

Co-location and Integration of HIV Prevention and Medical Care into Behavioral Health (Co-located and Integrated Care)

Supporting Statement

A. Justification

A1. Circumstances of Data Collection

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS), Center for Substance Abuse Treatment (CSAT) and Center for Substance Abuse Prevention (CSAP) is requesting a revision from the Office of Management and Budget (OMB) for data collection activities associated with its grant programs which focus on the intersection of HIV, Hepatitis and prevention/treatment of substance use disorders and/or mental health disorders. SAMHSA is requesting approval to amend its **Co-location and Integration of HIV Prevention and Medical Care into Behavioral Health** (Co-located and Integrated Care) data collection. The current Co-located and Integrated Care OMB data collection (OMB No. 0930-0343) expires on September 30, 2017. The currently approved data collection includes:

- **A Combined Rapid HIV/Hepatitis Testing Form (RHHT)** a brief form that provides information on each individual receiving HIV and/or hepatitis testing services.
- **A program-specific version of SAMHSA's TRansforming Accountability (TRAC) System.** The questions contained in the Co-located and Integrated Care version of TRAC are similar in content and length to the current OMB-approved version of CMHS's TRansforming Accountability (TRAC) System.
- **HIV-Specific Indicators**, a supplemental module that will be added to the Co-located and Integrated Care version of TRAC. The module will collect client-level service and outcome data for individuals receiving HIV-related medical services.

This data collection is needed to provide SAMHSA with objective information to document the reach and impact of services funded to address HIV and Hepatitis in the context of substance use disorders and mental health disorders. The information will be used to monitor quality assurance and quality performance outcomes for organizations funded by its grant programs. Collection of the information included in this request is authorized by Section 505 of the Public Health Service Act (42 USC 290aa-4) – Data Collection.

Further support for this collection was provided in the 2013 Senate Appropriations Report 113-71. The report urged SAMHSA to “focus its efforts on building capacity and outreach to individuals at risk or with a primary substance abuse disorder and to improve efforts to identify such individuals to prevent the spread of HIV.” Additional support for this data collection effort is provided by the 2013 National HIV/AIDS Strategy which instructed SAMHSA to “support and rigorously evaluate the development and implementation of new integrated behavioral health models to address the intersection of substance use, mental health, and HIV.”

A2. Purpose and Use of the Information Collected

The funded grant programs will be collecting HIV and hepatitis testing data in support of integrated behavioral health and physical health services for racial/ethnic populations at high risk for behavioral health disorders and at high risk for contracting HIV and/or Hepatitis.

Any client coming into these programs will be eligible to receive evidence-based prevention services, including pre and post-test HIV/hepatitis counseling, and rapid HIV and Viral Hepatitis testing.

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 of the estimated 1.1 million Americans infected with HIV, approximately 1 in 6 are unaware of their HIV status.¹ 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 51.3 per 100,000 for African-Americans, 16.2 per 100,000 for Latinos, and 8.0 per 100,000 for American Indians/Alaska Natives.²

In the United States, the most common Hepatitis infections include Hepatitis A, B and C. Individuals who are at risk for becoming infected with these Hepatitis infections include but are not limited to men who have sex with men, injection and non-injection drug users, a person having multiple sex partners and individuals having sexual contact with an infected person. According to a person's risk profile, vaccination against Hepatitis A and B may be warranted.^{3,4} Although there is currently no vaccine for Hepatitis C, in addition to taking preventive measures to avoid infection (e.g., avoidance of using shared or reused needles, syringes and other equipment used to inject drugs, not sharing personal items that may have come in contact with a person's infected blood)⁵, there are treatment options available to those individuals who become infected with Hepatitis C.⁶ Hence, screening for these Hepatitis infections is critical in order to develop the appropriate type of health care intervention.

The RHHT form is used to collect data that will assist in the enhancement of preventive services for those who test negative for HIV and hepatitis and referral to high-quality treatment/medical care for those who test positive. The form is also used for quality assurance and monitoring. This information collection is needed to provide SAMHSA with objective information to document the reach and efficacy of its designated funded grant programs.

