

“Assessing School-Centered HIV/STD Prevention Efforts in a Local Education Agency”

OMB #0920-1035
Expiration Date: 11/30/2017

Supporting Statement Part A
Revision

June 13, 2017

Supported by:

Division of Adolescent and School Health
Centers for Disease Control and Prevention

Catherine Rasberry, PhD
CDC/OID/NCHHSTP, Health Scientist
(404) 718-8170
fh6@cdc.gov

Table of Contents

A. 1	Circumstances Making the Collection of Information Necessary.....	5
A. 2	Purpose and Use of Information Collection.....	8
A. 3	Use of Improved Information Technology and Burden Reduction.....	11
A. 4	Efforts to Identify and Use of Similar Information.....	11
A. 5	Impact of Small Businesses or Other Small Entities.....	12
A. 6	Consequences of Collecting the Information Less Frequently.....	12
A. 7	Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	13
A. 8	Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	14
A. 9	Explanation of Any Payment or Gift to Respondents.....	14
A. 10	Assurance of Confidentiality Provided to Respondents.....	14
A. 11	Institutional Review Board (IRB) and Justification for Sensitive Questions.....	15
A. 12	Estimates of Annualized Burden Hours and Costs.....	16
A. 13	Estimates of Other Annual Cost Burden to Respondents or Record Keepers.....	17
A. 14	Annualized Cost to Federal Government.....	17
A. 15	Explanation for Program Changes or Adjustments.....	18
A. 16	Plans for Tabulation and Publication and Project Time Schedule.....	19
A. 17	Reason(s) Display of OMB Expiration Date is Inappropriate.....	21
A. 18	Exceptions to Certification for Paperwork Reduction Act Submissions.....	21

List of Attachments

Attachment Number	Document Description
1	Public Health Service Act Legislation
2	60 Day FRN
2a	Public Comments Received
3	Youth Health and School Climate Questionnaire
4	Parental Consent Form
5	Detailed Description of Questionnaire Revisions
6	Letter of Agreement Between the LEA and Schools Participating in the Program and Related Evaluation
7	Teacher Proctor Instructions and Script
8	Products of Previously Approved Data Collection
9	Organizations and Individuals Providing Consultation on the Information Collection
10	IRB Approval Letter
11	Description of Additional Validity Checks for Study-Developed Questions
12	Example Data Analysis Table Shells

Section A: Justification for Information Collection

Goal: The Centers for Disease Control and Prevention (CDC) requests a 1-year OMB approval for a revision of the information collection entitled, “Assessing School-Centered HIV/STD Prevention Efforts in a Local Education Agency” (OMB #0920-1035). The goal of this study is to conduct in-depth assessment of HIV and STD prevention efforts that are taking place in one local education agency (LEA) funded by the Centers for Disease Control and Prevention (CDC), Division of Adolescent and School Health (DASH) under strategy 4 (School-Centered HIV/STD Prevention for Young Men Who Have Sex with Men) of PS13-1308: *Promoting Adolescent Health through School-Based HIV/STD Prevention and School-Based Surveillance*. This revised OMB approval is intended to cover the third in a series of three data collections, two of which were covered under the previous ICR (OMB# 0920-1035).

Intended use of resulting data: Data collection will provide data and reports for the funded LEA and allow the LEA to identify areas of the program that are working well and other areas that will need additional improvement. In addition, the findings will allow CDC to determine if changes in key outcomes took place following the implementation of currently recommended strategies and make changes to those recommendations if necessary.

Methods: Data will be collected through a self-administered paper-and-pencil questionnaire from an estimated 16,500 high school students enrolled in the 7 of the schools participating in the CDC-funded program. Data will be collected in the 2017-2018 school year from a census of all students in the participating high schools.

Subpopulation to be studied: The study focuses on high school students from 7 high schools participating in a CDC-funded program using school-centered approaches to prevent HIV with a specific focus on black and Latino adolescent young men who have sex with men (YMSM). Because program activities are designed to be tailored to YMSM while also reaching all students, data collection is designed to allow analysis of data from both the full population of students in these 7 schools as well as the subpopulation of particular interest, YMSM.

Data analysis: Data will be analyzed using both descriptive and inferential statistics. Data reduction techniques/factor analyses and item correlation analyses will be used to develop scales as needed. T tests and chi-square analyses will be used to assess differences between years; linear or logistic regression will be used to examine predictors of outcomes of interest (such as HIV or STD testing).

A. 1 Circumstances Making the Collection of Information Necessary

Background

The Centers for Disease Control and Prevention (CDC) requests a 1-year OMB approval for a revision of the information collection entitled, “Assessing School-Centered HIV/STD Prevention Efforts in a Local Education Agency” (OMB #0920-1035). The information collection uses a self-administered paper-pencil questionnaire, the Youth Health and School Climate Questionnaire, to conduct in-depth assessment of HIV and STD prevention efforts that are taking place in one local education agency (LEA) funded by the Centers for Disease Control and Prevention (CDC), Division of Adolescent and School Health (DASH) under strategy 4 (School-Centered HIV/STD Prevention for Young Men Who Have Sex with Men) of PS13-1308: *Promoting Adolescent Health through School-Based HIV/STD Prevention and School-Based Surveillance*. This revised OMB approval is intended to cover the third in a series of three data collections, two of which were covered under the previous ICR (OMB# 0920-1035). Revisions consist of modifying the survey to add options to existing questions, remove and add questions and or change the order of questions. A detailed description of questionnaire revisions is provided in **Attachment 5**.

Under this cooperative agreement, the participating school district identified 7 high schools in which it would conduct programmatic work. As part of the agreement to receive program activities from the school district, each of the 7 participating schools also agreed to participate in the evaluation activities requested by the district (which includes this proposed information collection) (see **Attachment 6** for the letter of agreement the district used to recruit schools for participation in the program as well as the related evaluation components). CDC’s role in this information collection is that it is helping provide technical assistance and support for the local education agency (school district) to conduct this evaluation of its CDC-funded programmatic work.

