

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) are requesting approval from the Office of Management and Budget (OMB) for new data collection activities associated with their **Co-location and Integration of HIV Prevention and Medical Care into Behavioral Health (Co-located and Integrated Care)** Program. Specifically, SAMHSA is requesting clearance to collect information using the following instruments:

- **A Combined HIV/Hepatitis Testing Form**, 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.

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.

Jointly funded by CMHS, CSAT and CSAP, SAMHSA plans to launch the Co-location and Integration of HIV Prevention and Medical Care into Behavioral Health Program in FY 2015. The program is designed to support 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.

Funded behavioral health agencies (those providing substance abuse and/or mental health services) will either co-locate or fully integrate HIV prevention and medical care services at their facility. 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.

While many models exist that integrate behavioral health services into primary care settings, providing Co-located medical services that are integrated within behavioral health programs is less frequent. The effectiveness of HIV care that is Co-located within behavioral health treatment programs is essentially undocumented in scientific literature.

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

Further support for the program 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

This information collection is needed to provide SAMHSA with objective information to document the reach and impact of the Co-located and Integrated Care program. Table 1 provides an overview of each instrument and the data collection method.

Table 1. Data Collection Instruments

Instrument	Data Collection Method	Attachment
Combined HIV/Hepatitis Testing Form	Web	Attachment 1
Co-located and Integrated Care version of TRAC	Paper and Pencil; Moving to Web in early-mid 2015	Attachment 2
HIV Indicators	Paper and Pencil; Moving to Web in early-mid 2015	Attachment 3

Included Measures

A summary of the three instruments is provided below.

Combined HIV/Hepatitis Testing Form. The combined HIV/Hepatitis Testing Form is a streamlined version of two data collection instruments that are currently used by SAMHSA-funded programs: the MAI-TCE Hepatitis Testing Form (OMB #0930-0300) and the MAI-TCE HIV testing form (OMB # 0930-0295). Both forms have been in routine use for several years.

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

Grantees will complete and submit a testing form for each individual receiving an HIV and/or hepatitis test. Information included in the form will be used to: document that the intended target populations for this program are being tested for HIV and hepatitis; provide information about the substance abuse and sexual risk factors of individuals being tested; and document that individuals are being referred to appropriate HIV and hepatitis services. Types of information collected by the Combined HIV and Hepatitis Testing Form is outlined in Table 2. It is expected that the completion of this form will take approximately 8 minutes.

Table 2. Information Included in the Combined HIV/Hepatitis Testing Form

Section A	Site Characteristics
Section B	Client Demographics
Section C	Risk Behaviors
Section D	Rapid HIV Testing Results
Section E	Rapid Hepatitis B & C Testing Results
Section F	Confirmatory Testing- HIV
Section G	Confirmatory Testing – Hepatitis B&C
Section H	Types of HIV Services Provided
Section I	Types of Hepatitis B&C Services Provided

Co-located and Integrated Care Version of TRAC: This instrument will be used to provide information that will inform SAMHSA's understanding of how the Co-located and Integrated Care Program is operating, to assist SAMHSA to identify strengths and weaknesses of each program, to help identify programs that would benefit from additional support or technical assistance, and to inform future funding decisions. Information contained in the Co-located and Integrated Care version of TRAC will also be used to monitor performance outcomes related to this grant, including the impact of services on mental health and substance abuse outcomes. Detailed information regarding the composition of the Co-located and Integrated Care version of TRAC is included in Attachment 4.

Clients who receive HIV prevention services **or** integrated medical care for HIV will be required to report some information via TRAC at baseline and follow-up time periods. The amount of information reported for each individual will vary depending on the type of services that are provided to each client.

- Individuals who test positive for HIV and receive co-located or integrated medical care through this grant program will be required to complete the entire Co-located and Integrated Care TRAC interview at baseline, at each six-month reassessment, and at discharge. It is expected that completion of the Co-located and Integrated Care TRAC tool will take approximately 35 minutes.
- Individuals who only receive prevention services will be required to complete the following modules of the Co-located and Integrated Care tool at baseline: Records Management; Demographics; and up to five “pre-test” questions from Section H that focus on HIV knowledge and/or attitudes. The questions will be selected by the program to reflect the specific content of the prevention services being delivered. It is expected that completion of these sections should take approximately 7 minutes.

At discharge from prevention services, clients who have only received prevention services will be required to respond to the same Section H questions that they answered at baseline. It is expected that these questions should take approximately 2-3 minutes to complete.

HIV-Specific Indicators. The HIV-specific indicators are comprised of 14 items. These items will only be reported for individuals who are HIV positive, and whom are receiving integrated medical care through this program.

