HIV test result and a confirmatory HIV test result.

This form once implemented would: 1) increase rapid HIV testing among racial and ethnic minorities; 2) refer individuals who test HIV-positive to treatment/medical care; and 3) enhance preventive services for those who test HIV-negative.

The form collects essential information that allows SAMHSA to report on the following:

- The demographics of persons being tested or offered testing through funded substance abuse treatment programs
- A description of the substance abuse and sexual risk factors of persons who enter or have contact with staff members in substance abuse and HIV/AIDS service settings
- An account of persons who were previously diagnosed as HIV-positive and of persons who are newly diagnosed as HIV-positive
- The number of individuals who are aware of their HIV zero-status

The RHT form that was approved in 2009 is currently used by SAMHSA-funded TCE-HIV grantee programs that serve racial and ethnic minority communities that are disproportionately affected by substance abuse and HIV. Current TCE-HIV grantees have been trained on the administration of the RHT form and continue to submit data through the online system, which allows for real-time data collection. The service providers offer each client a rapid HIV test and

complete a RHT form for all clients. The form will be used in the same manner with new grantees under the MAI-TCE program. All grantees under the MAI-TCE program will receive training on administration of the form and proper submission of RHT data.

RHT form data collection is authorized by Section 505 of the Public Health Service Act (42 USC 290aa-4) – Data Collection.

Background. The spread of HIV in the United States is fueled in part by the abuse of both illicit (e.g., heroin, methamphetamine) and non-illicit (e.g., prescription medication, alcohol) substances. Although HIV transmission is associated with individuals sharing syringes and other drug-injection equipment, it can also occur through sexual contact with injection-drug users who are HIV-positive or with other partners who are HIV-positive. Moreover, substance abuse increases the risk for HIV transmission because of the potential for impaired decision-making regarding sexual risk behavior. Thus, it is critical that individuals with a substance abuse history be tested for HIV as an important part of their treatment. If they are found to be HIV-positive, the integration of testing as part of their treatment will allow for the timely and appropriate referral to high-quality medical care and secondary prevention services to effectively treat the individual and reduce further HIV transmission.

Although many HIV-positive persons have been identified through traditional risk-based approaches to HIV testing, the Centers for Disease Control and Prevention (CDC) estimate that approximately one-quarter of the estimated 1 to 1.2 million Americans infected with HIV are unaware of their HIV status. The CDC also reports that each year about one-third of people who test positive for HIV using standard HIV tests, which typically take 2 to 14 days, do not return for their results. Ethnic and racial minority groups are disproportionately affected by the AIDS epidemic. AIDS rates are 72.1 per 100,000 for non-Hispanic Blacks, 25.0 per 100,000 for Hispanics, 9.9 per 100,000 for American Indians/Alaska Natives, and 4.4 per 100,000 for Asian/Pacific Islanders (HIV/AIDS Surveillance Supplemental Report 2006, Vol. 12, No. 1).

In response to the AIDS epidemic, SAMHSA has awarded numerous grants to providers that implement rapid HIV testing as an integral part of their services. These awards are intended to enhance and expand substance abuse treatment and/or outreach and pretreatment services for racial and ethnic communities highly affected by the substance abuse and HIV/AIDS epidemics. Grantees are required to offer rapid HIV testing to all clients and to complete an RHT form for each person, regardless of whether the client agrees to a rapid HIV test. All service providers are also required to meet readiness criteria established by SAMHSA before implementation of rapid HIV testing, including obtaining a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. Furthermore, as State jurisdictions often require pre- and post-test counseling and referral strategies, it is important for SAMHSA to know whether compliance with these requirements is being met.

The objective of these SAMHSA-funded grants is to build and/or strengthen organizational capacity of providers to provide substance abuse treatment services and HIV/AIDS education to ethnic and racial minority communities; reduce the stigma associated with HIV/AIDS through outreach and education; and increase the number of at-risk individuals who know their HIV status and are referred to appropriate and timely medical care or prevention services.

2. Purpose and Use of Information

The RHT form is used to collect data that will assist in the enhancement of preventive services for those who test HIV-negative and referral to high-quality treatment/medical care for those who test HIV-positive. The form is also used for quality assurance and monitoring. The form does not require the collection of identifiable patient-specific information from individuals participating in any of the SAMHSA-funded programs. The RHT form is designed primarily to inform SAMHSA that the intended target populations are being tested, that individuals found to be HIV-positive are being referred to care, and about the substance use and sexual risk behaviors of persons who enter or come in contact with substance abuse treatment programs.