Data will be collected from an estimated 16,500 high school students from all 7 of the participating schools in the middle of the 2017-2018 school year (mostly likely December 2017-February 2018). This is the third and final data collection of a 4-year project that includes 3 data collections; previous data collections occurred in December 2014 and December 2016. The goal of the data collection is to provide data and reports for the funded LEA and allow the LEA to identify areas of the program that are working well and other areas that will need additional improvement. In addition, the findings will allow CDC to determine if changes in key outcomes took place following the implementation of currently recommended strategies and make changes to those recommendations if necessary. Data will be collected by LEA staff with support from a CDC-funded evaluation contractor. The questionnaire includes questions on the following topics: demographic information; HIV and STD risk behaviors; use of HIV and STD health services; experiences at school, including school connectedness, harassment and bullying, homophobia, support of LGBTQ students; receipt of referral for HIV and STD prevention health services; and health education.

CDC’s DASH awarded funds to implement PS13-1308: *Promoting Adolescent Health through School-Based HIV/STD Prevention and School-Based Surveillance* in order to build the capacity of state and local education agencies and support the efforts of national, non-governmental organizations (NGOs) to help priority school districts (districts) and schools

develop and implement sustainable adolescent-focused program activities. Within that cooperative agreement, three local education agencies and one national, non-governmental organization were funded under strategy 4 for to prevent HIV and STDs among 13-19 year old black and Latino young men who have sex with men (YMSM). In this project, YMSM are defined to include young men who report sexual activity with other males, attraction to other males, or who identify as gay or bisexual. Program activities funded by the cooperative agreement will focus on impacting short-term and intermediate outcomes believed to lead to the prevention of HIV and STDs. Of specific interest, are increasing access of students (particularly YMSM) to key sexual health services and making the school environment safer and more supportive for YMSM. The safer and more supportive environment for YMSM is seen as a foundational requirement for school staff to be able to increase access to sexual health services. The primary programmatic activities include implementation of a referral system for connecting youth to key services, programs and professional development to improve school climate, social marketing campaigns that address key outcomes, and educating staff on existing policies that are related to access to care or the school environment. These program activities are expected to impact key short-term and intermediate outcomes (preventive and risk behaviors, and perceptions) assessed by the student questionnaire in this ICR, including HIV and STD risk behaviors; use of HIV and STD health services; experiences at school, including school connectedness, harassment and bullying, homophobia, support of LGBTQ students; receipt of referral for HIV and STD prevention health services; and health education. The purpose of this ICR is to collect data to directly assess changes in these key outcomes, all of which are tied to specific aspects of the programmatic work. These key short-term and intermediate outcomes are believed critical for movement in the longer-term goal of preventing HIV and other STDs.

In addition, it is important to note that although the focus of the work is to prevent HIV and STDs among YMSM, the specific nature of school settings often requires that programs to reach YMSM be broader in scope such that they reach and serve all students (or larger subgroups of students, such as all males) within the schools. This broader frame is essential so that YMSM can receive critical services even in instances where they are not comfortable disclosing sexual identities to others in the schools. Given this, the activities of this program are currently designed to reach all youth in the schools (for example, a referral system will be implemented to link any student in the school to necessary services), and will have aspects or components that are designed to specifically meet the unique needs of YMSM. Because of this, data will also be analyzed to look for changes in key outcomes among all students as well as among the priority group of YMSM students.

HIV infections remain high among young men who have sex with men.¹ The estimated number of new HIV infections increased between 2008 and 2010 both overall and among MSM ages 13 to 24.² Furthermore, sexual risk behaviors associated with HIV, other sexually transmitted disease (STD), and pregnancy often emerge in adolescence. For example, 2015 Youth Risk Behavior Surveillance System (YRBSS) data revealed 41.2% of U.S. high school students reported having had sex, and among those who had sex in the previous three months, only 56.9% reported having used a condom during last sexual intercourse.³ In addition, 2001-2009 YRBSS data revealed high school students identifying as gay, lesbian, and bisexual and those reporting sexual contact with both males and females were more likely to engage in sexual risk-taking behaviors than heterosexual students.⁴

Given the disproportionate risk for HIV among YMSM ages 13-24, it is important to find ways to reach the younger youth (i.e., ages 13-19) in this range to decrease sexual risk behaviors and increase health-promoting behaviors such as routine HIV testing. Schools provide one opportunity for this. Because schools enroll more than 22 million teens (ages 14-19)⁵ and often have existing health and social services infrastructure, schools and their staff members are well-positioned to connect youth to a wide range of needed services, including housing assistance, support groups, and sexual health services such as HIV testing. As a result, CDC's DASH has focused a number of HIV and STD prevention efforts on strategies that can be implemented in or centered around schools.

The proposed data collection applies to only strategy 4 of PS13-1308, and it is part of a multi-component assessment of the HIV and STD prevention work conducted by the three LEAs and one NGO funded for strategy 4. The proposed data collection will involve the third in a series of three administrations of paper-and-pencil questionnaires to all students in the seven high schools participating in the project in one of the funded LEAs. This component of the assessment is designed to provide in-depth assessment findings for a single LEA. All students will be invited to participate in questionnaire administration for two reasons: (1) program activities are designed in a manner that will reach all students even though certain aspects will be more tailored to YMSM, and (2) it is critical to collect data from all students in order to have a sufficient number of YMSM included in the analysis sample to support statistical analyses for that subgroup of interest. YMSM students are estimated to make up a small percent of the general student population; as a point of reference, weighted data from 10 school districts participating in the Youth Risk Behavior Surveillance System (YRBSS) between 2009 and 2011 revealed that 5.4% of males reported being gay or bisexual, and an additional 3.0% reported being not sure about their sexual identity.⁶