¹ CDC. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data – United States and 6 U.S. dependent areas – 2011. HIV Surveillance Supplemental Report 2013;18(No. 5). Available at: <http://www.cdc.gov/hiv/library/reports>. Published October 2013. (Accessed March 27, 2014).

² Centers for Disease Control and Prevention, [National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention \(NCHHSTP\) Atlas](#), accessed March 27, 2014

³ Centers for Disease Control and Prevention, Vaccine Information Statements – 2011. <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-a.html>

⁴ Centers for Disease Control and Prevention, Hepatitis General Information – 2010. www.cdc.gov/hepatitis/HBV/PDFs/HepBGeneralFactSheet.pdf

⁵ Centers for Disease Control and Prevention [Hepatitis C General Information - 2015](#). www.cdc.gov/hepatitis/HCV/PDFs/HepCGeneralFactSheet.pdf

⁶ Centers for Disease Control and Prevention. Viral Hepatitis – Hepatitis C Information – 2015 <http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#section4>

Changes

SAMHSA is requesting the deletion of the following tools under this OMB submission:

- 1) **The program-specific version of SAMHSA’s TRansforming Accountability (TRAC) System.** Co-located and Integrated Care grantees are approved to collect GPRA data under the GPRA data collection (OMB No. 0930-0346), and this program-specific version of TRAC is no longer needed.
- 2) **HIV-Specific Indicators.** Co-located and Integrated Care grantees are approved to collect this information under the GPRA OMB data collection. (OMB No. 0930-0346).

SAMHSA is also requesting that OMB approve minor modifications to the RHHT form. A summary of the proposed changes is provided in Table 1. Proposed changes to the RHHT form are highlighted in the RHHT Form found in Attachment 1. A fully formatted version of the final form can be found in Attachment 2.

In addition, SAMHSA is requesting that OMB extend approval to collect the RHHT form to three additional CSAT grant programs and three additional CSAP programs. This change represents an effort to align data collection for all SAMHSA grant programs that focus on the intersection of HIV, Hepatitis and prevention/treatment of substance use disorders and/or mental health disorders.

Table 1. Changes to RHHT Form

| Section | Question(s) | Type of Change | Requested Change |
|---------|-------------|-----------------------|--|
| A | 4 | Clarification | Wording of question has been updated to clarify that form is asking for a unique RHHT ID. |
| A | 5 | Question Added | Requests ID from GPRA (if applicable) to assist with the data matching process |
| A | | Question Added | Rapid HIV Test Kit Lot Number |
| C | 2 | Response Option Added | Response option added for “Inhalants (Specify_____)” |
| E | Directions | Clarification | Directions amended to include “If applicable” |
| E | 1 | Clarifications | Directions amended to include “that apply” |
| E | 2-4 | Questions Added | Form now asks for separate results for Hepatitis B and Hepatitis C |
| G | Directions | Clarification | Directions amended to include “If applicable” |
| G | 1-2 | Question Added | Form now asks for separate results for Hepatitis B and Hepatitis C |
| G | 2 | Question Removed | Question regarding type of Confirmatory Hepatitis test removed |
| H | | Clarification | One response option has been clarified. An option including the language “Client attended a routine HIV medical care visit in past three months” has been updated to “Client attended a routine HIV medical care visit within three months of HIV diagnosis” |
| I | Directions | Clarification | One response option has been clarified. An option including the language “Client attended a routine |

| | | | |
|------------|------------|---------------------------|--|
| | | | Hepatitis medical care visit in past three months” has been updated to “Client attended a routine Hepatitis medical care visit within three months of Hepatitis diagnosis”. The selection box next to Hepatitis vaccination has been removed. Hepatitis dosage number and corresponding dates has been added for Hepatitis A, Hepatitis B and Hepatitis A & B (Twinrix). |
| I | Directions | Question Added | Following the possible answer of ‘No’ regarding Hepatitis Vaccination, the question added is “If no, reason?” |
| Site Codes | | Response Options Modified | One response option has been added (Community Setting – Mobile Unit) and several have been re-numbered. |

A3. Use of Information Technology

SAMHSA has made every effort to limit the burden on individual respondents and participating agencies through the use of information technology. Grantees will be asked to complete a RHHT Form for each individual that receives an HIV or Viral Hepatitis testing service. Each testing form will be completed at the time that the medical testing takes place. The design of the RHHT Form encourages the use of automation to reduce burden on participating grantees. Testing forms will be completed at each grantee site and electronically submitted to an Evaluation Contractor for secure storage and analysis through a secure web portal. The HIV/Hepatitis Testing Form has been designed to not include any personally identifiable information, and all electronic transmissions will be designed to be FISMA compliant.