The RHT form takes 8 minutes to complete. Although the RHT form does not contain patient-specific identifiers, it does contain a space to include the rapid HIV test kit lot number in the event that problems associated with a specific lot of test kits arise. Such problems have already occurred in several areas of the United States, making this information critical to substance abuse treatment providers and their clients.

Content of the RHT Form. The RHT form is divided into seven sections, which provide information about the following items:

Section A: Site Characteristics

- Grantee number
- Client ID number
- Date of visit
- Site type code

Section B: Demographics

- Gender
- Ethnicity
- Race
- Age
- Previous HIV test

Section C: Reason for Test or Reason for Refusal to Take Test

Section D: Risk Behaviors

- Sexual risk behaviors
- Substance-use risk behaviors
- Previous psychological and substance use treatment history

Section E: RHT Test Results and Retest Results

Section F: Types of Services Provided

Section G: Confirmatory Test Results

Changes

Within Section A of the RHT Form, the *Grantee or partner staff member initials* were removed at the request of SAMHSA's Confidentiality Officer. This change was made to reduce the likelihood of personal identifiable information being utilized to track patient's test results. The SAMHSA Client ID number was relabeled to *Client ID number* to reduce confusion as to whether SAMHSA keeps a list of client IDs. The Client ID number is a randomly assigned number by the grantee and is not a patient ID that can be used to re-identify a patient. These are the revisions that were made to the RHT form.

3. Use of Information Technology

The implementation of the RHT form began in 2009 with a paper/pencil administration. To facilitate data collection and minimize errors on the RHT form, an online data collection system was developed. Since January 2011, the online data collection system is required for submission of RHT form data. The online system allows the grantees to fill out the RHT form in two ways. Grantee staff can complete the RHT form directly in the online system. Alternatively, grantee staff can print a blank copy of the RHT form from the online system, mark information on the paper form, and enter the data in the online system at a later time. Data management technology will continue to be used to manage, secure, and store the data to ensure data management control.

RHT Form Submission and Management. Grantee staff administers the RHT form during in-person encounters when a rapid HIV test is offered or administered. RHT form data are entered at the grantee site into the password-protected online system. Each day, contractor staff members complete a backup of the online system data and upload the data over a secure network connection directly to a server at their headquarters, where the data are also encrypted and password protected. Protected electronic data is the most secure form of data management because it eliminates the possibility of paper documents being lost by the survey staff or of data being lost in transit or delivered to an incorrect location.

4. Efforts to Identify Duplication

The RHT form is similar to the OMB-approved CDC HIV Test Form (OMB No. 0920-0696, Exp. Date: 08/31/2013). However, SAMHSA's RHT form includes additional questions that specifically focus on the intersection of substance use and HIV risk behaviors. These questions are critical to the analysis of service integration. We have tried to ensure that data elements from these two HIV test forms share consistent definitions whenever possible. The Dictionary with the required data element definitions that will be provided to the MAI-TCE grantees was based on the definitions utilized by CDC for their reporting form. This will ensure alignment wherever the data elements overlap.

Currently CDC requires that grantees that are directly funded by CDC for HIV prevention activities complete the CDC EvaluationWeb 2012 HIV Test Template Form. In addition, most states require that CBOs who are funded through state HIV funds also complete the EvaluationWeb 2012 HIV Test Template Form. However, many of the grantees of the health departments who may be providing services as part of this SAMHSA MAI TCE initiative may not be receiving such funds and therefore will not be completing the EvaluationWeb 2012 HIV Test Template Form. For these grantees, the SAMHSA MAI Rapid Testing Clinical Information Form will be the only data collection form required.

5. Involvement of Small Entities

Approximately 60 percent of grantees that will be conducting rapid HIV testing are small not-for-profit organizations that are not dominant in the treatment field and would be considered "small entities" by OMB. The burden associated with the RHT form poses no significant impact on these organizations.

