Supporting Statement A

Assessing Client Factors Associated with Detectable HIV Viral Loads; and Models of Care and the Ryan White HIV/AIDS Program

OMB Control No. 0906-XXXX-New

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB) is requesting approval from the Office of Management and Budget (OMB) for data collection activities to conduct two distinct evaluation studies with Ryan White HIV/AIDS Program (RWHAP) provider sites. The sharing of data collection instruments will minimize the burden on RWHAP provider sites related to data collection, increase the sample size that could be used for data analysis resulting in greater generalizability of results, and provide richer and more robust data that may offer additional depth to the findings of each study. The scope of these evaluation studies is limited to only clients receiving RWHAP-funded services and sites funded through the RWHAP.

The *Assessing Client Factors Associated with Detectable HIV Viral Loads* evaluation study will identify characteristics of RWHAP clients and health facilities that are associated with the ability of clients to achieve and sustain an undetectable HIV viral load as compared to the characteristics that are associated with sub-optimal HIV viral load suppression. This study will enable the development of better-targeted interventions for improved HIV viral suppression rates among those clients served within the RWHAP network. The *Models of Care and the Ryan White HIV/AIDS Program* study will compare HIV and primary health outcomes across various models of care to determine which are most effective in responding to HIV as a chronic disease with likely co-morbidities related to normal aging. The results from this study will enable improvements or redesigns of effective delivery of HIV care among Ryan White providers. In both studies, an analysis of the perceptions of providers and clients will further support the understanding of the impact of individual and system level factors on achieving health outcomes among those clients served within the RWHAP network. The two studies will share data to inform each's objectives, allow for a larger sample size from which to generalize conclusions, and reduce the overall burden of response on RWHAP providers. In particular, these studies will build upon and complement HRSA HAB's study, Ryan White HIV/AIDS Program Outcomes and Expanded Insurance Coverage (Ryan White Outcomes) (OMB#: 0906-0030), focusing on RWHAP outcomes within the context of the changing health care landscape and will utilize the RWHAP site survey and medical record abstraction instruments that were submitted as part of that study. For the purposes of this request, the following documents have been included for review: "HIV Viral

Suppression" Provider Interview Guide (Attachment A), Client Survey (Attachment B), and Client Semi-Structured Interview Guide (Attachment C); and the "Models of Care" Provider Interview Guide (Attachment D), Client Focus Group Guide (Attachment E), IRB Approval Letters (Attachment F), OMB Notice of Award for Ryan White Outcomes (Attachment G), the and Public Health Service Act (Attachment H).

The first evaluation study, *Assessing Client Factors Associated with Detectable HIV Viral Loads*, will explore individuals' specific facilitators and barriers to achieving and sustaining viral suppression among those clients served within the RWHAP network. Early and effective treatment for HIV has been shown to greatly reduce associated morbidity and mortality. In spite of the known benefit of treatment, many individuals remain out of care or access care only intermittently. In 2013, CDC estimated that approximately 45% of people living with HIV (PLWH) in the United States were not virally suppressed, representing a lost opportunity for treatment and prevention. In spite of the increased attention on retention in care and the overarching goal of viral suppression, little data exist regarding the specific individual factors that are associated with sub-optimal viral suppression. Such information would be important to target programs to reach the populations that are currently not achieving viral suppression.

The second evaluation study, *Models of Care and the Ryan White HIV/AIDS Program*, seeks to answer the critical questions of what individual and system-wide factors, including the models of care employed among RWHAP provider sites, contribute to better health outcomes for PLWH. While advances in treatment have improved survival in patients with HIV, longer lives are associated with increased prevalence of adverse effects of HIV infection and therapeutic complications, concurrent with medical conditions related to aging processes that would occur in the absence of HIV. These long-term complications amplify chronic disease management as a major issue for the HIV population and a challenge for the delivery of effective health care. Yet, there is little known about how the method of health services delivery (the "model of care"), contributes to better health outcomes, including HIV-related outcomes. Understanding the most effective models of care will be important for HIV specialists, primary care physicians, and other clinicians who care for PLWH as they design and coordinate a full array of primary care and support services for their HIV patients. These primary care and support services have a direct impact on viral suppression, which, in turn, improves life expectancy and quality of life, and prevents HIV transmission.