CDC is authorized to collect the data described in this request by Section 301 of the Public Health Service Act (42 USC 241). A copy of this enabling legislation is provided in **Attachment 1**. In addition to this legislation, there are several national initiatives and programs that this data collection would serve to support, including but not limited to:

- *Healthy People 2020*, which provides national health objectives and outlines a comprehensive plan for health promotion and disease prevention in the United States. Of the Healthy People 2020 objectives, 31 objectives align specifically with PS-13-1308 activities related to reducing HIV infection, other STD, and pregnancy among adolescents.
- The *National Prevention Strategy* (NPS) calls for “medically accurate, developmentally appropriate, and evidence-based sexual health education.” The NPS encourages the involvement of parents in educating their children about sexual health, the provision of sexual and reproductive health services, and the reduction of intimate partner violence.⁷
- The U.S. Department of Health and Human Services' (DHHS) *Teen Pregnancy Prevention Initiative* supports the replication of teen pregnancy prevention (TPP) programs that have been shown to be effective through rigorous research as well as the testing of new, innovative program activities to combat teen pregnancy.⁸
- The NCHHSTP program imperative calls for *Program Collaboration and Service Integration* (PCSI) to provide improved integration of HIV, viral hepatitis, STD, and TB prevention and treatment services at the user level.⁹

- *CDC Winnable Battles*, including prevention of HIV infection and TPP, have been chosen by CDC based on the magnitude of the health problems and the ability to make significant progress in improving outcomes. These are public health priorities with large-scale impact on health with known, effective strategies to address them.¹⁰

The privacy act does not apply as no individually identifiable information will be collected. Data collection involves collecting anonymous data from students through the use of a self-administered paper-and-pencil questionnaire. CDC will receive no personal information.

A. 2 Purpose and Use of Information Collection

This data collection system involves administration of a paper-and-pencil questionnaire to seven high schools participating in the HIV/STD prevention project of a local education agency (Broward County Public Schools in Broward County, Florida) funded with support from CDC's PS13-1308. This LEA was selected as the site for enhanced efforts to assess activities of PS13-1308. Data collection partners include LEA staff and CDC contractors (with oversight from CDC staff). Data gathered from these questionnaires will allow the funded local education agency to assess program activities conducted under PS13-1308. It will allow them to ensure their activities are helping improve HIV/STD prevention practices and services in schools, and to determine if their activities are impacting HIV/STD preventive and risk behaviors among students. In particular, the approach of collecting data from all students in the participating schools allows a sufficient sample size for the LEA to examine key outcomes for the subgroup of interest, young men who have sex with men (defined in this project to include young men who report sexual activity with other males, attraction to other males, or who identify as gay or bisexual). This supports a major public health goal of reducing disparities in HIV/STD infections experienced by adolescent young men who have sex with men.

The Youth Health and School Climate Questionnaire will be administered to up to 16,500 students across the seven schools. Questionnaire items were selected from valid and reliable instruments whenever possible. The questionnaire contains questions on the following topics: demographic information; HIV and STD risk behaviors; use of HIV and STD health services; experiences at school, including school connectedness, harassment and bullying, homophobia, support of LGBTQ students; sexual orientation; receipt of referral for HIV and STD prevention health services; and health education. For this data collection, we are making a few minor changes to our originally approved questionnaire (see updated questionnaire in **Attachment 3**). We are slightly revising 3 questions and adding 1 primary question and 4 sub-questions to provide more refined data and allow for analysis of associations between key outcomes and participation in or awareness of specific program activities initiated after the baseline data collection had been approved. A detailed description of questionnaire revisions is provided in **Attachment 5**. Questionnaires will be completed in scannable Scantron questionnaire booklets. No individually identifiable information will be collected. The required OMB number and related language will be included on the front page of the questionnaire once approval is received (see placeholder language in **Attachment 3**).

The questionnaire format and administration have been designed to mirror those procedures designed and approved for school-based student data collection through the National

Youth Risk Behavior Survey in Florida schools, and was pilot tested by fewer than 10 evaluation contractor staff to estimate the length of time necessary for survey administration. In addition, the first two rounds of data collection supported the length of time estimated for survey completion. The questionnaire was previously administered in 2014 and 2016. This approval is requested for the final data collection in the 2017-2018 school year (most likely December 2017-February 2018, depending partially on the schedules at the schools). These data collection points coincide with the initiation of project activities and the mid-way and end points of the PS13-1308 cooperative agreement. We anticipate that each year of data collection will yield data from up to 16,500 high school students in grades 9 through 12 at the selected school. The first two data collections yielded data from about 11,000-12,000 each. We are leaving our possible participant and burden hour estimates a bit higher to account for any fluctuation that might occur in student attendance. Although some students may take the questionnaire in multiple years, this is not a longitudinal design and students' responses will not be tracked across the years. No personally identifiable information will be collected.

At least one week prior to data collection, school staff will distribute passive parental consent forms (**Attachment 4**) that describe the study and allow parents to return a signed form if they prefer their children not complete the voluntary questionnaire. These forms will be provided in English, Spanish, and French Creole. Students whose parents opt them out of the data collection will be given an alternate activity during the time of questionnaire administration. This process for parental consent has been approved by CDC contractor's IRB and the participating LEA's research office.

