

Generic Clearance

“Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth”

OMB #0920-1235
Expiration: 06/30/2019

Extension

Supporting Statement Part A

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Supported by:

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

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List of Attachments

Attachment	Document Description
1	Public Health Service Act Legislation
2	60 Day FRN
3	Sample Instrument: Youth Questionnaire
4	Sample Instrument: Youth Pre/Post Questionnaire
5	Sample Instrument: Youth Focus Group Guide
6	Sample Instrument: Parent/Caregiver Survey
7	Sample Instrument: Parent/Caregiver Interview/Focus Group Guide
8	Example Student Survey Items
9	Example Passive Parental Consent Form
10	Example Active Parental Consent Form

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10	Example Active Parental Consent Form

11	Example Youth Verbal Assent Language
12	Example Adult Consent Form

Goal: To conduct qualitative and quantitative data collection from adolescents (ages 11-19) and their parents/caregivers for the purpose of needs assessment and program refinement for programs and services designed to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among middle and high school aged adolescents.

Intended use of resulting data: The data will be used to improve program and service practices and to adapt existing programs to reduce sexual risk behaviors and adverse health outcomes among adolescents. The program and/or services to be refined with information from the collection will be clearly identified in any ICRs under this generic clearance, and data elements will be cross-walked to the aspects of the program that the project team is seeking to improve.

Methods: Methods will include quantitative data collection through paper, telephone, and web-based questionnaires; and qualitative interviewing including in-depth interviews and focus groups.

Subpopulation to be studied: Priority populations for this generic clearance ICR are:

- Adolescents (11-19 years old) of middle and high school age who are participating in, or can inform, interventions to decrease sexual risk behaviors and adverse health outcomes.
- Parents/caregivers of adolescents who are, or may be included in, programs and services to reduce adolescent sexual risk behaviors and decrease adverse health outcomes

Data analysis: Individual data collections will vary in their analytic methods and proposed analysis plans will be submitted for each individual data collection activity.

Section A: Justification for Information Collection

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), Division of Adolescent and School Health (DASH) requests a 3-year approval for an extension of the generic information collection package entitled, “Assessments to Inform Program Refinement for HIV, other STD Prevention, and Pregnancy Prevention among Middle and High-School Aged Youth,” that supports collection of quantitative and qualitative information from adolescents (ages 11-19) and their parents/caregivers for the purpose of needs assessment and program refinement for programs and services designed to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among middle and high school aged adolescents.

Background

NCHHSTP conducts behavioral and health service assessments and research projects as part of its response to the domestic HIV/AIDS epidemic, STD prevention, TB elimination and viral hepatitis control with national, state, and local partners. Adolescents are a population with specific developmental,¹ health and social,² and resource needs.³ Their health risk factors and access to health care³ are addressed as a primary mission by the Division of Adolescent and School Health (DASH), and adolescents are a population of interest for several other NCHHSTP divisions. The assessment and research conducted by NCHHSTP is one pillar upon which recommendations and guidelines are revised and updated. Recommendations and guidelines for adolescent sexual risk reduction require that foundation of scientific evidence.⁴ Assessment of programmatic practices for adolescents helps improve programs through better identification of strategies relevant to adolescents as a population as well as specific sub-groups of adolescents at highest risk for HIV and other STDs so that programs can be better tailored specifically for them.⁵

DASH has awarded funds to implement PS18-1807: *Promoting Adolescent Health through School-Based HIV Prevention* in order to build the capacity of local education agencies (LEAs) and support the efforts of national, non-governmental organizations (NGOs) to help school districts and schools develop and implement effective and sustainable adolescent-focused program activities. Under this cooperative agreement, funded partners will be selected to participate in mixed-methods assessments to better understand program delivery and the strengths and weaknesses of key program strategies. Data collection among adolescents and their parents/caregivers who are served by programs prevent HIV and other STDs among youth is critical to understand the context, types, and promising strategies of those programs and services. Findings from studies of such programs directly inform CDC recommendations for funded partners as well as school districts and other youth serving organizations across the country. As promising strategies are identified, CDC can encourage uptake of these activities by its other funded partners, and can encourage partners to move away from strategies that appear to less

feasible or less acceptable to the intended audiences. Such assessments allow for better program design and refinement.