The HIV indicators include clinical data needed to calculate HHS's Core HIV Measures, as well as indicators designed to offer global assessments of each client's behavioral health and physical health functioning. These indicators include items from the Clinical Global Impressions (CGI) Scale as well as the Karnofsky Performance Scale. These observer-rated scales are vital sources of practical information needed to complement the other clinical data elements. Both scales are routinely used by clinicians and offer high levels of face validity.

*The Clinical Global Impressions (CGI) Scale*³ is commonly used in behavioral health settings to assess the severity of client's mental health problems and global improvement over time. Behavioral health providers, who are already treating clients at each grantee site, will be asked to provide an index score for each client's severity of illness (CGI-S) at baseline.

The CGI-S Scale is a 7-point scale that requires behavioral health clinicians to rate the severity of the client's mental illness at the time of assessment, relative to the clinician's past experience with patients who have the same diagnosis. Clients will be assessed on the severity of their mental illness and substance abuse at the time of rating using a scale that ranges from 1 (normal, not at all ill) to 7 (extremely ill).

The CGI – Improvement Scale (CGI-I). At each follow-up data collection interview, behavioral health providers will also be asked to complete an additional measure rating each client's global improvement compared to baseline. The CGI-I scale is a 7-point scale that requires behavioral health providers to assess how much the client's illness has improved or worsened relative to a baseline state at the beginning of the intervention. Clients will be assessed on their mental health and substance abuse status using a 7 point rating scale that ranges from 1 (very much improved) to 7 (very much worse).

Clinicians will be asked to enter CGI scores into each client's medical record, so that it can be easily retrieved by grant staff during each baseline and reassessment interview. Both CGI Scales are commonly utilized tools in many behavioral health settings. SAMHSA anticipates that behavioral health providers at most grantee sites will be familiar with the instrument and its scoring. In the event that they are not familiar, SAMHSA will provide specialized training (via webinars) to ensure reliability of scoring. A copy of both CGI Scales and detailed rating information is provided in Attachment 5.

³ Forkmann, Thomas, et al. "The clinical global impression scale and the influence of patient or staff perspective on outcome." *BMC psychiatry* 11.1 (2011): 83.

The Karnofsky Performance Scale ⁴ will be used to measure clinician's ratings of client's physical health status. Medical personnel, who are providing HIV care to clients at each grantee site, will be asked to provide an index score for each client's functional impairment. Clients will be assessed using a 100-point scale, from 100% (normal; no complaints; no evidence of disease) to 0% (death). Clinical staff will be asked to provide ratings at baseline and at clinical appointments that correspond with each subsequent 6-month reassessment interview. Clinicians will be asked to enter this information into each client's medical record, so that it can be easily retrieved by grant staff, and entered into the **HIV Indicator** instrument during each baseline and reassessment interview. A copy of the Karnofsky Scale and rating information is provided in Attachment 6.

It is expected that the vast majority of the clinical data needed to report the HIV indicators will be obtained by grantee staff during a review of each client's medical chart and/or electronic medical record. As behavioral health settings that are also providing co-located or integrated HIV medical care, grantee sites will have access to systems that contain all of the needed data elements. It is expected that responding to these indicators will take approximately 20 minutes at baseline, and 15 minutes at subsequent reassessment interviews.

The indicators included in this module, along with the frequency of administration, are listed in Table 3.

Table 3. HIV Specific Indicators and Frequency of Administration

	Indicator	Frequency of Administration
1	Rapid HIV Testing Results	Baseline Only
2	Is this a new or existing HIV diagnosis?	Baseline Only
3	If this is a new diagnosis, is patient classified as having a Stage 3 HIV infection (AIDS)?	Baseline Only
4	Has client received ART treatment for HIV, prior to this assessment?	Baseline Only
5	What is the client's CGI-Severity rating for mental health? What is the client's CGI-Severity rating for substance abuse?	Baseline and Every Reassessment
6	What is the client's CGI-Improvement rating for mental health? What is the client's CGI-Improvement rating for substance abuse?	Every Reassessment
7	What is the client's Karnofsky Performance Scale percentage for physical health?	Baseline and Every Reassessment
8	Did the client attend a routine HIV medical care visit within 3 months of current HIV diagnosis?	First Six-Month Reassessment Only
9	Did the client have at least one HIV medical care visit in the past 6 month period? If so, list dates of all HIV-related medical visit(s) since last reassessment.	Baseline and Every Reassessment
10	Has the client been prescribed Antiretroviral Medication (ART), in	Baseline and

⁴ O'Dell, M. W., Lubeck, D. P., O'Driscoll, P., & Matsuno, S. (1995). Validity of the Karnofsky performance status in an HIV-infected sample. *JAIDS Journal of Acquired Immune Deficiency Syndromes*, 10(3), 350-357.

	past 6 Months?	Every Reassessment
11	Most recent Viral Load Count (copies/ml) _____ DATE of Test _____	Baseline and Every Reassessment
12	Date client left the program/ or last date client received medical services: _____	At Discharge

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 combined HIV/Hepatitis Testing 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 Combined HIV/Hepatitis Testing 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.