The questionnaire will take one class period of 35-45 minutes to complete (estimated to be 40 minutes). The questionnaire will be administered by teacher proctors who will have been trained by the project team to proctor the questionnaire. Students who choose to participate in the self-administered Youth Health and School Climate Questionnaire will be asked to read through the questions in the booklet and fill out the Scantron answer choices for each question. Students will be informed of how long they have to complete the questionnaire through a script read aloud by the trained teacher proctor. Students will not sign their names to student assent forms. The student assent language is provided on the first page of the questionnaire. Students will then read the assent language and instructions on the first page of the questionnaire which will include a description of the study and clear statement that completing the questionnaire is voluntary and they can choose not to participate without penalty. This language is presented clearly in the third paragraph of the student assent statement on the front of the questionnaire (see page 1 of **Attachment 3**). The instructions also clearly state that students may skip any question they are not comfortable answering. In addition, training materials used for teacher proctors (**Attachment 7—Teacher Proctor Instructions and Script**) prompt the proctors to emphasize that students can choose not to take the questionnaire and this will have no penalty or impact on their grades (see highlighted sections of **Attachment 7**). This process for student assent is consistent with what the school district uses for other student questionnaires such as the Youth Risk Behavior Survey, and it has been approved by the Contractor's IRB and the LEA's research office.

Upon completion of the questionnaire, students will place questionnaires into a large envelope at the front of the classroom. This envelope will be collected by members of the project team and logged by classroom to ensure all data are collected. These will be sealed and

mailed to the CDC contractor's data processing facility for processing, scanning, and creation of the analytic data file. All paper-pencil questionnaires will be shredded after creation and verification of the data file.

To date, data collected during the previous OMB approval period, have been analyzed for the first baseline data collection. These data were used to inform the LEA of students' needs and experiences, and the LEA has used this data to build support among school administrators and staff for their program. In addition, the cross-sectional baseline data have been analyzed for important associations between key student experiences (prior to the intervention) and relevant outcomes. As an example, one analysis published in the *Journal of School Nursing* found that having been referred by school staff for HIV or STD testing was associated with sexually experienced students being three times as likely to have actually received HIV or STD testing. These types of findings help the LEA and CDC better understand which types of program approaches can be useful for achieving key health goals. A full list of publications, presentations, and reports from the baseline data collection is provided in **Attachment 8**. Data from the mid-point data collection are currently being cleaned and prepared for analysis. Data are expected to be analyzed after the mid-point and final data collections as well, and all analyses will be provided to the LEA. The resulting analyses (which may include frequencies, tests for differences between sub-populations of students, or comparison from across data collection points) will be used by the LEA to identify areas for program improvement and to assess program impact.

Furthermore, this data collection will provide the most extensive assessment to date of a set of new and innovative school-based strategies for HIV and STD prevention efforts that are being supported under PS13-1308, a cooperative agreement that scheduled to be funded by DASH through 2018. The approach of collecting data from all students in each participating school will allow assessment of the impact of project strategies on all students (which is a logical outcome given the nature of some program strategies), but it allows for data collection from a large enough number of YMSM students that those data can be analyzed separately to determine the impact of tailored approaches on this critical subgroup that experiences disproportionately high risk for HIV and STD. In baseline data collection, the full sample of more than 11,000 students yielded data from approximately 300 who were classified based as YMSM based on self-reported identity, attraction, and/or behavior. The findings from this information collection have had and will continue to have practical utility to the government because they directly impact both the activities used by the CDC-funded LEA and the strategies and approaches the CDC recommends for use in schools.

Without this data collection, the LEA would be unable to determine if their program activities had the desired impact on the school climate and the students' health-enhancing and risk behaviors related to HIV and STD. More specifically, this third and final data collection comes in the last year of the program's funding and will provide data after the highest levels of program implementation have occurred, allowing the best opportunity for gathering data from students who have experienced program activities. In addition, without collecting this data, the CDC would have little evidence on several of the new and innovative strategies that are being used to enhance HIV and STD prevention efforts in schools. Furthermore, neither the LEA nor the CDC would be able to identify the impact of these strategies on the small group of students at particularly high risk for HIV and STDs, the subgroup of students who are young men who have

sex with men.

In this third and final data collection for this program, a few very minor changes have been made to the instrument to provide more refined data and allow for analysis of associations between key outcomes and participation in or awareness of specific program activities initiated after the baseline data collection had been approved. The specific items to be added and replaced are outlined in **Attachment 5**.

Data have been, and will continue to be, shared in aggregate with the local education agency so that they can determine program impact and identify areas for program improvement. CDC staff and contractors will work with the LEA to ensure secure the data storage systems are in place. All data collectors and project team members are asked to sign agreements that specify how data collection and data management needs to be handled to maintain anonymity and security.

In addition, CDC contractors have, and will continue to, assist the LEA with data analyses and provide all findings to the LEA. Summaries of findings may also be shared with other stakeholders (e.g., the other LEAs and the NGO funded under strategy 4 of PS13-1308, CDC staff) and researchers in the field, once appropriate permissions and clearances have been secured from both CDC and the LEA.

A. 3 Use of Improved Information Technology and Burden Reduction

This proposed information collection does not involve the use of automated, electronic, mechanical, or other technological collection techniques or forms of information technology. Although information technology certainly can reduce burden of information collection in some cases, it is not always appropriate or feasible. In this information collection, we determined electronic submission of data by respondents was not feasible. We considered various means of electronic submission, but because data collection will be conducted with all students in each school during the same 35-45 minute class period, the technology resources in each school were not sufficient to provide all students with simultaneous access to electronic forms of submission. Furthermore, the expense of and logistics involved in bringing in devices to support such data collection was too restrictive to make this feasible.

The use of paper-and-pencil questionnaires in the school setting actually makes it easier for the schools to participate in data collection with minimal disruption to the school day and minimal loss of instructional time. Students can remain in their regular classrooms and can return to normal classroom activities upon completion of the questionnaire.

A. 4 Efforts to Identify and Use of Similar Information

The complete content of the questionnaire used in this information collection is not duplicated in any other single data collection system. However, a few items on this questionnaire have been pulled from other existing data collection systems. Several demographic and risk behavior questions on this questionnaire came from the Youth Risk Behavior Survey (YRBS), and the school climate and school connectedness questions came from National School Climate Survey conducted by the Gay, Lesbian, and Straight Education Network (GLSEN) and the National Longitudinal Study of Adolescent Health.

