

# Supporting Statement A

## Building Futures: Supporting Youth Living with HIV

### OMB Control No. 0906-XXXX

#### A. Justification

##### 1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB) administers the Ryan White HIV/AIDS Program (RWHAP). Authorized under Title XXVI of the Public Health Service Act and amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, the RWHAP provides grants to states and U.S. territories, eligible metropolitan areas, and clinics to improve the quality and availability of HIV care for uninsured or underinsured individuals and families affected by the disease.<sup>1</sup>

Youth (defined for the purposes of this project as age 13 through 24) in the United States are disproportionately impacted by HIV. In 2014, 9,731 (22 percent) of the 44,073 new HIV diagnoses in the U.S. were among youth between the ages of 13 and 24, with a large majority (81 percent) of these youth diagnoses among older youth aged 20-24.<sup>2</sup> Young people living with HIV also experience disparities in outcomes along the HIV care continuum.<sup>3</sup> Among RWHAP clients in 2014, older youth aged 20-24 had the lowest rates of retention in care and both 15-19 year olds and 20-24 year olds had notably lower rates of viral load suppression as compared to other age groups. Additionally, certain subpopulations such as young men who have sex with men (MSM) of color, lesbian, gay, bisexual, transgender and questioning youth (LGBTQ), and young women of color bear a disproportionate share of the disease burden and have poorer outcomes in the areas of retention in care and viral suppression.<sup>4,5</sup>

HRSA/HAB is requesting approval from the Office of Management and Budget (OMB) for a study that will strengthen RWHAP engagement with young people aged 13-24 living with HIV to improve their health outcomes. Through this project, HRSA/HAB will systematically document strategies used by providers funded by the RWHAP who have strong outcomes in areas of youth retention in care and viral suppression. HRSA/HAB will also learn about gaps and

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1 Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111-87 (October 30, 2009). Available from <http://www.gpo.gov/fdsys/pkg/PLAW-111publ87/html/PLAW-111publ87.htm>.

2 Centers for Disease Control and Prevention, "Diagnoses of HIV Infection in the United States and Dependent Areas, 2014," HIV Surveillance Supplemental Report; Vol 26, November 2015, <http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf>.

3 "HIV/AIDS Care Continuum," accessed January 26, 2016, <https://www.aids.gov/federal-resources/policies/care-continuum/>.

4 Centers for Disease Control and Prevention, "HIV Among Youth," *HIV Among Youth*, June 30, 2015, <http://www.cdc.gov/hiv/group/age/youth/index.html>.

5 "Youth and Young Adults in the Ryan White HIV/AIDS Program," September 2015, <http://hab.hrsa.gov/data/reports/youthdatareport2015.pdf>.

challenges from providers that have demonstrated poorer outcomes in these areas. Findings will inform technical assistance (TA) products to improve provider performance in engaging HIV-positive youth in care and optimizing health outcomes.

## **2. Purpose and Use of Information Collection**

With the goal of increasing the capacity of RWHAP providers in their work with youth, under the *Building Futures: Supporting Youth Living with HIV* project, DSFederal and partners (hereafter mentioned as the project team) will conduct site visits with two types of providers: 1) providers with patients with high rates of viral load suppression and 2) providers with patients with low rates of viral load suppression. The purposes of these visits are the following:

1. **Specialized Site Visits to 10 Sites:** To identify, understand, and document replicable evidence-based best practices and models of care among providers with patients with high rates of viral load suppression.
2. **Performance Improvement Site Visits to 16 Sites:** To better understand gaps and challenges to providing RWHAP care to youth, share best practices and lessons learned from specialized site visits, and provide action-oriented TA to overcome barriers and optimize health outcomes.

## **3. Use of Improved Information Technology and Burden Reduction**

During site visits, the project team will collect qualitative data through in-person interviews with provider staff members and interviews and/or focus groups with HIV-positive youth. Conducting in-person interviews allows the project team's researchers to connect with participants, respond to individual answers in real time, and ask relevant follow up questions. Importantly, focus groups allow participants to hear, address, and respond to the stories and responses of other participants. This leads to a richer, more meaningful discussion that follows the flow and direction set by multiple participants.