During the course of this project, SAMHSA plans to transition from its current TRAC system to the Common Data Platform (CDP). SAMHSA's CDP contract is currently in its base year, having been awarded in January, 2014. Within the base year, CDP will assume all data collection and reporting responsibilities currently managed by TRAC. Awards for the Co-located and Integrated Care program are likely to be made in September, 2014. Until the CDP is operational, grantees will be asked to collect TRAC and HIV Indicator data via paper and pencil methods. That information will then be sent to the evaluation contractor for secure storage and analysis.

HIV 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 Combined HIV/Hepatitis Testing Form, SAMHSA anticipates that there will be relatively little duplication of effort associated with these two forms.

Although SAMHSA cannot determine the degree of overlap between grantees that will be funded by this project and those funded by CDC, SAMHSA anticipate that the vast majority of funded grantees will not be receiving CDC prevention funds. Thus, SAMHSA expects that for the vast majority of our grantees, this information will not be duplicative.

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 combined HIV/Hepatitis Testing Form as the screening and confirmatory testing should be completed before referral to this care. It is possible there will be limited duplication surrounding the HHS HIV Core Indicators if the client is formally enrolled in the HRSA program as well. However, as a part of the required memorandum of understanding between the two entities, the behavioral health provider will have access to the medical data and there will be no additional burden on the HRSA grantee.

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 the Co-located and Integrated Care program.

For individuals who test negative for HIV, and receive no further services, completion of the Combined HIV Hepatitis Testing Form is the only time point at which data will be collected.

For individuals who test negative for HIV, and only receive prevention services, grantees will be asked to report a limited number of data points at baseline and at discharge through the TRAC system.

For individuals receiving integrated HIV services, data will be reported every six months. Extending the interval for the reassessments beyond this interval could lead to loss of contact with clients, significantly diminishing the response rates and lowering the value of the data for performance reporting use by losing measurement of intermediate effects.

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 April 25, 2014 (79 FR 23000). 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 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 each instrument is provided below:

The Combined HIV/Hepatitis Testing Form includes questions concerning sensitive information such as the patient's risk factors, but no personally identifying information is collected. The form utilizes Client ID numbers that are assigned by the grantee. Grantees will be instructed that the Client IDs must be randomly generated and that patient IDs, which may be able to re-identify a patient, cannot be used for the Client ID. Participating programs will retain all patient identifying information and the code 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 a yet to be identified 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 award of a contract for this work, 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.

Co-located and Integrated Care Tool and HIV Indicators. All client-level data that will be submitted to the evaluation contractor will utilize unique ID numbers and not by name. Thus, data cannot be directly linked to a specific person. The grantee providing the data will maintain the link between the identifier and the name of the client. The contractor will not have access to existing consumer clinical records, which are under the control of the respondent programs.

Neither the contractor nor SAMHSA personnel can link individual clients to the data reported by the respondent programs.

Confidentiality During the Testing Process: Grantee staff members administer the Combined HIV/Hepatitis Testing Form and the TRAC Interview 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 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/CSAT'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 goal of the Co-location and Integration of HIV Prevention and Medical Care Program 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. 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, information on mental health functioning, and hepatitis and HIV 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 1,143 hours for the period from September, 2014 through September, 2015. Table 4 below summarizes the annualized respondent burden estimate.

The annualized cost to respondents is based on the latest publicly available data (May 2012) 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 4a. 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
HIV Testing Form	5,000	1	5,000	0.13	650	\$22.01	\$14,307
Co-located and Integrated Care Tool- Baseline							
Clients with HIV Receiving Integrated Medical Services	200	1	200	0.58	117	\$22.01	\$2,568
Individuals only Receiving Prevention Services	1,000	1	1,000	0.12	120	\$22.01	\$2,641
Co-located and Integrated Care Tool – Follow Up							
Clients with HIV Receiving Integrated Medical Services ²	120	1	120	0.58	69.6	\$22.01	\$1,532
Co-located and Integrated Care Tool - Discharge							
Clients with HIV Receiving Integrated Medical Services – Interview with Client ³	28	1	28	0.58	16.2	\$22.01	\$357
Clients with HIV Receiving Integrated Medical Services – Interview with Client – Client not available – Administrative Data Only ⁴	42	1	42	0.33	13.9	\$22.01	\$305
Individuals only Receiving Prevention Services ⁵	800	1	800	0.06	48	\$22.01	\$1,056
HIV Indicators – Baseline							
Clients with HIV Receiving Integrated Medical Services	200	1	200	0.33	66	\$22.01	\$1,453
HIV Indicators – Follow Up							
Clients with HIV Receiving Integrated Medical Services	120	1	120	0.25	30	\$22.01	\$660
Annual Total	5,000		7,510		1,143		\$24,879