6. Consequences if Information Is Collected Less Frequently

The RHT form is used by all SAMHSA-funded grantees that are required to conduct rapid HIV testing as part of the conditions of their award. The respondents or users of this form will be the clinical workers initiating the rapid HIV test and the clients (patients) receiving the test. Each client is offered a rapid HIV test at program entry. Some individuals may request or can be offered a second test if they: (1) continue to engage in high-risk sexual and drug-taking behaviors, (2) have been recently exposed to HIV (within 3 months), or (3) suspect that they have been exposed to HIV.

In terms of the second rapid HIV test, although the second test will more than likely be a rapid test, there is the possibility that a grantee may use another form of testing per their clinic protocols.

7. Consistency with the Guidelines in 5 CFR 1320.5 (d)(2)

This information collection fully complies with the guidelines in 5 CFR 1320.5 (d)(2).

8. Consultation Outside the Agency

The notice required by 5 CFR 1320.8 (d) was published in the Federal Register on April 12, 2012 (Vol. 77, page 21984). No comments were received in response to this notice.

The RHT form is currently being used by 47 TCE-HIV grantees funded in 2008, 16 TCE-HIV services grantees funded in 2009, and 26 RHT supplemental grantees funded in 2011. Please see Attachment B for a list of the grantees. Since its implementation in 2009, no grantees have reported an issue with the burden.

9. Payment to Respondents

There is no payment to respondents for the completion of the RHT form.

10. Assurance of Confidentiality

The SAMHSA contractor trained grantees on the administration of the RHT form, developed a Web-based data collection system, and trained grantees on the use of the online data collection system. The contractor's systems and procedures for collecting and processing data are designed to help ensure the privacy, to the extent of the law, of program participants and of the data they provide. In documents that contain individual clients' data, the clients will only be identified by their Client ID, which as described above, cannot be used to re-identify a patient.

Grantee staff members offer clients a rapid HIV test, although the test is not mandatory, and inform them that their treatment will not be affected if they decline the test. Grantee staff members then briefly explain to clients the reason for the RHT form, describe the form length, and explain the process. If clients agree to take a rapid HIV test, the grantee staff members administer the rapid HIV test and complete the RHT form while waiting for the test results.

Some clients do decline taking a rapid test. The reasons for this include prior knowledge and confirmation of their seropositive status or not wanting to be aware of their status. For clients with a known and confirmed status, grantees will only collect the remaining information on the form (e.g., demographic, risk behaviors, types of services). In the case of refusals, that will be indicated on the RHT form

Grantee staff members administer the RHT form to individual clients in a private location (e.g., an office) to ensure privacy. For each question that requires the client's responses, staff members read the questions and the list of responses to the client and record his or her answers. The RHT form will include the new OMB number, expiration date, and the statement of survey burden.

Grantees have the option of completing the form in real time, by entering data directly into the online system, or by printing a blank paper copy of the form, marking information on the paper form, and entering the data on the online system at a later time. The RHT form data are entered into a password-protected online system at the grantee site. Each day, the contractor staff uploads the data over a secure network connection directly to a server at their headquarters, where the data are also encrypted and password protected.

Contractor staff members are well trained on handling sensitive data and understand the importance of privacy. As a further precautionary measure, the data being collected have no identifying information that can be linked to the client. In keeping with 45 CFR 46, Protection of Human Subjects, the procedures for data collection, consent, and data maintenance are formulated to protect respondents' rights and the privacy of information collected.

SAMHSA's Information Technology Officer reviewed the contractor's IT security plan and found it is reasonable, responds to SAMHSA/CSAT's IT Requirements, and adequately meets all SAMHSA and Federal Security Plan Requirements of the program.

11. Questions of a Sensitive Nature

The RHT form includes questions of a sensitive nature such as the client's substance use and sexual risk factors. However, no client-specific identifier information is collected on the RHT form or provided to the Federal government. The clinical information obtained is information that is typically collected in the course of conducting HIV testing in the community. Providers retain all client-specific information and securely maintain the code by which a specific client can be identified. The Federal government receives only de-identified information on whether participants received a rapid HIV test as well as demographic and referral information about the individuals tested.