The two studies inform each other in that the degree to which RWHAP clients are virally suppressed may be attributed partly to the model of care practiced at their clinic. Likewise, the degree to which its clients have achieved viral suppression may drive a clinic to practice a particular model of care. The two studies will collect several identical data elements through their individual collection instruments, allowing data to be aggregated across the two studies. The aggregation of data across the two studies will minimize the burden on RWHAP provider sites related to data collection, increase the sample size that could be used for data

analysis resulting in greater generalizability of results, and provide richer and more robust data that may offer additional depth to the findings of each study.

Table 1 describes the evaluation questions and corresponding data sources for the Assessing Client Factors Associated with Detectable HIV Viral Loads project.

Table 1: Evaluation Questions by Data Source and Analysis, Suppression Study			
Evaluation Question	**Supporting Evaluation Questions**	**Data Source**	**Analysis**
1. What are the correlates associated with detectable viral load in RWHAP Clients?	• What clinical factors are positively correlated with RWHAP clients' who do not achieve or maintain viral suppression (e.g. co-morbidities, time since HIV diagnosis, antiretroviral (ARV) regimen [type, initiation, exposure length])? • Do RWHAP core medical and support services affect RWHAP clients' rates of viral suppression? If so, how and why? • What barriers to engagement and retention in care are most positively correlated with RWHAP clients' who do not achieve or maintain viral suppression? • What psycho-social factors and social determinants of health (e.g., SES, self-efficacy, stigma, trauma, medical mistrust, food insecurity, transportation) are most positively correlated with RWHAP clients' who	• Charts/Records Abstraction • Ryan White HIV/AIDS Services Report (RSR) Client Data • Site Survey • Provider Interview • Client Survey • Client Interview	• Qualitative and quantitative: Investigate overall client characteristics and viral suppression status. • Qualitative and quantitative: Determine which clinical factors affect RWHAP clients' ability to achieve and maintain viral suppression (e.g. co-morbidities, time since HIV diagnosis, ARV regimen [type, initiation, exposure length])? • Qualitative and quantitative: Assess differences in service use patterns by viral suppression status. • Qualitative: Examine barriers to care and limits in RWHAP core medical and support services correlation with Viral Suppression. • Quantitative: Investigate the effect of various psycho-social factors and social determinants of health on viral suppression.

Table 1: Evaluation Questions by Data Source and Analysis, Suppression Study			
Evaluation Question	**Supporting Evaluation Questions**	**Data Source**	**Analysis**
	do not achieve or maintain viral suppression? • For clients who are virally suppressed and have similar challenges and barriers to those with detectable viral load, what factors resulted in the client reaching viral suppression? • What are some barriers or challenges experienced by medical providers and support service providers helping clients to achieve and maintain viral suppression? • What are some successful interventions employed by providers to: o Link clients to the services? o Combat social determinates of health in treating clients with a detectable viral load? o Increase ARV use among clients who initially refuse ARV? o Increase adherence to medications?		• Qualitative: Identify successful strategies employed by clients to overcome barriers to suppression. • Qualitative: Assess barriers or challenges experienced by service providers in helping clients to achieve and maintain viral suppression. • Qualitative: Identify successful strategies employed by providers to help clients overcome barriers to suppression.

Table 2 describes the evaluation questions and corresponding data sources for the Models of Care and the Ryan White HIV/AIDS Program project.

Table 2: Evaluation Questions by Data Source and Analysis, Models of Care Study			
Evaluation Question	**Supporting Evaluation Questions**	**Data Source**	**Analysis**
1. Which models of care have better HIV clinical outcomes?	• What are the models of care used by RWHAP clinical care providers? • Do models of care differ for different populations within a clinic based on insurance, disease acuity or co-morbidities? • Does the impact on HIV outcomes for different models of care vary by key subpopulations? • Whether and how do patients seek out specific models of care? • What barriers or challenges (internal or external to the clinic) are inherent in the different models of care?	• Charts/Records Abstraction • RSR Client Data • Site Survey • Provider Interview • Client Focus Group	• Qualitative and quantitative: Identify care services associated with each of the three models of care. • Qualitative and quantitative: Assess models of care most frequently available to/accessed by RWHAP clients based on insurance, disease acuity or co-morbidities. • Quantitative: Assess differences in key HIV health outcomes for RHWAP clients by model of care stratified by subpopulations. • Qualitative: Investigate RWHAP clients' care model seeking behaviors and preferences. • Qualitative: Examine barriers to care and limits in RWHAP core medical and support services with and across models.
2. Which models of care have better outcomes in primary care	• How do models of care used in the treatment of other complex chronic diseases differ from the models of care used in treatment of HIV?	• Charts/Records Abstraction • RSR Client Data	• Qualitative: Compare similarities and differences in treatment services and approaches for HIV and other chronic diseases.