RHHT Testing Forms will be submitted electronically to the evaluation contractor for the life of this project.

A4. Efforts to Identify Duplication

Currently CDC requires that grantees that are directly funded by CDC for HIV prevention activities complete the CDC EvaluationWeb 2012 HIV Test Template Form. While the CDC HIV Form includes some of the same information as our RHHT Form, SAMHSA anticipates that there will be relatively little duplication of effort associated with these two forms.

It is possible that the behavioral health entities will partner with HRSA Ryan White Care Act grantees to provide the medical care to clients living with HIV. SAMHSA anticipates that there will not be duplication with the RHHT Form as the screening and confirmatory testing should be completed before referral to this care.

A5. Impact on Small Business

The information collected will not have an impact on small business entities.

A6. Consequences of Collecting the Data Less Frequently

The current request represents SAMHSA's need to know information about every individual served by grant programs which focus on the intersection of HIV, Hepatitis and prevention/treatment of substance use disorders and/or mental health disorders.

A7. Consistency with the Guidelines in 5 CFR1320.5(d)(2)

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

A8. Consultation Outside the Agency

The notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on July 23, 2015 (80 FR 43785). No comments were received.

A9. Payment or Gifts to Respondents

No payments or gifts will be offered or provided to respondents.

A10. Assurances of Privacy

This data collection effort will include sensitive topics such as mental health information, substance abuse information and HIV/hepatitis status. Participating grantees will be expected to meet the requirements of the HIPAA and its associated Privacy Rule, and for those with substance use disorders, 42CFR requirements that set the standards for the use and disclosure of an individual's health/mental health/substance use information.

Individual grant projects use informed consent forms as required and as viewed appropriate by their individual organizations.

The informed consent forms usually contain the following elements:

- Explanation of the purpose of the program or research.
- Expected duration of the subject's participation.
- Description of the procedures to be followed.
- Identification of any procedures which are experimental.
- Description of any reasonably foreseeable risks or discomforts to the subject.
- Disclosure of appropriate alternative procedures or courses of treatment.
- Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- Contact names & phone numbers for participants to ask questions about program, participant rights, and injury.

SAMHSA's evaluation contractors will train grantees on the administration of all data collection instruments. In documents that contain individual client-level data, clients will only be identified by unique IDs, which cannot be used to re-identify a patient.

Specific information relating to the RHHT Form is provided below:

The RHHT Form includes questions concerning sensitive information such as the patient's risk factors, but no personally identifying information is collected. The form utilizes two unique Client IDs that are assigned by the grantee, a Client RHHT ID and a GPRA ID. Grantees will be instructed that both IDs must be randomly generated and that patient IDs, which may be able to re-identify a patient, cannot be used for either type of ID. Clients who are not receiving program services other than testing will not be required to complete a GPRA interview, and thus will not have a GPRA ID. However, in instances in which clients are receiving SAMHSA-funded services in addition to testing services, GPRA data interviews are required. In an effort to simplify the data matching process, we are asking grantees to report both IDs at the time of testing to ensure that all information is available for analysis.

Participating programs will retain all patient identifying information and the codes by which a specific patient can be identified. The form also contains a grantee provider number for tracking purposes only.

Testing forms will be stored and compiled by the evaluation contractor. At this time, SAMHSA anticipates that grantees will be uploaded into a password-protected online system maintained by the evaluation contractor. Contractor staff will upload the data over a secure network connection directly to a server at their headquarters, where the data will be encrypted and password protected.

Prior to the collection of this information by the evaluation contractor, SAMHSA's Information Technology Officer will review the contractor's IT security plan to ensure that it responds to SAMHSA IT Requirements and adequately meets all SAMHSA and Federal Security Plan Requirements.

