Rapid HIV Testing Clinical Information Form
For the Minority AIDS Initiative for Ethnic and Racial Minorities at Risk for Substance Use and HIV/AIDS

SUPPORTING STATEMENT

A. Justification

1. Information Collection

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment *(*CSAT) is requesting OMB approval for a revision and reinstatement of the Minority AIDS Initiative (MAI) Rapid HIV Testing Clinical Information Form (OMB No. 0930-0295), which expired on March 31, 2009. The original data collection form was used by the Technical Capacity Expansion for American Indians and Alaska Natives (TCE-AI/AN) program and was previously thought to be a one-time data collection activity. However, the TCE AI/AN program obtained additional MAI funds to continue conducting rapid HIV testing. In addition, the revised form will be utilized by providers of the Technical Capacity for HIV (TCE-HIV) program also located within CSAT who serve individuals affected by the twin epidemics of HIV and substance abuse.

The Form is being submitted as a "reinstatement" since there is a critical public health need to continue conducting rapid HIV testing among ethnic and racial minorities who are disproportionately affected by HIV (Human Immunodeficiency Virus) through drug use. The MAI HIV Rapid Testing Clinical Information Form (see Attachment A) would allow SAMHSA/CSAT to collect essential clinical information that will be important for individuals found to be HIV positive to receive timely and appropriate referrals to quality medical care and prevention services. The information on the Form will also be useful for quality assurance and product monitoring on approximately 20,000 rapid HIV test kits that will be provided to substance abuse treatment provider organizations.

This 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 drugs of abuse (both illicit and non-illicit drugs such as alcohol and marijuana). In addition to HIV transmission associated with individuals sharing syringes and other drug injection equipment, HIV transmission can also occur through sexual contact with injection drug users who are HIV positive. Moreover, the use of both injected and non-injected drugs increases the risk for HIV/AIDS 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 integral part of their treatment. If they are found to be HIV seropositive, the integration of testing as part of their treatment will allow for the opportunity of a timelier and more appropriate referral for quality medical care and secondary prevention services to effectively treat the individual and reduce further HIV transmission.

Although many HIV-infected persons have been identified through traditional risk-based approaches to HIV testing, CDC estimates that approximately one quarter of the estimated 1 to 1.2 million Americans infected with HIV are unaware of their HIV status. As noted above, ethnic and racial minority groups are disproportionately affected by the AIDS epidemic. AIDS rates are 72.1 per 100,000 for non-Hispanic Black, 25.0 per 100,000 for Hispanic, 9.9 per 100,000 for American Indian/Alaska Native adults and adolescents, and 4.4 per 100,000 for Asian/Pacific Islanders (HIV/AIDS Surveillance Supplemental Report 2006, Vol. 12, No. 1). Despite these staggering statistics, in addition to CDC's estimation that a quarter of individuals with HIV/AIDS are unaware of their HIV status, about a third who test positive for HIV each year do not return for their results when standard HIV tests that typically take 2 to 14 days are used.

In response to the AIDS epidemic, SAMHSA /CSAT has awarded approximately 160 grantees/providers who will implement rapid testing as an integral part of their proposed service grants to enhance and expand substance abuse treatment and/or outreach and pretreatment services for African American, Latino/Hispanic, and/or other racial and ethnic communities highly affected by the twin epidemics of substance abuse and HIV/AIDS. Grantees are required to offer rapid HIV testing to all substance abuse treatment participants and test a minimum of 80% of these individuals using rapid HIV test kits. All substance abuse treatment 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 which necessary to conduct rapid HIV is testing. Furthermore, since State jurisdictions often require pre- and post-test counseling and referral strategies, it is important for SAMHSA/CSAT to know whether compliance with these expectations is being met.

The objective of these CSAT funded grants is to build and/or strengthen organizational capacity of providers to provide HIV/AIDS education, prevention, and treatment services 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/AIDS status and are referred to appropriate and timely medical care.

2. Purpose and Use of Information

The MAI Rapid HIV Testing Clinical Information Form will be used to collect data that will assist in the delivery of timely and appropriate medical care and prevention services to individuals found to be HIV positive. The Form can also be used for quality assurance, quality performance, and product monitoring. The form does not require identifiable patient specific information to be collected from individuals participating in the MAI program. The form is designed primarily to inform SAMHSA/CSAT that the intended audience is being tested and that individuals found to be HIV seropositive are being referred to care.