12. Estimate of Project Hour Burden

The 0.133 hour per 1 response burden calculation is based on the current use of the RHT form in the field Respondents are the individuals being tested and the clinicians administering the RHT form. In addition, a portion of the 64,000 individuals who will be tested for HIV will be retested (see Exhibit 1). The current recommendation is that individuals who continue to engage in high-risk behaviors for HIV or who have had a recent (within 3 months) known or possible exposure to HIV should be re-tested (http://www.cdc.gov/hiv/topics/testing/resources/factsheets/rt_counseling.htm). Based on SAMHSA's 12 years of experience working with populations that are dually affected by substance abuse and HIV, it is estimated that approximately 6.25 percent, or 12,000, of the 192,000 total test recipients (over a three year period) will be retested based on their persistent risk behaviors. This may be a rapid or conventional test, depending on the grantee.

Exhibit 1: RHT Form Data Collection Burden on Grantees

Instrument/ Activity	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours	Hourly Wage	Total Cost*
RHT Form (FY 2008 and FY 2009 – 63 TCE-HIV Grantees)	20,000	1	20,000	0.133	2,660	$ 30.00	$39,900
RHT form for 11 HIV (MAI-TCE) program FY 2011 grantees (public health departments)	40,000	1	40,000	0.133	5,320	$30.00	$79,800
Rapid HIV Testing Clinical Information Form (Re-test)	4,000	1	4,000	0.133	1,596	$ 30.00	$23,940
TOTAL	64,000	--------	64,000	--------	9,576	--------	$143,640

**Total respondent cost is calculated as hourly wage × time spent on survey × number of respondents.*
**Wage estimates based on rates used from current Rapid HIV Testing Clinical Information Form (OMB No. 0930-0296)*

Estimate of the Total Hour Burden of the Data Collection. The total sample size for the RHT form data collection effort is estimated to be a maximum of 64,000 respondents (74 sites, 11 of which are public health departments, 2 respondents at each site (the client and the clinician administering the RHT). Exhibit 1 presents estimates per year of total burden. To summarize, the table shows a total sample size for the RHT form data collection to be a maximum of 64,000 respondents. Of this 64,000, 4,000 respondents will be retested. In total, a maximum of 192,000 respondents are estimated for completing the RHT form, with 12,000 of these respondents being retested over the 3 year period of the MAI-TCE program.

Estimate of the Total Cost Burden of the Data Collection. There are no direct costs to respondents other than their time to participate in the program. The total cost of the time that all grantee staff spend completing RHT forms is $143,640 (number of grantee staff hours × $30.00).

13. Estimate of Annualized Cost Burden to Respondents

The information collected on the form is routinely maintained as a part of customary and usual business practices. There are no costs associated with the data collection to respondents.

14. Estimate of the Annualized Cost to the Government

The annualized cost to the government includes approximately 260 hours for the Government Project Officer (GS-13, Step 1) to coordinate with the provider organization ($10,330). Approximately $450,000 will be expended to cover activities related to training, collection, storage, and analysis of the RHT form for an estimated annualized cost to the government of $460,330.

15. Changes in Burden

The following adjustments and clarification have been added to this response to clarify changes in burden.

Currently there are 3,192 burden hours in the OMB inventory (OMB No# 0930-0295). SAMHSA is now requesting to increase this ceiling to 9,576 total burden hours. The increase of 6,384 hours is due to the following:

- The inclusion of both clinicians and clients in our "respondent" calculations
- The program adjustment of 20,000 respondents/2,660 burden hours is due to a recalculation of the actual number of respondents receiving a rapid HIV test and the inclusion of 1,333 retested respondents/532 burden hours. The 1,333 retested respondents and 532 burden hours reflects one third of the re-test population highlighted in Exhibit 1.
- The program change of 40,000 respondents/5,320 burden hours is due to the addition of eleven 2011 MAI-TCE grantees and a program change increase of 2,667 respondents/1,064 burden hours to be retested for the 11 new grantees. The 2,667 retested respondents and 1,064 burden hours reflects two-thirds of the re-test population highlighted in Exhibit 1.
- 4000 respondents, on average, per year will be retested to ensure that a read of this submission is transparently clear.

The only changes to the revised form is the removal of "SAMHSA" from the client ID and the removal of requiring the staff initials. Aside from this small change no other changes have occurred to the form from its prior iteration.

16. Time Schedule, Publications, and Analysis Plans

Time Schedule. Exhibit 2 outlines the key time points for the collection of RHT data. The proposed period also allows for online training for grantees and preparation activities associated with the systematic process required for data collection.