Privacy During the Testing Process: Grantee staff members administer the RHHT 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. All data collection instruments will include the OMB number, expiration date, and the statement of survey burden.

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 personally 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 will review the evaluation contractor's IT security plan to ensure that it is reasonable, responds to SAMHSA's IT Requirements, and adequately meets all SAMHSA and Federal Security Plan Requirements of the program.

A11. Questions of a Sensitive Nature

SAMHSA’s mission is to improve the quality and availability of prevention, early intervention, treatment, and rehabilitation services for substance abuse and mental illnesses, including co-occurring disorders, in order to improve health and reduce illness, death, disability, and cost to society. The overarching goal of the programs that are being proposed to use the RHHT form is to support behavioral health screening, primary prevention, and treatment for racial/ethnic populations at high risk for behavioral health disorders and at high risk for or living with HIV/hepatitis. In carrying out these goals, it will be necessary for grantees to collect sensitive items such as substance use, information on sexual risk factors for HIV/hepatitis, information on mental health functioning, and hepatitis and HIV/hepatitis status.

The data that will be submitted by each grantee will include data that many of the programs are already routinely collecting. This includes information on client demographics, mental health condition/illness and treatment history, services received, and client outcomes. The additional information related to HIV/hepatitis risk factors and related clinical data are essential to assess the reach and impact of the program.

Funded projects will utilize informed consent procedures as required and as viewed appropriate by the individual organizations.

A12. Estimates of Annualized Burdens and Costs

The total estimated respondent burden is 6,097 hours for the period from November, 2015 through November, 2016. Table 2 below summarizes the updated annualized respondent burden estimate.

The estimated hourly wage is based on the latest publicly available data (May, 2014) from the Occupational Employment Statistics Survey (OES), a mail survey that measures occupational employment for wage and salary workers in non-farm establishments in the US. The OES collects data from over 1.2 million business establishments through six semiannual panels over a three year period. It is sponsored by the Department of Labor, Bureau of Labor Statistics, and uses the OMB-required occupational classification system (the Standard Occupational System (SOC)).

Table 2. Updated Annualized Estimate of Respondent Burden.

| Instrument | Number of Respondents | Number of Responses per Respondent | Total Number of Responses | Hours per Response per Respondent | Total Burden Hours | Hourly Wage Rate ¹ | Total Cost |
|---|-----------------------|------------------------------------|---------------------------|-----------------------------------|--------------------|-------------------------------|------------|
| RHHT Testing Form | | | | | | | |
| Co-Located and Integrated Care Program (CMHS, CSAT, CSAP) | 5,000 | 1 | 5,000 | 0.13 | 650 | \$20.13 | \$13,085 |
| Targeted Capacity Expansion: Substance Use Disorder Treatment for Racial/Ethnic Minority Populations at High-Risk for | 5,000 | 1 | 5,000 | 0.13 | 650 | \$20.13 | \$13,085 |

| Instrument | Number of Respondents | Number of Responses per Respondent | Total Number of Responses | Hours per Response per Respondent | Total Burden Hours | Hourly Wage Rate ¹ | Total Cost |
|---|-----------------------|------------------------------------|---------------------------|-----------------------------------|--------------------|-------------------------------|------------------|
| HIV/AIDS CSAT RFA: TI-15-006 | | | | | | | |
| Targeted Capacity Expansion: Substance Abuse Treatment for Racial/Ethnic Minority Women at High Risk for HIV/AIDS CSAT RFA: TI-13-011 | 8,000 | 1 | 8,000 | 0.13 | 1,040 | \$20.13 | \$20,936 |
| Targeted Capacity Expansion Program: Substance Abuse Treatment for Racial/Ethnic Minority Populations at High-Risk for HIV/AIDS CSAT RFA: TI-12-007 | 10,400 | 1 | 10,400 | 0.13 | 1,352 | \$20.13 | \$27,216 |
| Minority Serving Intuitions (MSI) Partnerships with Community-Based Organizations (CBO) (MSI CBO). FY 2013 CSAP | 4,000 | 1 | 4,000 | 0.13 | 520 | \$20.13 | \$10,468 |
| Minority Serving Intuitions (MSI) Partnerships with Community-Based Organizations (CBO) (MSI CBO). FY 2014 CSAP | 3,500 | 1 | 3,500 | 0.13 | 455 | \$20.13 | \$9,159 |
| Minority Serving Intuitions (MSI) Partnerships with Community-Based Organizations (CBO) (MSI CBO). FY 2015 CSAP | 5,000 | 1 | 5,000 | 0.13 | 650 | \$20.13 | \$13,085 |
| Capacity Building Initiative for Substance Abuse and HIV Prevention Services for At-Risk Racial/Ethnic Minority Youth and Young Adults (HIV CBI) FY 2015 CSAP | 6,000 | 1 | 6,000 | 0.13 | 780 | \$20.13 | \$15,701 |
| | | | | | | | |
| Annual Total | 46,900 | | 46,900 | | 6,097 | | \$122,735 |