Table 2: Evaluation Questions by Data Source and Analysis, Models of Care Study			
Evaluation Question	**Supporting Evaluation Questions**	**Data Source**	**Analysis**
conditions among HIV patients?	• How are other types of care, including behavioral health and preventative care, integrated in the models of care used among RWHAP clinic providers? • Whether and how do HIV patients with clinical comorbidities seek out specific models of care?	• Site Survey • Provider Interview • Client Focus Group	• Qualitative: Determine level and manner of integration of care services (other than and in addition to HIV care) within and across models of care. • Qualitative: Compare RWHAP clients' care model seeking behaviors and preferences for clients with and without significant co-morbidities.

This program is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment H).

2. Purpose and Use of Information Collection

The *Assessing Client Factors Associated with Detectable HIV Viral Loads* (hereinafter referred to as *HIV Viral Suppression*) study will identify characteristics of RWHAP clients and health facilities that are associated with the ability of clients to achieve and sustain an undetectable viral load as compared to the characteristics that are associated with sub-optimal viral load suppression. This study will enable the development of better-targeted interventions for improved viral suppression rates among those clients served within the RWHAP network. The *Models of Care and the Ryan White HIV/AIDS Program (*hereinafter referred to as *Models of Care)* study will compare HIV and primary health outcomes across various models of care to determine which are most effective in responding to HIV as a chronic disease with likely co-morbidities related to normal aging. The results from this study will enable improvements or redesigns of effective delivery of HIV care among Ryan White providers.

In both studies, an analysis of the perceptions of providers and clients will further support the understanding of the impact of individual and system level factors on achieving health outcomes. The two studies will share data to inform each's objectives, allow for a larger sample size from which to generalize conclusions, and reduce the overall burden of response on RWHAP providers and clients.

The objectives of both studies will be achieved through collection of the following data:

- ***RWHAP provider interviews*** – Site staff interviewees (in person);
- ***RWHAP client surveys*** – Clients with detectable and undetectable viral load at each clinic (administered only in *HIV Viral Suppression* study);
- ***RWHAP client records abstraction*** – Medical chart and administrative records (e.g., service utilization and health outcomes data);
- ***RWHAP client semi-structured interview*** – Clients with detectable and undetectable viral load (Face-to-face, on site; administered only in *HIV Viral Suppression* study); and
- ***RWHAP client focus groups*** – Client group discussion (Face-to-face, on site; administered in *Models of Care* study only).

The following presents a description of the data to be collected:

"HIV Viral Suppression" Provider Interview – Face-to-face, on site: (Attachment A) Using structured interview protocols, we will conduct in-person interviews with up to five RWHAP site administrators or other service providers at 25 sites. Interviews will focus on perceived or real barriers for clients to achieve and maintain HIV viral suppression and other health outcomes, as well as programs employed by the RWHAP site to increase viral suppression among their patients.

"Models of Care" Provider Interview – Face-to-face, on site: (Attachment D) Using structured interview protocols, we will conduct in-person interviews with up to five RWHAP site administrators or other service providers at 50 sites. Interviews will focus on assumptions regarding which model of care is employed by their clinic; community setting and systems context (e.g., state health policies, clinic setting); range/completeness of available services; workforce mix; service coordination; provider-to-provider consultation and information exchange systems; collaboration with other community service providers; and facilitators and barriers of care coordination, including across (referrals) and within service provider organizations.

"HIV Viral Suppression" Client Survey – Face-to-face, on site: (Attachment B) Using a structured interview protocol that includes both survey questions and open-ended responses, we will conduct in-person interviews with up to 20 clients at each of the 25 sites selected for the *HIV Viral Suppression* study. This survey will include the Client Life Experiences Survey and is designed to elicit information about perceived stigma, medical mistrust, HIV knowledge and more general socio-demographic information.