Given the qualitative nature of this project, data collection will not rely heavily on information technology. Interviews and focus groups will be audio-recorded, allowing respondents to speak at their own pace without jeopardizing comprehensive data collection. In addition, participating providers will have the option to complete a pre-site visit questionnaire via SurveyGizmo.com. SurveyGizmo streamlines data collection through skip logic, Likert scales, radio buttons and question grids, which present information clearly and concisely. Additionally, the survey will have a section for providers to upload organizational documents for the project team to review in advance of the site visit, which will reduce back and forth communication via e-mail or phone. In the survey, providers will have the option to save their progress and continue completing the survey at a later time. If they select to save their progress, they will be sent an e-mail from SurveyGizmo with a unique link that will allow them to continue completing the survey. This will allow multiple members of a provider agency to contribute to the survey at their convenience. This pre-visit questionnaire will provide the project team with valuable background information, and streamline the site visit process by allowing team members to delve deeper into preliminary findings.

The project team plans to reduce burden primarily by creating a profile on each RWHAP

provider prior to the site visit. These profiles will provide the project team with provider-specific information and operational context, so the interviews and focus groups can focus on new information not available through other sources. Profiles will involve gathering all readily available statistics on the provider and the HIV-positive youth they serve, including an analysis of Ryan White Services (RSR) data. The project team will also compile information on state Medicaid policies and state minor confidentiality rights. Finally, the project team will review documents received from RWHAP providers from the survey and HRSA/HAB in advance of site visits, including consumer satisfaction surveys and grant applications.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

Given that this is a new research topic area for HRSA/HAB, there is no other data source available that will provide the needed information for this study.

#### **5. Impact on Small Businesses or Other Small Entities**

No small businesses will be involved in this study.

#### **6. Consequences of Collecting the Information Less Frequently**

Respondents will respond to the data collection one time only.

#### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

The request fully complies with 5CFR 1320.5

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

##### **Section 8A**

A 60-Day Federal Register Notice was published in the *Federal Register* on 04/27/2016, vol. 81, No. 81; pp. 24822-24824. There were no public comments.

##### **Section 8B**

To develop the site visit protocol, the project team consulted with experts on HIV-care for youth. In addition, the study team piloted the interview and focus group instruments with the following providers to ensure the clarity and usefulness of questions.

- Adolescent AIDS Program, Montefiore Medical Center, Bronx, NY, Dr. Donna Futterman, Director, and Dr. Alisha Liggett, Attending Physician
- SUNY Downstate Medical Center, Brooklyn, NY, Dr. Jeffrey Birnbaum, Director
- Sidney Borum at Fenway, Boston, MA, Dr. Ralph Vettters, Medical Director
- Grady Infectious Disease Program, Pediatric Department, Atlanta, GA, Stephanie Hackett, Physician's Assistant

#### **9. Explanation of any Payment/Gift to Respondents**

Respondents will not receive any payments or gifts.

## **10. Assurance of Confidentiality Provided to Respondents**

While contact information (i.e., name, title, e-mail address, and telephone number) of RWHAP provider staff members will be used to schedule and coordinate site visits, this information will not be retained as part of the data collection.

Names and personal identifiers will not be collected as part of the interviews or focus group with HIV-positive youth. The interview and focus group protocols for HIV-positive youth do not require any information or ask any questions that could identify individual clients. Youth participating in an interview or focus group must sign a participant assent form prior to their participation. Parents of youth participating in an interview or focus group must sign a parent consent form prior to their child's participation. The assent and consent forms inform participants of confidentiality, voluntary participation, mandatory reporting, and potential risks of participating.

Recordings of interviews and focus groups will only be heard by members of the project team. Once the reports are written, the recordings will be destroyed. The project team will also take notes during the interviews. Only the names of program staff, not youth clients, will be documented in the notes. Notes will be stored on an encrypted laptop during the site visit. Once all interviews are completed, the site visit lead will securely transfer files through HP Voltage Security software to a computer server, permanently deleting files from the laptop. Computers are password protected, and servers are stored behind locked doors. Information gathered will never be linked back to individual participants. Participants' responses will be kept confidential, and no reported data will be attributed to any individual respondent. Participants will never be identified and none of their information will be disclosed.