Despite the fact that questions similar to our existed in other data collection systems, only

one of those questionnaires (the YRBS) is currently being used in the local education agency participating in this project. We were unable to use the YRBS for our assessment activities for two reasons. First, we needed to include questions that examined outcomes that were not captured by the YRBS, such as use of HIV and STD health services; a broad range of experiences at school, including school connectedness, homophobia, support of LGBTQ students; and receipt of referral for HIV and STD prevention health services. Second, we needed to administer our questionnaire to all students in the participating high schools in order to capture the largest possible number of students who met our project's definition of young men who have sex with men. By collecting data from all students in the schools, we enhance our ability to conduct statistical analyses with sufficient power to make statement about this subgroup of students at disproportionate risk.

A. 5 Impact of Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in or impacted by this data collection.

A. 6 Consequences of Collecting the Information Less Frequently

This information collection was planned to occur in 2014, 2016, and 2018. The first two data collections took place in December 2014 and December 2016. The third and final data collection is scheduled for the 2017-2018 school year, the last year of the program's CDC funding and is anticipated to occur between December 2017 and February 2018, depending on the preferences of school administrators. These time points align with the initiation of program activities (for baseline data collection in 2014) and an approximate mid-way point (2016) and end point (2018) of program activities funded under PS13-1308. The first two data collections (2014 and 2016) were covered by OMB #0920-1035, and the final data collection will be covered by this approval.

There would be a number of consequences to collecting the data less frequently. First of all, this was designed to use the fewest data collections to achieve project goals. The 1308 Strategy 4 program components are planned and about to begin in Broward County School District. Therefore the first data collection served as a true baseline for our evaluation outcomes and present an accurate picture of what students' experiences were like prior to initiation of program activities and strategies. Without this first data collection, it would have been impossible to determine if the program had any impact. Furthermore, the initial baseline data collection provided critical information that LEA staff used to determine the most appropriate focus of their activities. It allowed them to determine areas of greatest need that could be incorporated into program planning.

The second (mid-point) data collection (in 2016) was critical to our evaluation of the program because the Strategy 4 program components are staggered in their planned implementation and designed to have a cumulative, additive effect on the outcomes of interests to this evaluation. The midpoint data collection was intended to capture the effects of development of more formalized referral systems for participating schools and any initial changes in school climate for YMSM; these components were delivered to the initiative schools

in the first years of the program. The staggered and multi-component nature of the program implementation made it necessary to have more than just beginning and end-point data collection periods to adequately capture the effects of the initiative as it unfolds in the school district, and the final data collection allows measurement of relevant outcomes following the full implementation of the program.

In addition, one of the key purposes of the assessment is not simply to know if activities worked, but to be able to make mid-course corrections to improve the likelihood that future activities can have even greater impact. The mid-program data collection (currently being prepared for analysis) will allow the LEA to assess impact midway through the program and to make improvements based on strengths or weaknesses revealed by the 2016 data. Evaluators anticipate looking most closely at outcomes related to school climate and referral for sexual health services with the data from the 2016 mid-point data collection. The presence or absence of significant changes in outcomes at this mid-point of the program may help program staff determine where to best focus their limited resources. For example, if data reveal improvements in perceptions of school climate, but no significant increase in the number of students reporting receipt of referrals from school staff, program staff could refocus their efforts on activities to help support staff in referring youth for services. Another valuable aspect of the 2016 data collection at the mid-point of the program is that it increases the evaluators' options for data analysis. It allows for the analysis of 2 cohorts of students—group one (those in 9th or 10th grade in 2014, and in 11th or 12th grade in 2016) and group two (those in 9th or 10th grade in 2016, and in 11th or 12th grade in 2018).

The third and final data collection allows analysis of the effects of programs implemented in the final year of the program, which includes additional school climate and HIV and STD testing activities. It is essential for determining the full impact of the funded activities and will allow time for program activities to actually result in changes at the student level. Without these three data collection points, the LEA and CDC would not be able to achieve both goals of improving program activities and assessing their impact—both for all students in general, and for the specific group of young men who have sex with men who are at disproportionately higher risk for HIV and STDs.

In addition, collecting data from all students is essential to reaching the goals of the information collection. By sampling students rather than taking a census, the project team could easily miss some of the students who meet the project's definition of young men who have sex with men. In fact, other student data collections that sample students (rather than take a census of all students) find relatively low numbers of students who fit into this group and have found it necessary to combine multiple years or jurisdictions of data in order to get sufficient numbers of responses to support statistical analyses.⁶ The census approach is essential in this information collection for the project team to be able to answer questions about program impact among YMSM. As previously stated, the initial baseline data collection with over 11,000 students yielded data from approximately 300 students classified as YMSM based on their self-reported identity, attraction, and/or behavior.

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

There are no special circumstances. This request fully complies with the regulation 5

CFR 1320.5.

A. 8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. As required by 5 CFR 1320.8(d), a 60-day Notice was published in the *Federal Register* on Thursday, April 13, 2017, page #17838, Vol. 82, No. 70 (see **Attachment 2**). Seven non-substantive public comments were received. Upon review of them, two were duplicates and one comment was for another federal register notice that was posted in error. (See **Attachment 2a**).

B. The local education agency involved in this information collection was consulted to discuss all aspects of the data collection. They provided extensive feedback on the availability of existing data, other data collections in their LEA and the frequency of data collection for this project. In addition, CDC contractors provided extensive input into the clarity of instructions and reporting format and the data elements that will be reported. LEA staff also reviewed and approved this information.

These consultations took place in 2013 and 2014 and again in 2016. A list of organizations and individuals consulted is provided in **Attachment 9**. There were no major problems that arose during the consultation, and all issues raised were resolved.