¹ Wage data source: Bureau of Labor Statistics. May, 2014 *Wage Data for Occupation*: 21-1011.00, Substance Abuse and Behavioral Disorder Counselors. Available online at: <http://www.bls.gov/oes/current/oes211011.htm>

A13. Estimates of Annualized Cost Burden to Respondents or Record Keepers

There will be no capital, start-up, operation, maintenance, nor purchase costs incurred by the programs participating in this data collection, or by clients receiving services funded by this project.

A14. Estimates of Annualized Cost to the Government

The contract award to cover evaluation of this project is \$3,972,000 over a 48-month period. Thus, the annualized contract cost is \$993,000.

Additional costs will be incurred indirectly by the government in personnel costs of staff involved in oversight of data collection. It is estimated that one SAMHSA employee will be involved for ten percent of their time. Cost of staff time will approximate \$11,000 annually.

The estimated annualized total cost to the government will be \$1,004,000.

Table 3. Annualized Estimate of Government Costs

| | Total Cost |
|-----------------------------|--------------------|
| Evaluation Contract | \$993,000 |
| Government Oversight | \$11,000 |
| Annual Total | \$1,004,000 |
| | 0 |

A15. Changes in Burden

Currently there are 1,143 burden hours in the OMB inventory. SAMHSA is requesting 6,097 hours. The program change of 4,954 hours is due to the additional programs that will use the revised form. The proposed RHHT form will replace SAMHSA’s OMB-approved RHT Form (OMB No. 0930-0295) which will be expiring on November 30, 2015, and included a total of 9,576 burden hours.

The deletion of the program-specific version of TRAC form reflects: -397 hours, -1,200 respondents, and -2,196 responses.

The deletion of the HIV-Specific Indicators form reflects: -96 hours, -200 respondents and -320 responses.

A16. Time Schedule, Publication, Analysis Plans

a. Time Schedule

All instruments will follow the same time schedule, which is summarized in Table 4.

Table 4. Time Schedule

| Task | Date |
|----------------------|---------------------------------|
| Obtain OMB Approval | Pending |
| Data Collection | One week following OMB approval |
| Data Collection Ends | September 30, 2018 |
| Data Analysis | Ongoing – Annual |
| Reporting | Ongoing - Annual |

b. Publication Plans

Aggregated data will be presented at annual Grantee meetings in order to provide a summary of overall grantee performance. Data collected as part of this effort may be used at SAMHSA

sponsored conferences, and in reports to the Secretary of Health and Human Services, Congress, and other audiences.

SAMHSA will work with contractor staff to develop a series of products that clearly and concisely present results so that they can be appreciated by both technical and nontechnical audiences. Contractor staff will be expected to:

- 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; and
- Disseminate reports and materials to entities inside and outside SAMHSA.

c. Analysis Plans

RHHT Form. First, the data will be summarized in descriptive statistics to describe the characteristics of individuals who are being tested (or refusing testing). 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 RHHT 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. Information from the RHHT forms will also be linked to GPRA data, when available. Analyses Grantees will be instructed to offer HIV/hepatitis testing to all those screened for services. Even if they refuse testing or have been tested before, Sections A-C will be completed, providing a large database for analysis.

A17. Display of Expiration Date

All data collection instruments will display the expiration date of OMB approval.

A18. Exceptions to the Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions.