Minority AIDS Initiative for Collaboration for Prevention and Treatment Improvement for American Indians and Alaska Natives at Risk for Substance Use and HIV/AID Rapid HIV Testing Clinical Information Form

SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center Substance Abuse Treatment (CSAT), is requesting an emergency OMB review and approval of the Minority AIDS Initiative (MAI) for Collaboration for Prevention and Treatment Improvement for American Indians and Alaska Natives at Risk for Substance Use and HIV/AID, Rapid HIV Testing Clinical Information Form. The MAI HIV/AID Rapid Testing Clinical Information Form (see Attachment A) would allow SAMHSA/CSAT to collect essential clinical information that will be used for quality assurance, quality performance, and product monitoring on approximately 50,000 Rapid HIV Test Kits to be provided to American Indian and Alaska Native (AI/AN) communities at no cost to the recipient provider organizations.

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

The target population for the initiative is Tribes, Tribal organizations, and Urban Indian Health Organizations that reside in Alaska, Arizona, California, Florida, Michigan, Nevada, New Mexico, New York, North Carolina, Oklahoma, Texas, Utah and Washington who are at risk for substance use and HIV/AIDS. The selected states are those with the highest concentration of AI/AN population based on United States Census 2000. It should be noted that 6 of these states (California, Florida, Nevada, North Carolina, and New York) are also designated Block Grant HIV State-aside states (reported 10 HIV cases per 100,000 to CDC). Additionally, the top five AI/AN AIDS Case states are—California, Oklahoma, Washington, Arizona and Alaska, which also are part of the target population. The hope in these 13 States is to build and or strengthen tribes, tribal organizations and urban Indian health centers capacity to provide HIV/AIDS education and prevention services to American Indians and Alaska Natives; reduce the stigma associated with HIV/AIDS screening through outreach and education and increase the number of American Indians and Alaska Natives who know their HIV/AIDS status.

The American Indian/Alaska Native communities have been concerned about the availability of HIV testing and, hence, status, determination in their communities. CDC data suggest a disproportionately high amount of HIV seropositivity among the AI/AN populations. Unfortunately, the AI/AN populations are spread out even within the selected jurisdictions, making routine testing even more difficult.

The advent of the Rapid Test, either oral or blood, has made it easier to promote community level testing. Advocates within AI/AN communities believe that the HIV disease is being

allowed to spread within the AI/AN community, in part, due to the lack of HIV status determination associated with the Rapid test. Consequently, a growing sense of urgency necessitates a stepped up effort to make Rapid HIV Tests available to tribes, tribal organizations, Urban Indian Health Centers, and community based organizations invested in screening for HIV/AIDS their communities.

It should be noted that SAMHSA's data from the National Survey on Drug Use and Health reveals that while only 38% of those in AI/AN communities survey consume alcohol in the past month, of those who do consume alcohol over 80% are problem drinkers. It is well established that high risk behavior is often associated with substance use. It should also be noted that female members of the AI/AN community are at an increase risk of contracting the HIV virus through heterosexual transmission.

Additional funding was made available through the Office of the Secretary of the Department of Health and Human Services to the Substance Abuse and Mental Health Administration to provide HIV/AIDS education and prevention services to American Indians and Alaska Natives. To help reduce the stigma associated with HIV/AIDS; screening through outreach and education, it is hoped to increase the number of American Indians and Alaska Natives to be tested so they will be able to know their HIV/AIDS status. This process has taken longer than anticipated. Furthermore, associated with the testing process has been a necessary training effort to comply with the requirements for Rapid HIV testing.

As this project is a community clinical service involving the use of Federal government purchased, FDA approved Rapid HIV Test kits, rather than research, it is critical to get these test kits into the community as soon as possible. It is also important for us to know that the test kits are reaching their intended audience. Furthermore, since State jurisdictions often require associated pre- and post-counseling and referral strategies, it is important for us to know whether compliance with these expectations are occurring.

Emergency Nature of the Request

It was originally thought that the clinical information to be collected using the MAI HIV Rapid Testing Clinical Information Form was clinical exempt information associated with the testing of biological fluids. As a result, almost 20,000 test kits were received in June 2008 with a 6 month expiration date. It has now been determined that the MAI HIV Rapid Testing Clinical Information Form requires OMB approval.

In order to provide American Indian and Alaska Native communities immediate access to these critical Rapid HIV tests, which are inextricably linked to status determination, and to avoid future loss to the government of the almost 20,000 previously purchased Rapid Test Kits, SAMHSA is requesting an emergency approval of the MAI HIV Rapid Testing Clinical Information Form.

Given the history, SAMHSA could not have anticipated the need for this information any earlier. Even with an emergency OMB clearance, the timeline is extremely short for completing the

information gathering and taking all other needed steps to provide approximately 50,000 no cost Rapid HIV Test to American Indian and Alaska Native communities.

- Due to the six month shelf life of the Rapid HIV Test Kits it is unlikely that SAMHSA will be able to distribute the Rapid HIV Test Kits and collect the essential clinical information prior to the expiration of the existing 20,000 Rapid HIV Test Kits without the emergency OMB clearance of the MAI Rapid HIV Testing Clinical Information Form.
- With emergency OMB clearance of the MAI Rapid HIV Testing Clinical Information Form, all of the test kits will be available for immediate distribution, allowing up to 50,000 test kits to be distributed as quickly as possible.

2. Purpose and Use of Information

The data on the MAI Rapid HIV Testing Clinical Information Form will be used to collect clinical information that can be used for quality assurance, quality performance, and product monitoring. The form does not require patient specific information to be collected from parties participating in the MAI program. The form is designed to inform SAMHSA that the HIV Rapid Test Kits are reaching their intended audience, as many communities have expressed an interest in acquiring these no cost test kits to assist them in informing and protecting their citizens. The information that we require, will also serve to justify the use of Federal funds to benefit the American Indian/Alaska Native community.

The MAI HIV Rapid Testing Clinical Information Form is a short form that takes only 10 minutes to complete. It is an abridged version of a form that that CDC has received OMB approval (OMB No. 0920-0696, Exp. Date: 08/31/2010). Furthermore, while the form does not contain patient specific identifiers, it does contain space for lot number identification in the event that the FDA determines that problems exist with a specific lot; such problems have already occurred in several areas of the United States, making this information of critical importance to providers and to patients.

3. Use of Information Technology

The SAMHSA MAI Rapid HIV Testing Clinical Information Form must be a hard copy form to properly document chain of custody at the collection site and each provider organization must include the initial HIV Rapid Test Kit Lot Number and in the event of an invalid result the provider organization must also include the HIV Rapid Test Kit Lot Number for the retest on the original MAI Rapid HIV Testing Clinical Information Form. Preprinted unique SAMHSA Client ID is included on the form to ensure that the form and the information on it can be directly associated with a specific Rapid Test Kit. After collection, two copies of the form goes into the client's record (page 2-3) , one copy (page 1) is sent to Westat, SAMHSA 's contractor and if a confirmatory test is required the information is recorded on page 2-3 of the original SAMHSA MAI Rapid HIV Testing Clinical Information Form and copy (page 2) is sent to Westat.. To reduce cost and burden, forms are preprinted and provided to the provider organization at no cost with each Rapid HIV Test Kit.

4. Efforts to Identify Duplication

The MAI Rapid HIV Testing Clinical Information Form is an abridged version of the OMB approved CDC HIV Test Form (Attachment B). Because the testing involved falls outside of the usual State Health Department process, the providers involved would not be using either State forms or the longer CDC form. The information contained on the SAMHSA MAI Rapid HIV Testing Clinical Information Form therefore does not impose an additional burden in terms of information collection on the recipients of the forms. Since the recipient of the SAMHSA sponsored kits will retain copies of the forms, they will be able to use the information on the forms to complete any State required information or CDC requested information. Furthermore, since the clinical information requested is attached to the Rapid HIV Test kits provided at no cost to the recipient provider, there will be no duplication of effort.

5. Involvement of Small Entities

Approximately 34 participating tribal organizations and/or Urban Health Center can be considered as small not-for-profit organizations that are not dominant in the field and would be considered to be "small entities" by OMB.

6. Consequences If Information Is Collected Less Frequently

The current form is a one-time data collection effort for each Rapid HIV Test Kit administered.

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 July 29, 2008 (Vol. 73, page 43945).

CSAT e-mailed the following potential respondents draft copies of the form on July 21 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

This form will be stored and compiled by a contractor which has experience in preserving the confidentiality of the data collection process. The contractor, WESTAT, also recognizes the importance of restricting access to data of this nature. The form itself is provider specific and not client specific. Nevertheless, the provider information will be restricted to only those with a need to know. The information shared will be abstracted.

11. Questions of a Sensitive Nature

The information collection does include questions concerning sensitive information such as the patient's risk factors. However, no patient identifier information is collected by the form or provided to the Federal government. The information collected by the form is associated with the clinical information normally attached to the use of HIV testing in the community. The community provider retains all patient specific information and retains the code by which a specific patient can be identified. The Federal government receives only a coded patient identifier which can only be used to determine that a specific unknown patient received the test kit and that certain demographic and referral information.

12. Estimates of Project Hour Burden

The .167 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 complete estimation is based on one-time-only responses for 50,000 test performed by a provider, 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, Occupational Employment Statistics). Fringe benefits (estimated at 27%) were added to the mean hourly wage.

Form	Number of Respondents	Responses/ Respondent	Hours/ Response	Total Hour Burden	Hourly Wage Cost ($)	Total Hour Cost ($)
MAI Rapid HIV Testing Clinical Information Form	50,0000	1	.167	8,350	$ 30.00	$250,500

13. Estimates of Annualized Cost Burden to Respondents

This information is routinely maintained as a part of customary and usual business practices. There are no costs associated with its collection.

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) and approximately $200,000 will be expanded to cover distribution and collection of the clinical information form for estimated annualized cost to the government is $201,788 .

15. Changes in Burden

This is a new project.

16. Time Schedule, Publication, and Analysis Plans

None of the information collected will be published.

Time Schedule

Activity	***Date***
OMB briefing on issues related to emergency request	July 22
SAMHSA submits package to Department	July 29
Federal Register Notice is published	July 29
OMB logs request into its docket	July 29
OMB approves request	August 28

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 will allow Tribes, Tribal Organizations and Urban Indian Health Centers within MAI designated States that meet SAMHSA's HIV Rapid Testing Readiness Requirement, Tribal and or State requirements to self-select.

The MAI consist of Tribes, Tribal organizations, and Urban Indian Health Organizations that reside in Alaska, Arizona, California, Florida, Michigan, Nevada, New Mexico, New York, North Carolina, Oklahoma, Texas, Utah and Washington who are at risk for substance use and HIV/AIDS. The selected states are those with the highest concentration of AI/AN population based on United States Census 2000. It should be noted that 6 of these states (California, Florida, Nevada, North Carolina, and New York) are also designated Block Grant HIV State-aside states (reported 10 HIV cases per 100,000 to CDC). Additionally, the top five AI/AN AIDS Case states are—California, Oklahoma, Washington, Arizona and Alaska, which also are part of the target population. SAMHSA may add new MAI states in future years, but this would not increase the number of responses from participating providers.

Table 1: Providers within the 13 MAI States.

State	Tribes	Tribal Organization.	Urban Indian Health Center	Total Providers
Alaska	244	6		250
Arizona	82	1	6	89
California	246	1	14	261
Florida	2			2
Michigan	8		2	10
Nevada	25	1	1	27
New Mexico	69	2	1	72
New York	10		1	11
North Carolina	1			1
Okalahoma	35	1	3	39
Texas	5		2	7
Utah	5		1	6
Washington	21		2	23
Total	753	12	33	798

Sample Size: 50,000 Rapid HIV Test Kits

2. Information Collection Procedures

When a client comes into the provider organization and request and/or the provider as the client if they would like to be screen for HIV/AIDS utilizing a Rapid HIV Test Kit; the provider would select a no cost Rapid HIV Test Kit along with the corresponding MAI Rapid HIV Testing Clinical Information Form. The provider would complete the Form at the time the test is performed. Upon completion of the form part is place in prepaid FEDEX envelope and sent to Westat (Contractor); part 2-3 is place in the client's records. If a confirmatory test is required after the results are returned the provider they would fill-out the confirmatory information at the same time that they giving the information to their client. Part 2 of the Form is then place in a prepaid FEDEX envelope to be sealed and sent to Westat (Contractor). The Forms can be sent back on a daily or bi-monthly. The provider should observe all privacy procedures.

3. Methods to Maximize Response Rates

CSAT anticipates that they will receive 100% response rate because the Form should be completed whenever a no cost 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 MAI Rapid HIV Testing Clinical Information Form is an abridged version of the CDC HIV Test Form, CDC 50,135a(E), (OMB No. 0920-0696, Exp. Date: 08/31/2010).

5. Statistical Consultants

This material had been reviewed by:

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List of Attachments

A. MAI Rapid Testing Clinical Information Form.

B. CDC HIV Test Form