The MAI HIV Rapid Testing Clinical Information Form takes only about 8 minutes to complete. Furthermore, while the Form does not contain patient specific identifiers, it does contain a space for lot number identification in the event that problems associated with a specific lot arise. Such

problems have already occurred in several areas of the United States, making this information critical to substance abuse treatment providers and their patients.

Changes
In addition to minor modifications in formatting, several changes were made to the previously approved Form:

1) In Section A, a list of testing site types was added and referenced on the back page of the Form.
2) In Section D, six questions related to HIV behavioral risk were added.
3) In Section D, a check-off list of drugs "used in the last 30 days" were added.
4) In Section D, three additional questions related to alcohol/drug treatment were added.
5) In section F, one additional option ("linked to prevention/ancillary services") was added to the 'Type of Services Provided'.

3. Use of Information Technology

The SAMHSA MAI Rapid HIV Testing Clinical Information Form will be available in hard copy format for proper documentation at the collection site. Each provider organization will include the initial rapid HIV test kit lot number on the hard copy. In the event of an invalid or indeterminate test result, the provider organization must also include the HIV Rapid Test Kit Lot Number on the Forms for re-tests. Preprinted unique SAMHSA Client Identification numbers will be included on the clinical information form to ensure it can be directly linked with the specific rapid HIV test kit. After the clinical information form is collected from each program participant, two copies (pages 2-3) of the Form go into the participant's record, and one copy (page 1) is sent to a contractor designated by SAMHSA/CSAT. If a confirmatory HIV test is required, the information is recorded on page 2-3 of the Form and the copy (page 2) is sent to the identified contractor. To reduce cost and burden, forms are preprinted and provided to substance abuse treatment provider organizations at no cost with each rapid HIV test kit.

4. Efforts to Identify Duplication

The MAI Rapid HIV Testing Clinical Information Form is a significantly abridged version of the OMB approved CDC HIV Test Form (OMB No. 0920-0696, Exp. Date: 08/31/2010). However, SAMHSA's MAI Rapid HIV Testing Clinical Information Form includes additional questions that specifically focus on the intersection of HIV risk behaviors and substance use. Because the rapid HIV testing required by SAMHSA falls outside of the usual State Health Department process, the grantee providers would not be using either the State forms or the longer CDC forms. There will be no additional burden since providers will retain copies of the Forms, and can extract the information that are also required by the State or requested by CDC.

5. Involvement of Small Entities

Approximately 50% of the grantees that will be conducting rapid HIV testing can be considered small not-for-profit organizations that are not dominant in the field and would be considered

"small entities" by OMB. The burden associated with the revised Form poses no significant impact on these organizations.

6. Consequences If Information Is Collected Less Frequently

The revised Form will be used by all CSAT funded grantees that are required to conduct HIV rapid testing as part of their conditions of award. Each grantee will offer the rapid HIV testing once at program entry. However, some individuals may be offered a second test if they continue to engage in high risk sexual and drug taking behaviors or if they have been recently (within 3 months) exposed or suspect that they have been exposed to HIV.

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

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

8. Consultation outside the Agency

The notice required in 5 CPR 1320.8 (d) was published on February 26, 2009 (Vol. 74, page 8802). No comments were received from this notice. CSAT e-mailed the following 3 potential respondents draft copies of the Form on May 8, 2009 to solicit their views on whether the information requested was reasonable and whether the form was written in plain, unambiguous language.

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9. Payment to Respondents

Respondents will not be paid.

10. Assurance of Confidentiality

The Forms will be stored and compiled by a contractor that has experience in preserving the privacy of the data collection process. The contractor also recognizes the importance of restricting access to data of this nature. The information obtained on the Form will be restricted to only staff that has a programmatic or clinical need for the information. The data collected from the Forms will be abstracted and the privacy of the client will be maintained in accordance with policies, procedures and regulations established by both the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule and Title 42 Code of Federal Regulations Part 2 – Confidentiality of Alcohol and Drug Abuse Patient Records (Title 42 CFR Part 2).

11. Questions of a Sensitive Nature

The revised Form includes questions of a sensitive nature such as the patient's risk factors. However, no patient specific identifier information is collected on the Form or provided to the Federal government. The clinical information obtained is information that is typically collected in the conduct of HIV testing in the community. Providers retain all patient specific information and securely maintain the code by which a specific patient 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 of individuals tested.

12. Estimates of Project Hour Burden

The 0.133 hour per 1 response burden estimate is based on CDC's burden estimates for completion of their HIV Test Form, CDC 50,135a(E), (OMB No. 0920-0696, Exp. Date: 08/31/2010). The estimation is based on responses of 20,000 tests performed annually by CSAT funded providers with the Hourly Wage Cost derived from the 2003 National Occupational Employment and Wage Estimates for Management Occupations, Social and Community Service Managers (Bureau of Labor Statistics, Office of Employment Statistics and Occupational Employment Statistics). Fringe benefits (estimated at 27%) were added to the mean hourly wage.