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 information 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.⁶
- The National HIV/AIDS Strategy for the United States provides a plan of action across the U.S. for preventing the spread of HIV, increasing access and use of HIV treatment services, and the overall reduction of HIV/AIDS disparities.⁷
- 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.⁵
- *CDC Winnable Battles*, including prevention of HIV infection and teen pregnancy prevention, have been chosen by CDC based on the magnitude of the health problems and the ability to make significant progress in improving outcomes. Many programs and services for adolescents focus on integrated approaches to reduce sexual risk behaviors that result in sexually transmitted diseases and pregnancies. These are public health priorities with large-scale impact on health with known, effective strategies to address them.⁸

A.2 Purpose and Use of Information Collection

This extension is to request a three-year approval period. Our funding has been changed from the original submission under cooperative agreement PS13-1308 to now reflect assessments under cooperative agreement PS18-1807.

The original Generic ICR was used for the approval of data collection for one assessment in the year that it was in place. This data collection, a set of focus groups with students from District of Columbia Public Schools (DCPS), allowed us to better understand the use of CDC-funded activities designed to help DCPS students connect to key sexual health services. These data were collected in Fall 2018 and are currently being analyzed to help inform program improvement. As expected, the existence of the Generic ICR was critical to our ability to collect data in a timely manner and within the necessary windows of the school district's academic calendar. We expect this to facilitate our ability to quickly translate results into recommendations for program improvement. We believe that the extension of the Generic ICR

with a 3-year approval period will allow us the continued benefit of being able to collect program assessment data in a timely manner and should facilitate efficient translation of key assessment findings into program improvement recommendations.

Data gathered from questionnaires can be quantitatively analyzed to allow CDC, funded state and local education and health agencies, national non-governmental agencies, CBOs, and healthcare providers to assess needs and refine program activities/services to reduce adolescents' risk of HIV and other STD transmission, including activities conducted under PS18-1807. These data will allow agencies and partners to improve the quality of their programs and services to prevent HIV, other STDs, and pregnancy among adolescents of middle and high school age.

CDC will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collection is voluntary;
- The collection consists of qualitative and/or quantitative data collections through electronic, telephone, or paper-based questionnaires, interviews, and/or focus groups;
- The collection is low burden for respondents (based on considerations of total burden hours, total number of respondents, or burden hours per respondent) and are low cost for both the respondents and the Federal Government;
- The collection includes participants who are middle- or high-school age adolescents and/or their parents/caregivers (i.e., program beneficiaries);
- The collection focuses on program processes, participant experiences, or proximal indicators of, or precursors to, HIV/STD or pregnancy outcomes [e.g., sexual risk or protective behaviors and related risk or protective factors (such as substance use, school environment, parental engagement)] rather than the long-term health outcomes themselves; and
- The collection is for the purpose of needs assessment and program refinement for HIV, STD, and/or pregnancy prevention programs for middle- or high-school age adolescents.
- The program and/or services to be informed or refined with information from the collection will be clearly identified, and data elements will be cross-walked to the aspects of the program that the project team is seeking to inform or refine.

If these conditions are not met, CDC will submit an information collection request to OMB for approval through the normal PRA process.

Quantitative data collection will allow CDC to assess program and service activities to prevent HIV, other STDs, and pregnancy among adolescents, and to generate recommendations to better reach and serve them. The quantitative data collection may also inform how to best design or adapt programs or services to better meet the needs of adolescent beneficiaries. Data will be provided to participating agencies and organizations and will be used to assess the processes and strategies of programs and services for adolescents over time, and in a timely fashion that allows on-going program improvements.

Qualitative data provide valuable information about the context of adolescents' and parents' school, social, familial, and community environments, and adolescent and parent perceptions of programs and services. Further, such data collection can assess the feasibility and acceptability of programs and services among those who receive them. Such data can allow for refinement of programs and services for given communities and populations of adolescents. These data will be shared with participating agencies and organizations, and CDC will collaborate with them for program and service improvement. Such data also provides information about strengths and weaknesses of programmatic activities and services that take into account contextual factors and individual experiences.

Participants in data collection include:

- Adolescents (11-19 years old) of middle and high school age who are participating in, or can inform, interventions to prevent HIV, other STDs, and pregnancy; and
- Parents and/or caregivers of adolescents of middle and high school age. For the purposes of this generic package, parents/caregivers include the adult primary caregiver(s) for a child's basic needs (e.g., food, shelter, and safety). This includes biological parents; other biological relatives such as grandparents, aunts, uncles, or siblings; and non-biological parents such as adoptive, foster, or stepparents.

The participants for this data collection are considered to be the “beneficiaries” of the types of programs that are funded by CDC/DASH. Typically, CDC/DASH programs are intended to have direct impact on proximal indicators such as sexual health-related knowledge, attitudes, perceptions, and behaviors. Furthermore, CDC/DASH currently recommends its funded partners use parent engagement as a strategy for improving sexual health outcomes among youth, and therefore, it is critical to also be able to collect data from parents who may themselves be receiving programs, materials, or services intended to have a cascading reach to their children.

The types of information collection activities included in this generic package are:

- 1) Quantitative data collection conducted in-person or remotely through electronic (via computers, tablets, other mobile devices, etc.), telephone, or paper questionnaires to gather information about programmatic and service activities related to sexual risk reduction or adverse health outcomes among adolescents of middle- and high-school age. Data collection for adolescents includes questions relating to demographic and social characteristics, including those that may be linked to increased HIV and STD risk; experiences with programs and services to reduce the risk of HIV and other STD transmission and adolescents' knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels. Data collected from parents may reflect demographic characteristics of the parents or their adolescents; parents'

- perceptions about programs and services provided to adolescents; parents' knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and parents' parenting knowledge, attitudes, behaviors, and skills.
- 2) Qualitative data collection conducted in-person or remotely through electronic (via computers, tablets, other mobile devices, etc.), telephone, or paper means to gather information about programmatic and service activities related to sexual risk reduction or prevention of adverse health outcomes among adolescents of middle- and high-school age. Qualitative data collection may involve focus groups and/or in-depth individual or group interviews. Questions for adolescents will be related to experiences of programs and services to reduce the risk of HIV and other STD transmission, and knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on individual, interpersonal, and community levels. Data collected from parents may reflect their perceptions about programs and services provided to adolescents; their knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and their parenting knowledge, attitudes, behaviors, and skills.

Attachments 3-7 provide sample instruments (both quantitative and qualitative) with a sample of questions reflecting the type that might be used by studies included in this request. Attachments 3 and 5 include are sample instruments from projects with OMB approval under previous ICRs. Attachment 8 includes a broader set of example questions pulled from studies found in the literature.

As previously stated, data collection instruments used with adolescents will include questions on experiences with programs and services to reduce the risk of HIV and other STD transmission, and knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels. For parents and caregivers, data collection instruments will include questions on parents'/caregivers' (1) perceptions about programs and services provided to adolescents; (2) knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and (3) parenting knowledge, attitudes, behaviors, and skills.

Because this request includes a wide range of possible data collection instruments, specific requests will include items of information to be collected and copies of data collection instruments. It is expected that all data collection instruments will be pilot-tested, and will be culturally, developmentally, and age appropriate for the adolescent populations included. Similarly, parent data collection instruments will be pilot-tested, and the data collection instruments will reflect the culture, developmental stage, and age of the parents' adolescent children.

A.3 Use of Improved Information Technology and Burden Reduction

When appropriate and feasible, data collection may be conducted using the most current modes of questionnaire data collection, including CAPI/CASI, ACASI, web-based survey, mobile device-based data collection, or other modes. Such methods of data collection reduce burden on participants through use of automated question skips and filters that reduce the number of questions participants must answer. Although these technologies will be used by many of the individual projects in this data collection, the nature of many of these proposed activities may require direct interaction between participants and project staff, particularly in the case of qualitative interviewing and focus groups. When possible and appropriate, qualitative data collection methods such as interview and focus groups may be conducted via electronic means such as phones or video messaging (i.e., Skype, FaceTime, etc.) to reduce the travel and scheduling burdens on participants.

A.4 Efforts to Identify Duplication and Use of Similar Information

CDC has one generic information collection (IC) that is related to the current collection. “Formative Research and Tool Development” (OMB Control # 0920-0840, expiration 01/31/2019) is designed for measurement testing and tool development for HIV, STD, tuberculosis, and Hepatitis prevention and formative qualitative data collection. The qualitative data collection under this new request allows for assessment of programs that are already in place. In addition, this new request allows for quantitative needs assessment, as well as assessment for the purposes of program refinement that is not covered under the existing generic IC. NCHHSTP has verified through RegInfo.gov that there are no other federal generic collections that duplicate the types of studies included in this request.

A.5 Impact of Small Businesses or Other Small Entities

Some assessment activities may involve data collections in collaboration with small businesses (e.g. medical offices) or small non-profit or governmental entities. Therefore, study and instrument development activities may also be conducted with these groups. If such activities are conducted, these businesses will be approached in the same manner as the individuals we normally recruit; we will ask the organization to identify the appropriate staff members with whom to conduct the activities.

A.6 Consequences of Collecting the Information Less Frequently

The amount of data collection would vary under the requests made under this package. Some data collection requests would involve a one-time collection of data. Other requests may involve multiple data collections. Such data collections are intended to provide timely information to inform quality improvement for programs and practices. Requests for multiple data collections may allow for assessing programs in an ongoing way to better understand

whether resulting program refinements were implemented as planned.

In requests for multiple data collections, there could be a number of consequences to collecting the data less frequently. The first data collection is essential to present an accurate picture of programs and services as provided by schools and other agencies and organizations and adolescent and knowledge, attitudes, behaviors, and skills. Without this first data collection, we would lack a point of comparison for all future data collections; it allows documentation of where programs and participants are starting. Furthermore, initial baseline data collection provides critical information that adult program and service providers can use to determine the most appropriate focus of their activities and allow them to determine areas of greatest need. Final data collection allows conclusions to be drawn in terms of full program influence, attenuation of effects, need for and timing of “booster activities,” necessary program and service changes, and the feasibility, and acceptability of programs and services. As indicated in Table A 12-1, no 12-month period will require participants to respond to the same instrument more than twice.

Individual requests under this package will use the fewest number of data collections necessary to achieve project goals using sound methods and will provide information and justification for frequency of data collection.

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

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

As required by 5 CFR 1320.8(d), a 60-day Notice was published in the *Federal Register* on November 15 2018, volume 83, number 221, pages 57486-57488 (see **Attachment 2**). No public comments were received. No other agency was consulted for the development of this request.

B. A variety of agency partners are expected to be consulted for each individual data collection request under this generic IC, including agency contractors, education and public health agency staff, school staff, community –based organization staff, and adolescent health care providers.

A.9 Explanation of Any Payment or Gift to Respondents

Tokens of appreciation for data collection participation are an important tool used in

many studies. Individual data collections may request incentives for adolescents and their parents, and are expected to provide specific justification for incentives and to make clear the need for incentives given use of other methods used to increase response rates. Such other methods include strategies such as repeated requests for response; use of short questionnaires when possible; personalized questionnaires and response appeals; use of stamped return envelopes for postal questionnaires; assurances of confidentiality; use of fonts, space, and white backgrounds on questionnaires; use of pictures in e-mail response appeals; and development of rapport with participants.^{9,10,11} Use of incentives for individual data collection requests would also be approved by Institutional Review Boards (IRBs) where applicable, and are not expected to exceed a value of \$40 for adults or \$30 for youth.

For quantitative data collection, we suggest that incentives be considered for individual data collection requests as appropriate. Response rates have fallen for questionnaires as they have become relatively more common and potential participants reachable by multiple channels, including mail, phone, and electronic recruitment.¹⁰ Monetary and non-monetary incentives, and lottery incentives (where permitted by law) have been helpful in significantly increasing response rates for mail and electronic questionnaires.¹⁰ Incentives provided in advance or along with the questionnaires have been more effective in increasing response rates than lotteries or incentives provided on completion. More importantly, several studies have found that incentives have improved sample composition in terms of socio-economic status, education, and political affiliation.¹² Furthermore, research suggests that initial incentives may decrease the need for incentives in subsequent responses, and that a limited number of repeated incentives may increase participation among those who declined to take part in prior questionnaires in longitudinal studies. Small to modest incentives are useful in increasing response rates, with the advantage that such incentives are unlikely to greatly increase research costs.^{10,11, 12}

We also propose use of incentives for qualitative data collection, particularly as scheduling time for these focus groups and interviews would require a great commitment from adolescent and adult participants and will likely require interviews to take place outside of school and working hours. Additionally, parents often must take scarce discretionary time and travel to participate in qualitative data collection for data collection activities that are likely to take between an hour and an hour and a half.

Specific justification for the incentive amount and need will be clearly described in each generic sub-study request. For the purposes of this generic clearance, packages may include monetary incentives for adults, but would only include non-monetary incentives (e.g., healthy snacks, water bottle) for youth. Use of incentives will also be based on the circumstances of the data collection, including administration mode and/or timing (e.g., whether data collections occurred within or outside of the normal school day). Incentives for surveys will be limited as much as possible. Any ICR under this generic clearance will include a thorough, comprehensive justification for any kind of proposed incentives.

A.10 Protection of the Privacy and Confidentiality of Provided by Respondents

The NCHHSTP Associate Director for Science office reviewed this information collection request and determined that the Privacy Act may or may not apply to the sub collections under this generic clearance. Although none of the data collections under the approved Generic package will require identifying or potentially identifying information, in some instances, identifying information (such as name, email, or phone number) may be used for the purposes of recruiting or scheduling participants. In such instances, the collections will be covered under the Privacy Act System Notice 09-20-0136, “Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC”, which enables the Centers for Disease Control and Prevention (CDC) officials to collect information to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community. PII will be kept separate from other collected data, and will be accessible only to data collectors or interviewers. This information will be destroyed when the participant’s contribution to the project has ended. Data will be aggregated in reports and any data shared will always be limited to the level necessary to protect the confidentiality of participants. We do not expect data collections under this generic IC to need certificates of confidentiality because no personally identifiable information will be included in the stored data.

Information might be collected electronically, by telephone, or on paper (depending on the individual information collection request). Electronic means include handheld devices, computer-assisted questionnaires or self-interview, computer assisted telephone interview or questionnaires, web-based surveys, or other point of service collection devices. Web-based methods for questionnaire data collection may involve the hosting of a website. Individual collection requests submitted under this generic approval will describe any web-based material involved. Telephone data collection may be used for questionnaires, in-depth interviews, or focus groups. Paper-based interview or focus group guides are a common type of instrument used for leading qualitative data collection, and paper-based questionnaires may be used for adolescents and/or parents/caregivers in settings where electronic access is not feasible or efficient. Because this request includes a wide range of studies, specific data collection requests will include items of information to be collected and copies of data collection instruments.

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

IRB Approval

Because methods and materials may differ between individual projects, appropriate human subjects review procedures will be conducted for each project as they are developed, and will meet special protections requirements for populations such as minors. IRB determinations will be conducted for each project, and where applicable, IRB approval will be submitted with a copy of the approval documents.

Projects under this generic IC are expected to contain no personally identifiable information (PII) in the stored data sets. When possible, projects will avoid collecting PII completely. Anonymous questionnaires would contain no PII. Some data collections may require PII (such as name, address, email, or phone number) to assist in recruiting and scheduling participants, but such PII will be kept separate from other collected data, and will be accessible only to data collectors or interviewers. This information will be destroyed when the participant's contribution to the project has ended. Data will be aggregated in reports and any data shared will always be limited to the level necessary to protect the confidentiality of participants.

Individual data collection requests may include sensitive *questions* for adolescents and their parents. For adolescents, such questions may revolve around sexual risk and protective behaviors, use of sexual health services, and other health risk behaviors related to sexual risk, such as substance use, violence, or injury. Parents may be asked sensitive questions related to their understanding of their child's sexual behavior or about communication with their adolescent child about sex. Some questions may ask adolescents about behaviors that are illegal within their jurisdictions, but answers to such questions will not be stored or connected to personally identifiable information in any way. The data, as recorded and stored, will not contain sensitive information because it will not be linked to any particular individual in an identifiable way.

All adult participants will provide informed consent following procedures outlined in the approved IRB protocol of each study. Students will be asked to provide verbal or written assent in addition to already having received parental consent. It is anticipated that any school-based data collections will involve either active or passive parental consent; the type of parental consent used will depend on both the nature of the data collection and the general practice and preference of the participating school districts. In some rare instances, youth data collection may warrant a waiver of parental consent. This is most likely in settings such as health clinics where youth are legally able to consent for themselves for sexual health-related services or when working with special populations (such as sexual minority youth), for whom, disclosure of participation in a project might introduce risk. All consent/assent procedures will undergo IRB review and approval, and they will be described in detail in each generic sub-study request.