## **11. Justification for Sensitive Questions**

The interview protocols and pre-site visit questionnaire that target RWHAP provider staff have no sensitive questions. The instruments that target HIV-positive youth have sensitive questions related to race/ethnicity, health care literacy, and utilization of health care.

HIV-positive youth that participate in the focus group will complete a pre-interview/focus group questionnaire. Responses will be recorded privately on paper and will not be shared with other participants. This questionnaire includes questions on race/ethnicity because data demonstrates certain racial/ethnic groups have poorer health care outcomes and are at higher risk for contracting HIV and for poorer outcomes related to retention and viral load suppression. The project team aims to assess whether race/ethnicity affects individuals' perceptions of their health care. In addition, focus groups should be representative of the RWHAP youth population overall. Collecting information on race/ethnicity will help the project team ensure racial/ethnic representativeness of focus groups. Other questions on the questionnaire assess the functional health literacy of participants, which could be a predictor of engagement in care and perceptions of health care quality. The project team aims to conduct focus groups with individuals that have a range of functional health literacy to capture more representative and meaningful findings.

In addition, both the focus group and interview protocols that target HIV-positive youth address health care utilization and perceptions on the quality of the care received. These questions are

essential to assessing the availability, appropriateness, and uptake of health services at various RWHAP provider sites. Based on our extensive experience conducting qualitative research in RWHAP settings and receiving feedback from similar study participants, the project team feels that participants will be comfortable discussing questions related to their own HIV care in a focus group containing only HIV-positive youth participants who receive care at the same RWHAP provider. However, as stated in both the assent and consent forms, participation is entirely voluntary. Participants do not have to answer any questions that make them feel uncomfortable, and participants can leave the interview or focus group at any time.

## 12. Estimates of Annualized Hour and Cost Burden

There are nine data collection mechanisms in the study. Both types of providers will complete an online or telephone questionnaire prior to the site visit. During each site visit, project team researchers will complete an onsite observational tool while accompanied by a provider staff member. In addition, there will be two sets of interviews with program staff at each site, one with program managers and clinical directors and another with program and administrative staff (e.g., mental health workers, intake staff). Note that the specialized and performance improvement site visits utilize different interview instruments for these two sets. Researchers will also conduct one interview with an HIV-positive youth and one focus group with approximately six HIV-positive youth. Only at the performance improvement sites will researchers facilitate a Panel/advisory Board. The time estimated to complete each of these instruments and total burden is described below.

### 12A. Estimated Annualized Burden Hours

<b>Form Name</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Total Responses</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>
Organizational Online Questionnaire	26	1	26	0.5	13
Organizational Onsite Observational Tool	26	1	26	0.5	13
Program Manager and Clinical Director Interview Guide (Specialized)	20	1	20	1.5	30
Program Manager and Clinical Director Interview Guide (Performance Improvement)	32	1	32	1.5	48

<b>Form Name</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Total Responses</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>
Program and Administrative Staff Interview Guide (Specialized)	50	1	50	1	50
Program and Administrative Staff Interview Guide (Performance Improvement)	80	1	80	1	80
Youth Focus Group	156	1	156	1	156
Youth Interview	26	1	26	0.5	13
Panel/advisory board of young people living with HIV (Performance Improvement)	80	1	80	1.5	120
<b>Total</b>	<b>496</b>		<b>496</b>		<b>523</b>

### **12B. Estimated Annualized Burden Costs**

The below calculations assume an hourly wage of a Medical and Health Services Manager (\$49.84) for the pre-site visit questionnaire, onsite observational tool, and the program manager and clinical director interview.<sup>6</sup> For the program staff interviews, the project team assumes the hourly wage of \$28.08 associated with a Social Worker.<sup>7</sup> The project team assumes a federal minimum wage (\$7.25) for youth given they may be students or low skill workers due to their age.