"HIV Viral Suppression" Client Semi-Structured Interview – Face-to-face, on site: (Attachment C) Client perspective is particularly important to test and validate provider perceptions of the client experience. On-site client semi-structured interviews will be conducted at each of the 25 study sites. The study teams will recruit six clients taking part in the client survey (above) to participate in an in-depth interview. The study teams will employ a semi-structured interview guide to query participants about their perception of challenges, barriers, and facilitators to achieve and maintain viral suppression, including effects of stigma and life stressors.

Medical Chart/Records Abstraction – On site: Instrumentation for the medical chart/ records abstraction will be the same for the two studies and will include a record abstraction protocol and a web-based abstraction form that has already been developed and reviewed under the Ryan White Outcomes study (OMB#: 0906-0030). This data abstraction will be conducted for 18-20 clients at the 75 sites (1400 abstractions total) selected across the two studies. Medical records data abstraction will include demographics, medical visit frequency, prescribed antiretroviral therapy, HIV clinical data (including ICD 9/10 codes), laboratory results, comorbidity data, substance use and/or mental health data, preventive screening and counseling, vaccinations, hospitalizations, and any gaps in care (e.g., lost or no longer in

follow up). If available, we will also collect data regarding Emergency Department visits, as well as substance use and mental health treatment facility stays. Additional billing and health coverage sections will focus on health care coverage sources (e.g., Medicaid, QHP, supplemental, no coverage) and on identifying gaps in coverage. The data for the Models of Care study will be recorded in a manner so that no protected health information (PHI) is collected; therefore, the data will be Health Insurance Portability and Accountability Act (HIPAA) de-identified and individual client consent will not be required[1], unless a clinic chooses to add such an additional requirement. The HIV Viral Suppression study will match medical records and client survey and client semi-structured interview data, consequently informed consent from clients will be obtained.

"Models of Care" Focus Groups – Face-to-face, on site: (Attachment E) On-site client focus groups will be conducted at 30 of the 50 study sites. The study teams will ask sites to gather a convenience sample of up to eight (8) clients. The study teams will employ a focus group guide to query participants about their perception of: successful/preferred treatment models offered by providers; facilitators and barriers of care coordination, including across (referrals) and within service provider organizations; barriers to positive health outcomes; internalized client stigma; clinic's institutional strengths and challenges to ameliorating stigma; clinic's institutional approach to addressing cultural competence in care; social determinants of health (e.g., education level, job status, housing, income level, language, health literacy); organizational and systems-level context contributing to outcomes (e.g., access to care and cost); and gaps in services.

Limitations: We estimate that this evaluation study will encounter unavoidable limitations due to the types of data collection instruments, which may result in over or understatement of the conclusions. The site interviews, focus groups, and site surveys will gather self-report qualitative data. Self-reported data are at risk of threats to reliability and validity. For example, the participants may not understand the questions, provide a desired answer, or provide inaccurate or misleading information. To address the limitation, we are taking a number of steps. We constructed the tools to ask open-ended questions and trained the interviewers on the evaluation study purpose and objectives. Additionally, we will use the qualitative information collected to contextualize the quantitative information.
Results will be generalizable to only those PLWH served by the national RWHAP network and will not reflect the experience of all PLWH in the U.S.

3. Use of Improved Information Technology and Burden Reduction

Provider Interviews—Face-to-face: In both studies, interviews with providers will be conducted face-to-face during site visits. Detailed notes will be taken in Word and audio-

[1] http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/research/index.html

recordings will be made to support written notes. Audio recordings will be erased upon finalization of the notes. These detailed notes (the data) will then be entered by HRSA contractor staff into NVIVO (software designed to organize, analyze, and identify insights in qualitative data) and stored on the contractor's project system. The interviews will be an average of two hours in length; and will not utilize electronic data collection, beyond electronic notetaking in Word and audio recordings. To further minimize burden, we have designed interview guides that ensure that the discussion is limited and the questions are well organized, flow well together, and are easy to understand and answer. Interviews will be scheduled at a date and time that is convenient for the interviewee. Only the minimum information necessary will be collected for this project. Names, email addresses and phone numbers will be collected and used only for the purpose of contacting and scheduling interviews. Names will not be included or used as part of the analytic data set and will be destroyed upon completion of the site visit.