¹Wage data sources: Bureau of Labor Statistics. *National compensation survey*. Retrieved from <http://www.bls.gov/nscs/>; O*NET OnLine. (2010). *Occupations* [Quick search for occupations matching 'substance abuse']. Retrieved from <http://online.onetcenter.org/find/result?s=Substance+Abuse>; Salary.com. *Salary wizard: Community health director* [Data report]. Retrieved from http://swz.salary.com/salarywizard/layouthtmls/swzl_compresult_national_HC07000465.html

² Based on 40 percent non-response for those eligible for six-month reassessment.

³ Based on an estimate that 35 percent will leave the program annually, and that 40% of those discharged will be available for an interview.

⁴ Based on the estimate that 35% will leave the program annually, and that 60% of those discharged will not be available for an interview, and only administrative data will be provided.

⁵ Due to the short duration of the prevention activities, it is estimated that 80% of those interviewed at baseline will participate in the discharge interview.

Table 4b. Annualized Summary Table

Instrument	Number of Respondents	Total Responses	Total Annualized Hour Burden
HIV Testing Form	5,000	5,000	650
TRAC – Baseline, Follow-up, Discharge	1,200	2,190	397
HIV Indicators – Baseline, Follow-up	200	320	96
Total	5,000	7,510	1,143

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 each 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

A15. Changes in Burden

This is a new data collection.

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, or Congress.

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
- Disseminate reports and materials to entities inside and outside SAMHSA

c. Analysis Plans

Combined HIV/Hepatitis Testing 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 Combined HIV/Hepatitis Testing 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. 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.

Co-located and Integrated Care Version of TRAC. The Co-located and Integrated Care version of TRAC includes web-based reports that provide information on client-level data including information on the number of clients served, their demographic characteristics, baseline status, and change scores for the various outcome domains. Data obtained from these reports will be analyzed and presented in performance reports using basic descriptive statistics. On the principle outcome items, a comparison of client status after receiving services to baseline data will be used to assess change in status; users will also be able to compare any of

the interviews completed by a client. The web-based reports also allow users to create basic cross tabulations of the data.

The Evaluation Contractor will employ a variety of methods to analyze TRAC data, from simple descriptive statistics to multivariate modeling techniques when appropriate. Descriptive statistics will be used for presenting information about the characteristics of grantee organizations and clients. Graphical techniques such as scatter plots and histograms will also be used to visualize the data and to help understand the characteristics of available data, as necessary precursors to more complex multivariate techniques, such as multiple regression or hierarchical linear modeling.

HIV Indicators. Much of the information contained in the HIV Indicator Module will be used to calculate the HHS Core HIV Measures.⁵ Information matching HIV Indicator data points to each relevant HHS Core HIV Indicator is presented in Table 5. SAMHSA will work with the Evaluation Contractor to calculate the HHS Core Measures and to analyze changes in the measures over time. When appropriate, multi-level modeling techniques, that will allow us to relate client-level and clinic-level characteristics to these outcomes will be used to determine which aspects of the intervention are associated with improved HIV outcomes.

Table 5. Information from the HIV Indicators Used to Calculate HHS Core HIV Measures

Question Number	Indicator	Relevant HHS Core HIV Indicator Data
3	If this is a new diagnosis, is patient classified as having a Stage 3 HIV infection (AIDS)?	HHS Core HIV Measure #3: Late HIV Diagnosis
7	Did the client attend a routine HIV medical care visit within 3 months of current HIV diagnosis?	HHS Core HIV Measure #3 Linkage to HIV Care
8	Did the client have at least one HIV medical care visit in the past 6 month period? If so, list dates of all HIV-related medical visit(s) since last reassessment.	HHS Core HIV Measure #4 Retention in HIV Care
9	Has the client been prescribed Antiretroviral Medication (ART), in past 6 Months?	HHS Core HIV Measure #5: ART Use Among Individuals in HIV Care
10	Most recent Viral Load Count (copies/ml) _____ DATE of Test_____	HHS Core HIV Measure #6: Viral Load Suppression Among People in HIV Care

⁵ <http://blog.aids.gov/2012/08/secretary-sebelius-approves-indicators-for-monitoring-hhs-funded-hiv-services.html>

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.