The goal of the individual data collections under this generic information request is to reduce adverse health consequences of sexual activity by youth, including HIV and STD acquisition, and pregnancy. By the very nature of this goal, sensitive questions may need to be asked of youth and their parents. Such questions generally pose no more risk to participants than mild and temporary discomfort or embarrassment. In rare cases, more general questions may prompt youth to disclose on-going sexual or physical abuse to adults, and may require legal reporting or mental health intervention.

Un-emancipated minors receive special human subject protections, including parental permission to participate in research projects as well as providing their own assent for participation. Further, data collection in schools, health care settings, and in households require

particular assurances of privacy for adolescents so that their level of participation and responses are not monitored by parents, teachers, other adults with authority over them, or their peers. IRB determinations will be conducted for each individual data collection project, and appropriate processes will be followed when sensitive questions are asked, including procedures to be followed if youth disclose on-going sexual or physical abuse. Each individual data request would provide justification for the use of sensitive questions for adolescents or their parents. They would also detail the processes used to minimize any consequences of the use of sensitive questions.

A.12 Estimates of Annualized Burden Hours and Costs

Burden hours. **Table A-12-a** provides the estimated annualized response burden for up to 15 individual data collections per year under this generic clearance at 57,584 hours. Average burden per response is based on pilot testing and timing of quantitative and qualitative instrument administration during previous studies. Response times include the time to read and respond to consent forms and to read or listen to instructions. (**Attachments 9-12** include sample informed consent forms and assent language.)

For a 1-time administration (in a 12-month period) of the youth questionnaire (sample instrument provided in **Att 3**), the total number of possible middle and high school age respondents is estimated at 20,000. This burden estimate allows for data collection from a multiple schools within a participating school district. The average burden is 50/60 of an hour, based on previous administrations of this sample questionnaire; this fits within the time restrictions often encountered in school-based data collection planned to occur within one class period. Total annualized burden for a 1-time administration of the youth questionnaire is 16,667 hours.

For 2-time (pre-post) administration (in a 12-month period) of the youth questionnaire (sample instrument provided in **Att 4**), the total number of possible middle and high school age respondents is estimated at 10,000. The average burden is 50/60 of an hour, based on previous administrations of this sample questionnaire; this fits within the time restrictions often encountered in school-based data collection planned to occur within one class period. Total annualized burden for a 2-time administration of the youth questionnaire to 10,000 participants is 16,667 hours.

For 2-time administration (in a 12-month period) of a youth interview/focus group guide (sample instrument provided in **Att 5**), the total number of possible middle and high school age respondents is estimated at 3,000. This allows for an average of 200 participants in each of the 15 data collections. The average burden is 1.5 hours, based on previous administrations of similar interviews and focus groups. Total annualized burden for a 2-time administration of a youth interview/focus group guide to 3,000 participants is 9,000 hours.

For a 2-time administration (in a 12-month period) of the parent/caregiver questionnaire (sample instrument provided in **Att 6**), the total number of possible parent/caregiver respondents

is estimated at 7,500. The average burden is 25/60 of an hour. Total annualized burden for a 2-time administration of the youth questionnaire to 7,500 participants is 6,250 hours.

For 2-time administration (in a 12-month period) of an adult interview/focus group guide (sample instrument provided in **Att 7**), the total number of possible parent/caregiver respondents is estimated at 3,000. This allows for an average of 200 participants in each of the 15 data collections. The average burden is 1.5 hours, based on previous administrations of similar interviews and focus groups. Total annualized burden for a 2-time administration of an adult interview/focus group guide to 3,000 participants is 9,000 hours.