Client Survey and Semi-Structured Interview (HIV Viral Suppression study sites only) — Face-to-face, on site: Interviews and surveys will be conducted face-to-face during site visits for the *HIV Viral Suppression* study only. Written notes will be taken during the semi-structured interviews and will be entered by HRSA contractor staff into NVIVO and stored on the contractor's project system. Audio recordings will be made to support written notes. Audio recordings will be erased upon finalization of the notes. The laptops used for data collection will employ full disk encryption. The application is designed to erase the source file upon confirmation of automatic upload to the HRSA contractor's secure servers. No PHI (i.e., none of the 18 HIPAA identifiers) will be collected as part of the client interview. Each record will only be identified by an encrypted unique client identifier (eUCI) created using a hashing algorithm that prevents recovery of the source data used to create it. The system will automatically generate the eUCI using information from: the first and third letters of the client's first name, the first and third letters of the client's last name, the full date of birth (DOB) and gender. Once entered, this information will automatically be converted to the eUCI - and the DOB will be transformed to age. The data entry program will simultaneously delete the name and DOB. Therefore, no personally identifying information will be transferred or saved in this upload (e.g., initials of client and date of birth). These pieces of information will only be used to create the unique client ID and then will be deleted before upload. In addition, any other data that could be a HIPAA identifier will be converted at the time of entry (e.g., service event will be recorded as month and year only).

To further minimize burden, we have designed the survey and interview guide to ensure that the discussion is limited and the questions are well-organized, flow well together, and are easy to understand and answer. Interviews will be scheduled at a date and time that is convenient for the interviewee. Only the minimum information necessary will be collected for this project. Names, email addresses and phone numbers will be collected and used only for the purpose of contacting and scheduling interviews. Names will not be included or used as part of the analytic data set and will be destroyed upon completion of the site visit.

Medical Chart/Records Abstraction—On-Site: All medical chart/records abstraction will be completed on-site at 75 sites for 18-20 clients at each site. Site staff will be involved for approximately one hour to identify and provide access to the records that will be abstracted. To minimize burden, the HRSA contractor will conduct all chart/records abstraction without the assistance of site staff. All data will be entered into a data entry application that has already been developed by the HRSA contractor and reviewed as part of the Ryan White Outcomes study. The laptops used for data collection will employ full disk encryption. The application is designed to erase the source file upon confirmation of automatic upload to the contractor's secure servers. No PHI (i.e., none of the 18 HIPAA identifiers) will be collected as part of the chart/records abstraction process. Each file will only be identified by a eUCI created using a hashing algorithm that prevents recovery of the source data used to create it. The system will automatically generate the eUCI using information from: the first and third letters of the client's first name, the first and third letters of the client's last name, the full DOB and gender. Once entered, this information will automatically be converted to the eUCI - and the DOB will be transformed to age. The data entry program will simultaneously delete the name and DOB. Therefore, no personally identifying information will be transferred or saved in this upload (e.g., initials of client and date of birth). These pieces of information will only be used to create the unique client ID and then will be deleted before upload. In addition, any other data that could be a HIPAA identifier will be converted at the time of entry (e.g., service event will be recorded as month and year only).

Focus Groups (Models of Care study sites only) —Face-to-face, on site: All focus groups will be conducted face-to-face with clients at 30 of the 50 sites for "Models of Care". The decision to conduct face-to-face focus groups is based on the need to develop and maintain rapport between the focus group facilitator and participants. During the face-to-face focus groups, evaluation staff will have the ability to provide clarification on complex questions and probe for details not likely to be captured through a survey. The focus groups will be an average of 90 minutes in length; and will not utilize electronic data collection, beyond electronic notetaking in Word and audio recordings made only to support written notes. Audio recordings will be erased upon finalization of the notes.

To minimize burden, we have designed the focus group protocol to ensure that the discussion is limited and the questions are well organized, flow well together, and are easy to understand and answer. Focus groups will be scheduled at a date and time that is convenient for the client participants but to occur during our scheduled site visit. Only the minimum information necessary will be collected for this project.

4. Efforts to Identify Duplication and Use of Similar Information

The overall evaluation strategy of both projects utilizes four sources of data: (1) Ryan White HIV/AIDS Services Report (RSR) data with AIDS Drug Assistance Program (ADAP) Data

Report (ADR) data, both already collected by HAB; (2) site surveys, already collected by the *Ryan White Outcomes* study; (3) provider interviews; and (4) medical chart/records abstraction. In addition, client interviews and client surveys will be utilized only in *HIV Viral Suppression* study; and client focus groups will be utilized only in the *Models of Care* study. Of all these data sources, only the provider and client interviews, client survey, focus groups, and medical chart/records abstraction will require collection of information not already available within this request for OMB approval. The site survey received OMB Approval as part of the Ryan White Outcomes Study (Attachment G).