<b>Form Name</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Respondent Costs</b>
Online Questionnaire	13	\$49.84	\$647.92
Onsite Observational Tool	13	\$49.84	\$647.92
Program Manager and Clinical Director Interview Guide	30	\$49.84	\$1,495.20

<sup>6</sup> <http://www.bls.gov/oes/current/oes119111.htm>

<sup>7</sup> <http://www.bls.gov/oes/current/oes211029.htm>

<b>Form Name</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Respondent Costs</b>
(Specialized)			
Program Manager and Clinical Director Interview Guide (Performance Improvement)	48	\$49.84	\$2,392.32
Program and Administrative Staff Interview Guide (Specialized)	50	\$28.08	\$1,404.00
Program and Administrative Staff Interview Guide (Performance Improvement)	80	\$28.08	\$2,246.40
Youth Focus Group	156	\$7.25	\$1,131.00
Youth Interview	13	\$7.25	\$94.25
Panel/advisory board of young people living with HIV (Performance Improvement)	120	\$7.25	\$870.00
<b>Total</b>	<b>523</b>		<b>\$10,929.01</b>

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

Other than time, there is no cost to respondents.

### **14. Annualized Cost to Federal Government**

The total cost of the *Building Futures: Supporting Youth Living with HIV* three-year contract (Contract No. HSH25034003T) to the government is \$1,139,144. These costs include study design, preparation of the Paperwork Reduction Act package, development and testing of the data collection instruments, study recruitment, data collection through site visits, data analysis, and the development of reports. In addition, the project team estimates about 500 hours of federal staff involved in project oversight. The cost is broken out into 250 hours of federal staff time at an average hourly wage of \$61.57 (GS-15 equivalent, step 1), for a total of \$15,392.50, and 250 hours of federal staff time at an average hourly wage of \$44.33 (GS-13), for a total of \$11,082.50. The total cost of the project is \$1,165,619.00. The *annualized* cost to the government, this amount divided by three, is estimated at \$388,539.76.

### **15. Explanation for Program Changes or Adjustments**

This is a new information collection.

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

The project team will conduct the specialized site visits immediately following OMB approval. Data collection is estimated to take approximately four months. During the first two months, the project team will recruit participating sites and finalize travel and scheduling logistics. Also during this time, participating providers will complete the pre-site questionnaire. Site visits will occur over the subsequent two-month period following OMB approval. The performance improvement site visits will be conducted during the second project year with a slightly expanded schedule due to the increased number of provider sites. The project team plans for two months of preparation and three months of site visits.

During site visits, the project team will record interviews and focus groups and take detailed notes. See Section 10 for mechanisms on how we will assure confidentiality of respondent information. The recordings will serve as a mechanism to clarify and enhance notes; the project team does not plan on transcribing the recordings. To facilitate standardized data collection and analysis across the various information sources, the project team has categorized all data collection instruments according to five areas of assessment: clinic systems and infrastructure, clinical standard and models of care, provider knowledge, skills and attitudes, collaboration with youth and families, and community presences and linkages. During the qualitative interviews, the project team will use structured note taking worksheets to document observations in the five areas, and these worksheets include columns for notes on core intervention and implementation components, as well as on the adaptable components of interventions. Information across data sources will be analyzed to determine which provider attributes contribute to positive health outcomes for youth and which attributes could be strengthened to improve performance.

The project team will summarize findings of each specialized site visit in a *Specialized Site Visit Report*. The report format is informed by the Active Implementation Framework (AIF)<sup>8</sup> and literature on replicating evidence-based practices,<sup>9</sup> and reports will document evidence-based best practices and promising strategies, models of care, environment suited for implementation, and resources needed to maximize effectiveness. A *Performance Improvement Site Visit Report* will summarize each performance improvement site visit, documenting evidence-based best practices and promising strategies for adoption and recommendations for actions to improve engagement, retention, and suppression for youth living with HIV.

The project team selected the providers based on rates of viral load suppression and retention in care, geographic representativeness, and client population make up. Findings will not be extrapolated to the RWHAP provider population overall; therefore, the project team does not plan on using advanced statistical analysis to summarize and present findings.

## **17. Reason(s) Display of OMB Expiration Date is Inappropriate**

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

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<sup>8</sup>Damschroder et al., “Fostering Implementation of Health Services Research Findings into Practice.”

<sup>9</sup>Metz, Bowie, and Blasé, “Seven Activities for Enhancing the Replicability of Evidence-Based Practices.”

## **18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.