A. 9 Explanation of Any Payment or Gift to Respondents

This data collection does not provide any payment, gift, or incentive to the respondents for their participation.

A. 10 Assurance of Confidentiality Provided to Respondents

The CDC NCHHSTP Privacy and Confidentiality Review Officer has assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act does not apply to the information collection. Activities do not involve the collection of individually identifiable information. CDC staff have reviewed this information collection request and determined that the Privacy Act does not apply.

We anticipate no adverse impact of the proposed data collection on respondents' privacy because no individually identifiable information will be collected. Data collection involves collecting anonymous data from students. After data are collected, they will be sealed and shipped to a CDC contractor for processing. The contractor will scan data and prepare an analytic output data file that will be sent to the CDC contractor's main office via a secure, password-protected server. All paper-pencil questionnaires will be shredded after creation and verification of the data file. The data file will remain stored on a password-protected server. At the end of the assessment, data will be shared in aggregate with the participating local education agency, but because no individually identifiable information will have been collected, there is no risk to respondents' privacy.

Parents will receive a passive parental consent form (see **Attachment 4**) that provides

information about the questionnaire and provides them with an opportunity to opt their children out of participation. Student participants will read a student assent form (see page 1 of the questionnaire in **Attachment 3**) that explains the study is completely voluntary and they may choose not to participate, or they may choose to skip any questions with no penalty. Both parents and the participants will be informed that providing the information for this data collection is voluntary.

No personally identifiable information is being collected; this data collection is completely anonymous. Once questionnaires are completed, they will be placed into envelopes that will be sealed and shipped by the project team to the CDC contractor's data processing center. During receipt and data processing, hard copy data will be stored on-site at the contractor's facility in locked filing drawers. Only approved project staff will be given access to the data. Hard copy data will be scanned and processed. Electronic data will be stored on a secure network location. Access to this network requires user authentication by entering a user name and password. Although CDC contractors are involved in data collection and the processing of the data, the data collected will be ultimately owned by the participating LEA.

Privacy Impact Assessment Information

- A. **Voluntary collection.**
- B. **Safeguards and security.**
- C. **System of records.** A system of records is not being created under the Privacy Act.

A. 11 Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This proposed data collection has been reviewed and approved by the existing contractor's IRB (see **Attachment 10**). In addition, the protocol has been reviewed and approved by the research office of the participating school district.

Sensitive Questions

A few questions in this information collection are of a sensitive nature. These include questions about sexual risk and protective behaviors and sexual orientation or attraction. These questions are necessary because they represent key outcomes of the program. In order to assess the impact of program strategies on behaviors that can impact HIV and STD transmission, it is essential to include questions about sexual behavior (such as whether or not the respondent has had sex, use of condoms, etc.). In addition, it is necessary to ask questions related to sexual orientation in order to identify respondents who are classified as YMSM for subgroup analysis of the program impact. Because YMSM are at such disproportionate risk for HIV and STDs, and because they are the focus of many program activities, it is essential for the project team to be able to analyse data to look for program impact among that subgroup of students. Participants will be given an overview of the content of the questionnaire in the assent form (and parents will have received an overview of the content of the questionnaire on their passive consent forms).

Parents may choose for their children not to participate, and a student may choose not to participate at any time. Students are also given the option to skip any question that makes them uncomfortable or that they do not want to answer. Furthermore, even though sensitive questions are being asked, there is no individually identifiable information being collected on the questionnaire, so there is no way to link any individual response with any particular student.

A. 12 Estimates of Annualized Burden Hours and Costs

Burden hours. **Table A.12-1** provides estimates of burden for the data collection. The amount of time required to complete the questionnaires was originally based on a pilot test with fewer than 10 evaluation contractor staff as well as estimates that DASH compiled relying on their experience with previous data collections on health risk and protective behaviors among high school students and their discussions with the local education agency during the process undertaken to develop measures. In addition, the first two rounds of data collection under the previous ICR provided evidence that students completed the questionnaires in less time than our original burden estimate. The revised version contains 1 new question with 4 subquestions. Because so few questions have been added and our original estimate of 40 minutes was slightly longer than what was required to complete the questionnaire on average for the first two rounds of data collection, we believe it is appropriate to maintain the burden estimate of 40 minutes for the updated questionnaire. Administration of will be completed via the paper-and-pencil questionnaire in classrooms of seven high schools. The questionnaire is listed in the burden table below. The estimated burden time includes the time for receiving instructions, reviewing the student assent, and completing, reviewing, and handing in the questionnaire.

An estimated 16,500 high school students from 7 schools will complete the questionnaire in the 2017-2018 school year. The estimated burden per response ranges from 35-45 minutes. This variation in burden is due to the slight variability in skip patterns that may occur with certain responses and variations in the reading speed of students. The burden estimates presented here are based on the assumption of an average 40-minute response time per response. Students in the 11th and 12th grade in December 2014 likely completed the questionnaire only once. It is estimated that students in the 9th and 10th grades in December 2014 may have completed it again in December 2016 when they were in the 11th and 12th grade students. In addition, students who were in the 9th, 10th, or 11th grades in December 2016 may also also complete the questionnaire during the 2016-2017 school year as 10th, 11th, or 12th grade students. Annualizing this collection over one year results in an estimated annualized burden of 11,000 hours.

Table A.12-1 Estimated Annualize Burden to Respondents

Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Students in the grades 9-12	Youth Health and School Climate Questionnaire	16,500	1	40/60	11,000

Total	11,000
-------	--------

Annualized cost. **Table A.12-2** provides estimates of the annualized cost to respondents for the collection of data. Because student respondents are expected to be under the age of 20, cost estimates for the value of time students spend in responding to the questionnaire are based on a Department of Labor fact sheet describing the minimum wage for students aged less than 20 years as \$4.25 an hour (<http://www.dol.gov/whd/regs/compliance/whdfs32.pdf>). Total cost has been rounded up to the nearest whole dollar.