Interviews and focus groups collect qualitative program-level data that will contextualize the information obtained through the RSR and surveys, and provide data that is not captured through these mechanisms. Medical chart/ records will provide client-level data that cannot be captured in the interviews, focus groups, surveys, or RSR/ADR data. The Medical chart/ records abstraction also provide key health outcome and service utilization data.

No extant or single data source can provide sufficient information to answer the key evaluation questions of the two studies. Triangulating across the qualitative and quantitative data sources described above will enable answering critical project-specific questions.

5. Impact on Small Business or Other Small Entities

Information collection will not have a significant impact on small entities.

6. Consequences of Collecting the Information Less Frequently

If these evaluation studies do not receive OMB review/approval, there will be a lost opportunity to develop better-targeted services for improved viral suppression rates and to enable improvements or redesigns of effective delivery of HIV care among Ryan White HIV/AIDS Program providers, which will improve HIV clinical outcomes such as viral suppression.

During both studies, the frequency of data collection from the sites and the clients they serve is held to the minimum necessary to meet the evaluation objectives. Data collection of each type will only be conducted once, between October 2017 and February 2018.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

The request fully complies with the regulation.

8. Comments in Response to the Federal Register Notice/Outside Consultation

8A. A 60-day Federal Register Notice was published in the *Federal Register* on 05/18/2017 (Volume 82, page 22838) which solicited comments on this data collection. Four responses were received to the 60-day Federal Register Notice (please see Attachment I):

- The first was a request to view the data collection instruments, and the instruments were sent in response.
- The second inquiry concerned the estimated number of facilities to be invited to participate from each grant area or region of the country. HAB responded that facilities will be selected based upon a balance across selection strata (e.g. model of care, size, percent of clients virally suppressed, urban/rural). The data collection instruments were also provided along with this response. A follow-up question to HAB's response was made to inquire whether all participants receive Ryan White Program funding, and HAB confirmed that this is true.
- The third and fourth comments were received from representatives of national organizations for nutrition, expressing the importance of adequate nutrition for PLWH and encouraging that food and nutrition services be included in the data collection.

8B. For the *HIV Viral Suppression* study, the HRSA contractor consulted with Michael Mugavero, MD (professor of Medicine at the University of Alabama at Birmingham (UAB), Co-Director of the UAB Center for AIDS Research (CFAR), and Director of the UAB CFAR Clinical Core) to determine applicability of health outcomes data regarding HIV/AIDS and other medical conditions of interest. No additional consultations were utilized for the *Models of Care* study.

9. Explanation of any Payment/Gift to Respondents

Gift cards with a value of no more than $20 from major stores (e.g., Walmart, TARGET) will be used as an incentive for clients to participate in the focus groups in the *Models of Care* study and the client survey in the *HIV Viral Suppression* study. An additional $25 will be offered to clients participating in the semi-structured interview in the *HIV Viral Suppression* study. Although participation is voluntary, respondents are likely to perceive a time cost and burden associated with their participation. Survey research literature suggests monetary incentives increase response rate, with no known adverse effect on reality (Dillman, 1978, 2000).

10. Assurance of Confidentiality Provided to Respondents

HRSA will review the evaluation design and procedures prepared by the HRSA contractor to ensure they meet industry standards to protect participants. This review will also ensure compliance with the spirit and the letter of regulations from the Department of Health and

Human Services (DHHS) governing such projects. Systems and procedures for collecting and processing data are designed to help ensure the protection of participants and the data they provide. The HRSA contractor will ensure this project has a data security plan with adequate provisions to protect the privacy of subjects and the confidentiality of their information in all methods of data collection. To ensure client confidentiality we will not collect any of the PHI direct client identifiers as part of our data collection; regardless, all data will be transmitted securely via the file transfer protocol (FTP) and will be maintained on secure servers.