In addition, among the 20,000 individuals who will be tested for HIV, a certain portion will be retested. CDC recommends 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 CSAT's 10 year experience working with populations that are dually affected by substance and HIV, it is estimated that about 20% or 4,000 of the 20,000 individuals will be retested based on their persistent risk behaviors.

Form	Number of Respondents	Responses/ Respondent	Hours/ Response	Total Hour Burden	Hourly Wage Cost ($)	Total Hour Cost ($)
MAI Rapid HIV	20,000	1	0.133	2,660	$ 30.00	$79,800

Testing Clinical Information Form (At Program Entry)						
MAI Rapid HIV Testing Clinical Information Form (Re-test)	4000	1	0.133	532	$ 30.00	$15,960
Total	20,000			3,192		$95,760

13. Estimates of Annualized Cost Burden to Respondents

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

14. Estimates of the Annualized Cost to the Government

The cost to the Government will include approximately 45 hours for the Government Project Officer (GS-13, Step 1) to coordinate with the provider organization ($1,788). Approximately $370,000 will be expanded to cover the distribution and collection of the clinical information form for an estimated annualized cost to the government of $371,788.

15. Changes in Burden

Previously 8,350 burden hours were estimated in the OMB inventory. CSAT is now requesting 3,192 total burden hours which is a decrease of 5,158 hours in burden from the earlier estimate. The previous estimate of 50,000 respondents has been modified to reflect a more realistic number of respondents of 20,000.

16. Time Schedule, Publication, and Analysis Plans

If the information collected is published, all identifiable information will be excluded and the data will be aggregated to protect the privacy of program participants.

Time Schedule

SAMHSA/CSAT anticipates starting the data collection using the approved form by the end of August 2009.

Activity

This data collection will continue for the next 3 years.

17. Display of Expiration Date

The expiration date for OMB approval will be displayed.

18. Exceptions to Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions. The certifications are included in this submission.

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

To minimize response burden, SAMHSA/CSAT will allow grantees of the TCE-HIV and TCE-AI/NA programs that meet SAMHSA/CSAT's HIV Rapid Testing Readiness Requirement to self-select.

The MAI consist of substance abuse treatment clinics, federal qualified health centers, community based organizations, local health departments, AIDS Service Organizations, as well as states receiving Block Grants that have reported 10 HIV cases per 100,000 according to 2006 CDC estimates. SAMHSA may add new MAI grantees in future years, but this would not increase the number of responses from participating providers.

Table 1: Grantees funded with MAI Funds through TCE-HIV awards.

Program Name	# Grantees/ (Providers)
TCE-HIV	135
TCE-AI/AN	25
Total	160

Sample Size of 20,000 Rapid HIV Tests is based on the estimation that each provider will be conducting an average of 125 rapid HIV tests per year.

2. Information Collection Procedures

The SAMHSA MAI Rapid HIV Testing Clinical Information Form will be available in hard copy form for complete and appropriate documentation at the collection site. Each provider organization will include the initial rapid HIV test kit Lot Number on the hard copy. In the event of an invalid or indeterminate test result, the provider organization must also include the HIV Rapid Test Kit Lot Number for retesting. Preprinted unique SAMHSA Client Identification numbers are included on the Form to ensure that it can be directly linked with the Rapid HIV Test Kit. After the clinical information form is collected from each program participant, two copies of the form go into the participant's record (page 2-3), and one copy (page 1) is sent to a contractor designated by SAMHSA/CSAT. If a confirmatory HIV test is required, the information is recorded on pages 2-3 of the SAMHSA MAI Rapid HIV Testing Clinical Information Form and the copy (page 2) is sent to the identified contractor. The Forms can be submitted on a daily or bi-monthly. The provider is required at all times to observe privacy procedures to protect client information obtained from the Form.

3. Methods to Maximize Response Rates

CSAT anticipates that they will receive 100% response rate because the Form should be completed whenever a rapid HIV test kit is used by the provider. The test kits will have a unique number as well as a lot number.

4. Test of Procedures

The previously approved MAI Rapid HIV Testing Clinical Information Form has been in use since the fall of 2008 and has encountered no problems related to either its implementation or completion.

5. Statistical Consultants

This material has been reviewed by:

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List of Attachments

A. MAI Rapid Testing Clinical Information Form.