Table A.12-2 Annualized Costs to Respondents

Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage Rate	Total Cost
Students in the grades 9-12	Youth Health and School Climate Questionnaire	16,500	1	40/60	\$4.25	\$46,750
Total						\$46,750

A. 13 Estimates of Other Annual Cost Burden to Respondents or Record Keepers

No capital, start-up, operation, or maintenance costs are involved.

A. 14 Annualized Cost to Federal Government

Cost will be incurred by the government in personnel time for overseeing the project. CDC time and effort for overseeing the contractor's assistance with data collection and answering questions posed by the contractor and funded agencies are estimated at 20% for one GS-13 level CDC employee (calculated based on a step 5) and 20% for a GS-14 level senior CDC employee (calculated based on a step 6) a year for the final year of the project. The senior level employee supervises the two GS13-level employees. The average annual cost to the federal government for oversight and project management is \$45,228 (**Table A.14-1**).

The contractor's costs are based on estimates provided by the contractor who will carry out the data collection activities. With the expected period of performance, the annual cost to the federal government from contractor and other expenses is estimated to be approximately \$170,381 (**Table A.14-1**). This is the cost estimated based on the current funding level of the contractor at approximately \$851,905 per year and the percentage of the contractor's effort that is anticipated for this specific data collection. It is estimated this data collection will take

approximately 15% of the contractor’s effort for data collection and processing, and approximately 5% of the contractor’s effort for analysis and reporting in the year covered by this approval. This includes the estimated cost of coordination with DASH, providing assistance to the LEA for data collection and processing, and support for analysis and reporting.

The total annualized cost to the government, including direct costs to the federal government and contractor expenses is \$215,609.

Table A.14-1. Annualized and Total Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
<i>Direct Cost to the Federal Government</i>		
CDC employee oversight for project (1 GS-13-step 5 staff member at 20% time)	CDC Supervisor labor costs	\$20,405
CDC oversight of contractor and project (1 GS-14-step 6 staff member at 20% time)	CDC Project Officers labor costs	\$24,823
Subtotal, Direct Costs to the Government per year		\$45,228
<i>Contractor and Other Expenses</i>		
Assistance with data collection and processing	Labor and other direct costs for supporting data collection and processing	\$127,786
Assistance with data analysis and reporting	Labor and other direct costs for supporting data analysis and reporting	\$42,595
Subtotal, Contract and Other Expenses per year		\$170,381
<i>Total of all annualized expenses</i>		<i>\$215,609</i>

A. 15 Explanation for Program Changes or Adjustments

This request extends the approval period of the original ICR and allows approval of a very slightly revised questionnaire. The approval period is being extended to continue approval for the third and final planned data collection of the project. The initial ICR for this project included mention that this extension would be requested.

The questionnaire contains very slight revisions to ensure the data collected provide a more refined level of detail and allow us to include questions to assess student exposure to specific program activities (e.g., on-site HIV testing, a pocket-sized health resource guide designed to assist youth in identifying appropriate health care providers) that were selected and

implemented after the approval for the initial data collection had been secured and, in some cases, even after baseline data collection had begun. These newly added questions will be analyzed as cross-sectional data to provide a better understanding of associations between exposure to program activities and key health-related outcomes among students. A detailed description of the few changes to the questionnaire is provided in **Attachment 5**. Because previous data collections provided evidence that students completed the original questionnaire in under the estimated burden time for the questionnaire, we are confident these few additions can be incorporated without further increasing our burden estimate.

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

Current plans for tabulation and publication of data from this information collection include analyzing data for differences in key outcomes between baseline and follow-up data collections and publication of these findings in written reports for the LEA and possibly, peer-reviewed journals. In addition, basic analyses of baseline (2014) data have been shared in written reports for the LEA, 1 published manuscript, and several peer-reviewed presentations.

Analysis Plan

Data will be analyzed using both descriptive and inferential statistics. As relevant (where multiple items were developed to measure a larger construct such as school climate), data reduction techniques/factor analyses and item correlation analyses will be used to develop scales from within the questionnaire items, as needed. In addition, because not all questions have been tested with youth (though all have been either used by youth, or tested and examined by experts on youth), close inspection of the data for aberrant or unexpected patterns in responses will be used to identify any questions that may not be performing appropriately. More detail on the study-developed questions and the validity checks for those questions is provided in **Attachment 11**.

Descriptive statistics of data will assist in data cleaning, generating additional hypotheses, and summarizing the characteristics, attitudes, intentions and behaviors of YMSM students, as well as for the full student population, for each of the seven schools, all schools pooled together, and at each data collection time point. In terms of analyses for each of the seven schools, it is important to note that the unique school identification codes will be applied to the questionnaires at the point of scanning and processing the questionnaires. These will allow for analysis of data for individual schools. For all school-specific analyses, the evaluation team will keep a close watch on the size of all sub-groups to ensure that (1) subgroups are large enough to support statistical analyses, and (2) any sub-group analyses (particularly subgroup analyses within specific schools) will be presented only if the subgroup is large enough that no individual within that subgroup could be identified. Summary reports will share summative findings from the survey aggregated across all 7 schools and selected school-specific data where cell sizes are not less than $n=20$ (the standard minimum for reliable estimates and a sufficient number to protect against identifying information being surmised by school/district partners). If cell size becomes problematic, the school identifier could be stripped from the data set prior to sharing the actual data set with school staff. (This was done for the baseline data set previously provided to the LEA.) To address our primary research question about the effect of the PS13-