Table A.12-1 Estimated Annualized Burden to Respondents

Respondents	Form name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Middle and High School Age Adolescents	Youth Questionnaire (Att3)	20,000	1	50/60	16,667
Middle and High School Age Adolescents	Pre/Post youth questionnaire (Att4)	10,000	2	50/60	16,667
Middle and High School Age Adolescents	Youth interview/focus group guide (Att5)	3,000	2	1.5	9,000
Parents/ caregivers of adolescents	Parent/Caregiver questionnaire (Att6)	7,500	2	25/60	6,250
Parents/ caregivers of adolescents	Parent/Caregiver interview/focus group guide (Att7)	3,000	2	1.5	9,000
Total					57,584

Annualized cost. **Table A.12-2** provides estimates of the annualized cost to respondents for the

collection of data. Because staff will likely work for a non-profit community based organization or a school-based health or wellness center, cost estimates for the value of time staff spend in responding to the questionnaire are based on Department of Labor (DOL) data from May 2014 providing national industry-specific occupational employment and wage estimates. These hourly wage estimates can be found on the DOL website (http://www.bls.gov/oes/current/naics4_999200.htm). Based on DOL data, the median hourly wage for all occupations is \$17.09; median hourly wage for teens was estimated from the median weekly earnings of 16-19 year olds, assuming a 40 hour work week at \$9.40. Total cost has been rounded up to the nearest whole dollar and are presented in Table A.12-2.

Table A.12-2 Annualized Costs to Respondents

Respondent	Form Name	Burden Hours	Average Hourly Wage Rate	Total Cost
Middle and High School Age Adolescents	Youth Questionnaire (Att3)	16,667	\$9.40	\$156,670
Middle and High School Age Adolescents	Pre/Post youth questionnaire (Att4)	16,667	\$9.40	\$156,670
Parents/ caregivers of adolescents	Youth interview/focus group guide (Att5)	9,000	\$9.40	\$84,600
Parents/ caregivers of adolescents	Parent/Caregiver questionnaire (Att6)	6,250	\$17.09	\$106,813
Middle and High School Age Adolescents	Parent/Caregiver interview/focus group guide (Att7)	9,000	\$17.09	\$153,810
Total				\$658,563

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

There will be no direct costs to the respondents or record keepers other than their time to participate in each information collection. No capital, start-up, operation, or maintenance costs

are involved.

A.14 Annualized Cost to Federal Government

Actual annualized costs to the government will vary depending on the specific needs of the individual information collection activity. Generally, each development activity will involve participation of at least one, and often two, CDC project officers at 4% time (GS-12, 13, or 14) who will be responsible for the project design, obtaining approvals, providing project oversight, and analysis and dissemination of the results. The CDC project officer will provide remote and onsite technical assistance to local areas implementing data collection. A CDC supervisor (GS-14) will provide oversight of the project at 2% time. Based on current data collection activities, contract costs were based on an average percentage of contract effort across three data collections involving adults working with adolescents in the school and community. An estimated average cost per individual activity is listed below, but detailed costs will be submitted with each individual collection request.

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	CDC supervisor labor costs for 1 employee at 2% time	\$2,680
CDC oversight of contractor and project	CDC non-supervisory employee labor costs for 2 employees, each at 4% time	\$8,626
Subtotal, Direct Costs to the Government per year		\$11,306
<i>Contractor and Other Expenses</i>		
Assistance with data collection, processing, and preliminary analysis	Labor and other direct costs for supporting data collection, processing, and analysis	\$34,932
Subtotal, Contract and Other Expenses per year		\$34,932
Total of all annualized expenses		\$46,238

A.15 Explanation for Program Changes or Adjustments

There have been no changes made to the example data collection instruments or to the types of

data collections this generic information collection request would include. There has been no increase or decrease in the annualized number of respondents or the annualized burden estimates since the initial 1 year approval.

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

Analysis Plan

Quantitative 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. Bivariate analyses will be used to assess associations and changes; linear or logistic regression will be used to examine predictors of outcomes of interest (such as successful partnerships), and multi-level data analyses will be performed as appropriate. Qualitative data analysis will be performed on notes or transcripts of interviews or focus groups to identify themes and commonalities across using inductive or grounded analysis or matrix analysis to develop reports, typologies, taxonomies, and/or frequency matrices. Individual data collections will vary in their analytic methods and proposed analysis plans will be submitted for each individual data collection activity.

Project Time Schedule

Individual data collections under this generic approval may occur once or at multiple times for purposes of follow-up assessment. Proposed timelines will be submitted for each individual data collection activity.

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. These activities comply with the requirements in 5 CFR 1320.9.

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