Data will be obtained from various individuals involved in implementing the program, including Site Administrators and Healthcare Providers (e.g., senior clinician), via interviews. Data will also be collected from clients who have received program services via focus group discussions, surveys, or semi-structured interviews. Interview, focus group, survey, or semi-structured interview participation is voluntary. Providers and clients will be provided with the purpose of the study and what taking part in the focus group, survey, or interviews will involve. If the provider or client chooses to participate, he/she will be asked to provide verbal consent stating that he/she understands the purpose of the study, is willing to participate but can change his/her mind at any time, and that all information gathered will be stored securely and used only for the purposes of this study. As with the client medical record abstraction data, no direct identifiers will be collected or associated with the interview or survey data collected from clients. Verbal consent is preferable as the signed consent form would create the only identifier indicating client participation in providing data about potentially sensitive topics.

Data across both projects will be kept confidential to the extent allowed by law. HRSA will likely be able to associate particular service models with specific facilities in the study reports from the *Models of Care* study. Therefore, the identities of site staff respondents may be recognized by HRSA staff. However, questions on the site's policies, practices and experiences are part of their regular business knowledge, and there are no questions of a personal nature or the personal choices or behaviors of respondents. In the *Models of Care* client focus groups, there is also a possibility that other participants in the group may reveal what was discussed; and in both studies, there is the possibility that people outside the research team will see the information provided. However, participants in the focus groups and on the research team will be asked to maintain confidentiality of those participating in these activities; and written notes will be kept on encrypted laptops and stored on secure servers.

(Please see Attachment F for IRB Approval Letters for both studies.)

11. Justification for Sensitive Questions

The client-level data collection components in each study will include questions about HIV/AIDS care and treatment. It is necessary to ask questions about HIV services received to

address the study evaluation questions. As part of consent procedures, respondents will be explicitly informed that they have the right to refuse to answer any question they may deem sensitive. All participants of the client-level data collection components are RWHAP clients, meaning all participants will be among peers also receiving HIV/AIDS care, hopefully reducing some of the stigma attached with certain sensitive questions. In addition, the focus groups, interviews, and surveys will be facilitated by a HRSA contractor team member with many years' experience working with and conducting studies involving RWHAP clients.

12. Estimates of Annualized Hour and Cost Burden

The total burden for the individual for data collection participation is estimated at 60 minutes for medical records sample selection guides (i.e., Site Administrators), 120 minutes for provider interviews, 30 minutes for client survey, 30 minutes for client semi-structured interview, and 90 minutes for client focus groups. Time estimates are based on experience with similar instruments in other studies of comparable organizations.

Number of Respondents, Frequency of Response, and Annual Hour Burden

Exhibit 12A below offers an estimate of the reporting burden for a sample of 1,500 respondents to the medical records sample selection guide, provider interviews, client survey and semi-structured interview, and focus groups. For all instruments, it is estimated that the total burden will be 1,510 hours.

- The medical chart/records abstraction will collect information from 1,400 records [Total number of sites =75, Number of records per site = 18 for Models of Care (50 sites) and 20 for HIV Viral Suppression (25 sites), Number of staff helping to identify sampled cases per site =1] and will take an average of 1 hour (60 minutes) for the Site Administrator to help to identify sampled cases for medical chart/records abstraction. HRSA contractor staff will conduct the actual medical chart/records abstraction after receiving guidance from the Site Administrator.
- The provider interviews will have 375 respondents [Number of sites =75, Number of respondents per site maximum of 5] and will take an average of 2 hours (120 minutes) for each interview. Site Administrators and Healthcare Providers will participate in the provider interviews.
- The focus groups (Models of Care study sites only) will have 240 respondents [Number of sites=30, Number of respondents per site=8] and will take an average of 1.5 hours (90 minutes) for each respondent to complete. Clients, adults over the age of 18, will participate in the focus groups.
- The client survey (HIV Viral Suppression study sites only) will have 500 respondents [Number of sites=25, Number of respondents per site=20] and will take an average of 30 minutes for each respondent to complete. Clients, adults over the age of 18, will participate in the client survey.

- The client semi-structured interview (HIV viral Suppression study sites only) will have 150 respondents [Number of sites=25, Number of respondents per site=6] and will take an average of 30 minutes for each respondent to complete. Clients, adults over the age of 18, will participate in the client semi-structured interview.

12A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
RWHAP Site Administra-tors (Private Sector)	Medical Records Sample Selection Guide*	75	1	75	1	75
RWHAP Service Providers (Private Sector)	Provider Interview Guide (HIV Viral Suppression)	125	1	125	2	250
RWHAP Service Providers (Private Sector)	Provider Interview Guide (Models of Care)	250	1	250	2	500
RWHAP Clients (Individual/ Household)	Focus Groups Guide	240	1	240	1.5	360
RWHAP Clients (Individual/ Household)	Client Survey	500	1	500	0.5	250
RWHAP Clients (Individual/ Household)	Client Semi-Structured Interview	150	1	150	0.5	75
	Total	1,340		1,340		1,510

* The medical records sample selection instrument has been previously submitted as part of the RWHAP Outcomes Study proposed data collection project.