Exhibit 2: Time Schedule for RHT Training and Data Collection

Activity	Time Schedule	Duration
Obtain OMB approval for RHT form	October 2012	NA
Provide online training to all new grantees on form administration	1.5 months post OMB approval for 2 months	2 months
Instruct grantees to begin collecting data using the RHT form	2 months post OMB approval for 21 months	21 Months
Analyze data for monthly reports	3 months post OMB approval to end of contract	33 Months
Disseminate findings via presentations, manuscripts, annual and a final report	18 months post OMB approval to end of contract	15 Months

Publications. The RHT Component is designed to implement rapid HIV testing activities among racial and ethnic minority communities and to collect data that help with referrals to services for those who test HIV-positive and help with referrals to prevention services for those who test

HIV-negative. It is therefore important to prepare and disseminate reports, journal articles, and oral presentations that clearly and concisely present results so that they can be appreciated by both technical and nontechnical audiences. The contractor staff will:

- Produce monthly summary reports
- Prepare and submit annual reports
- Prepare a final multi-site findings report, including an executive summary
- Deliver presentations at professional and federally sponsored conventions and meetings
- Prepare and submit articles for publication in peer-reviewed journals
- Disseminate reports and materials to entities inside and outside SAMHSA

Analysis Plan.

With few exceptions, the data on the RHT form are categorical and will be analyzed using summary frequencies and cross-tabulation. However, they can also play an important role in higher order analysis. With that in mind, we plan to use the data in two contexts.

First, the data will be summarized in descriptive statistics to describe the baseline characteristics of individuals who are being tested (or refusing). The rapid test technology and its accessibility has been an important step in HIV prevention and treatment. Therefore, knowing who this technology is reaching (and conversely, who if offered refuses the test) is critical in designing comprehensive outreach and treatment programming. Simple descriptive statistics displays and categorical data from the RHT form will be summarized in crosstabs describing the characteristics of those tested and those who refused testing---their demographics, risk activities, prior treatment, results and type of services provided. MAI-TCE grantees are instructed to offer the RHT to all those screened for services. Even if they refuse testing or have been tested before, Sections B and D will be completed, providing a large database for analysis.

Second, data from this form will be linked with the patient's information in TRAC-NOMS by a unique identifier to add to the understanding of client outcomes in the MAI-TCE programming. TRAC-NOMs includes a range of data on drug treatment, mental health and HIV prevention information, but does not include data on whether the individual has been tested or the result of that test. These two datasets combined, collected for all program participants regardless of whether they are tested, provides the opportunity to understand the role of testing in affecting behavior. For example, SAMHSA is interested in whether or not testing and/or knowledge of one's HIV status affects participation in services offered and/or in changes in risk behaviors. In this analysis the categorical variables of whether a test was taken (0, 1) and whether the test was positive (0, 1) would play a role in multiple regression analyses as independent variables in predicting outcomes.

Other data on the form will also be used in the evaluation of client outcomes (i.e., change in drug use, retention in treatment, and change in mental health status). For example, in Section D, the risk behaviors identified in (Q1) are not as fully covered in TRAC-NOMS as they are on the

RHT form. These reports of recent risk activity are also to be used as categorical variables (0, 1) and used as independent variables in in predicting service utilization and successful changes in behavior as reported in TRAC-NOMS. Willingness to be tested is in itself an important outcome measure for these programs. As the date of testing is included in the dataset, analysis may examine the effect of services provided (the independent predictors) on the decision to be tested (the dependent variable) in regression analysis.

This is a potentially large sample of people being tested that provides an opportunity to use predictive statistics and regression based modeling to understand the role that testing plays in seeking services, in patient compliance or retention in services, and in changing behaviors. As a stand-alone dataset (RHT data only), basic summaries of the data over time offer an interesting picture of who the technology is reaching and why they may have sought services (Section D). When combined with the client level data in TRAC-NOMS, as intended in this evaluation project, it adds important data in identifying the predictors of positive outcomes. **Trainings & Technical Assistance**

The training for grantees concerning the use of the RHT form and submission of RHT data will be conducted via webinar. Additional trainings will be offered to all grantees as new needs are determined. Technical assistance for the use of the form will be offered over the life of the MAI-TCE contract.

17. Display of Expiration Date

The expiration date for OMB approval will be displayed on the RHT form.

18. Exceptions to Certification Statement

There are no exceptions to the certification statement. The certifications are included in this submission.