1308 activities focused on teen YMSM in Broward County Public Schools, we plan to pool the data from YMSM students from across all 7 schools involved in the study. (The pooling of data across all schools enabled us to power the study to assess changes in outcomes among the program's priority population of YMSM students.) We will examine changes in attitudes, experiences, and testing behavior among YMSM students across three time points. The samples will be successive independent samples (non-linked). Logistic regression will be used to model changes in HIV and STD testing among the YMSM sample as a function of time. Multivariate linear regression will be used to assess for change over time in continuous outcomes of interest (referral receipt, perceived school climate, intention to test for HIV and STD) among the YMSM sample. Additional analyses will be explored to determine if school intervention implementation level (high v low implementation) may be used as a predictor of change in these models. In examining other predictors of testing related behaviors at single cross sections, linear and logistic regression models will be used to analyze data from this key subsample while controlling for covariates. Chi-square analyses and t-tests will also be used to examine differences between the YMSM sample and the non-YMSM sample on the list of dependent variables believed to be influenced by the activities supported by PS13-1308 (such as school climate, referral receipt and referral completion for sexual health services, testing behavior for HIV and STD). A few example table shells are provided in **Attachment 12**.

Although it is not the primary purpose of the questionnaire to develop point estimates or establish trends for the YMSM student population in Broward County Public Schools, the data will allow for some examination of these. Where this is the case, descriptive statistics (percentages and confidence intervals) will be calculated to quantify the extent of experiences, attitudes, or behaviors. This was done with the baseline 2014 data, and will likely be done for the final 2017-2018 data collection as well.

In addition to analyzing data for our subpopulation of interest, YMSM, we anticipate also conducting analyses (multivariate linear regression, logistic regression, chi-square analyses, and t-tests) to look for changes in the attitudes, experiences, and testing behaviors among all students in the schools (or designated larger subgroups of students, such as all males). This is a secondary purpose of the project, but because the program is designed in a way that all students will be exposed to many program activities, it is valuable for the district to also be able to assess the impact of the programs on the broader population of students. In addition, the full set of data (from all students—not only YMSM) will be used to provide Broward County Public Schools with information that can help them learn more about their current student population and their needs and experiences related to sexual risk and protective behaviors, school climate (including aspects like bullying and school connectedness), and access to health services.

Project Time Schedule

The final data collection is planned for the 2017-2018 school year, most likely to occur between December 2017 and February 2018. The data are likely to be cleaned, analyzed, and summarized in the spring and early summer of 2018. The reporting period (which would include production of both unpublished and published reports) would likely continue beyond summer 2018.

A one year clearance is being requested.

Figure A.16-1: DASH Project Time Schedule

Activity	Time Schedule
School staff trained to proctor the questionnaire	0-4 months after OMB approval
Parental consent forms distributed	0-4 months after OMB approval
Data collection	5-8 months after OMB approval
Data processing and cleaning	6-9 months after OMB approval
Data analysis	7-10 months after OMB approval
Writing (and revising) of baseline data summaries, reports, and/or manuscripts	8-12 months after OMB approval

The CDC contractor, with the review and approval of the CDC staff and the LEA, will develop specific reports for the LEA to use for program improvement and communication with the LEA’s stakeholders. CDC will use the LEA’s assessment findings during the project period to establish key recommendations for partners on program impact, sustainability, and continued program improvement.

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

The display of the OMB expiration date is not inappropriate. All data collection instruments will display the expiration date for OMB approval of the information collection.

A. 18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

- [1] Centers for Disease Control and Prevention. (2013a). HIV among gay and bisexual men. Retrieved March 3, 2014, from http://www.cdc.gov/hiv/pdf/risk_gender_238900B_HIV_Gay_Bisexual_MSM_FS_final.pdf
- [2] Centers for Disease Control and Prevention. (2012a). Estimated HIV incidence in the United States, 2007-2010. *HIV Surveillance Supplemental Report*, 17(4).
- [3] Kann L, McManus T, Harris WA, Shanklin S, Flint KH, Hawkins J, et al. Centers for Disease Control and Prevention. (2016). Youth Risk Behavior Surveillance--United States, 2015. *MMWR Surveillance Summaries*, 65(SS-6), 1-174.
- [4] Centers for Disease Control and Prevention. (2011). Sexual identity, sex of sexual contact, and health-risk behaviors among students in grades 9-12--Youth Risk Behavior Surveillance, selected sites, United State, 2001-2009. *MMWR*, 60(SS7), 1-133.
- [5] United States Census Bureau. (2013, September 3, 2013). School enrollment: CPS October 2012--Detailed Tables. Retrieved March 7, 2014, from <http://www.census.gov/hhes/school/>
- [6] Emily O'Malley Olsen, Laura Kann, Alana Vivolo-Kantor, Steve Kinchen, Tim McManus School Violence and Bullying Among Sexual Minority High School Students, 2009–2011. *Journal of Adolescent Health* - 23 April 2014 (Article in Press DOI: 10.1016/j.jadohealth.2014.03.002)
- [7] National Prevention Council, *National Prevention Strategy*, Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General, 2011(<http://www.healthcare.gov/prevention/nphpphc/strategy/report.pdf>).
- [8] Office of Adolescent Health. Teen Pregnancy Prevention Initiative. Available at <http://www.hhs.gov/ash/oah/oah-initiatives/tpp/index.html>. Accessed October 22, 2012.
- [9] Centers for Disease Control and Prevention. Establishing a Holistic Framework to Reduce Inequities in HIV, Viral Hepatitis, STDs, and Tuberculosis in the United States. Atlanta (GA): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; October 2010 (www.healthypeople.gov/hp2020/advisory/phaseI/glossary.htm and www.cdc.gov/socialdeterminants/docs/SDH-White-Paper-2010.pdf).
- [10] Centers for Disease Control and Prevention. Winnable Battles. Available at <http://www.cdc.gov/winnablebattles>. Accessed October 22, 2012.