Estimates of other Total Annual Cost Burden to Respondents or Record-keepers/ Capital Costs for the Hour Burdens

Exhibit 12B offers an estimate of the cost burden to respondents, by occupation. The following estimates are based on U.S. Government Bureau of Labor Statistics data published in May 2016 (posted at http://www.bls.gov/oes/current/oes_nat.htm).

- The hourly wage for Site Administrators is estimated at $52.58 (average hourly wage for Medical Health Services Managers, as published by the Bureau of Labor

Statistics, May 2016). The estimated cost burden for Site Administrators is $3,943.50 [Hours = 75, Hourly Wage= $52.58].

- The hourly wage for Healthcare Providers is estimated at $97.04 (average hourly wage for Internists, as published by the Bureau of Labor Statistics, May 2016). The estimated cost burden for Healthcare Providers is $72,780.00 [Hours = 750, Hourly Wage= $97.04].
- The hourly wage for Clients is estimated at $23.86 (average hourly wage for employees in all occupations in the United States, as published by the Bureau of Labor Statistics, May 2016). The estimated cost burden for clients is $16,344.10 [Hours = 685, Hourly Wage= $23.86].

12B. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
RWHAP Site Administrators (Private Sector)	75	$52.58	$3,943.50
RWHAP Service Providers (Private Sector)	750	$97.04	$72,780.00
RWHAP Clients (Individual/Household)	685	$23.86	$16,344.10
Total	**1,510**		**$93,067.60**

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

Other than their time, there is no cost to respondents.

14. Annualized Cost to Federal Government

The total cost of the two fixed-price contracts that support this two-year information collection is $1,936,901, annualized to $968,451. This includes the labor costs to create the sampling methodology, develop the data collection instruments, conduct data collection, and to analyze the survey, interview, medical chart/records abstraction, and focus group responses. In addition, there will be the cost for a GS 13 (Step 3) at 5% time (approximately $5,056) and a GS 14 (Step 6) at 5% time (approximately $6,535) time to monitor the project. The average annual total cost of the project is $980,042 and the total cost of the two-year project is 1,960,083.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation, Publication, and Project Time Schedule

Under the guidance and direction of HRSA, the contractor will conduct quantitative and qualitative analyses of the collected data. Final reports will be prepared following data collection and analyses. The project schedule is as follows.

Activity/Deliverable	*Target Date*

Begin data collection	September 2017
Draft final report to HRSA	January 2018
Final report to HRSA	February 2018

Interview notes, field notes, and any secondary data obtained will be saved in an NVivo 10.0 Database designed for this study. The contractor will code the qualitative data immediately after each site visit is completed and then aggregate and integrate the codes as appropriate in the final analysis.

Medical chart/records abstractions will be conducted using a secure electronic web-based abstraction tool on laptops with full disk encryption and uploaded using the HRSA contractor's secure servers in a format appropriate for import into SAS.

The *Assessing Client Factors Associated with Detectable HIV Viral Loads* study will identify characteristics of RWHAP clients and health facilities that are associated with the ability to achieve and sustain an undetectable viral load as compared to the characteristics that are associated with sub-optimal viral load suppression. This study will enable the development of better-targeted interventions for improved HIV viral suppression rates. The *Models of Care and the Ryan White HIV/AIDS Program* study will compare HIV and primary health outcomes across various models of care to determine which are most effective in responding to HIV as a chronic disease with likely co-morbidities related to normal aging. The results from this study will enable improvements or redesigns of effective delivery of HIV care among Ryan White providers.

In both studies, an analysis of the perceptions of providers and clients will further support the understanding of the effect of individual and system level factors on achieving health outcomes. The two studies will share data to inform each's objectives, allow for a larger sample size from which to generalize conclusions, and reduce the overall burden of response on RWHAP providers and clients. Key findings will be included in up to three manuscripts for each study, which will be submitted to peer-reviewed journals for publication.

17. Reasons Display of OMB Expiration Date is Inappropriate

The OMB number and Expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.