Understanding Decisions and Barriers about PrEP Use and Uptake Among Men Who Have Sex With Men

OMB# 0920-New
Section A: Supporting Statement

July 26, 2018

CONTACT
Deborah Gelaude, M.A.
Technical Monitor
Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention, BIRB
1600 Clifton Road, NE, Mailstop US8-5
Atlanta, GA 30333
Phone: 404-639-1905
Fax: 404-639-1950
E-mail: DGelaude@cdc.gov

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- **Goal of the study**: The goal is to understand why high risk HIV-negative men who have sex with men (MSM) who reside in Atlanta, GA; Chicago, IL., and Raleigh-Durham, NC., and are eligible to use pre-exposure prophylaxis (PrEP) to prevent HIV infection due to risk behavior, either a) refuse it when offered, b) fail to initiate after agreeing to use it, or c) are not on PrEP but eligible for PrEP per CDC guidelines (condomless anal sex within the last 3 months).
- **Intended use of the resulting data**: Inform ongoing CDC efforts to target PrEP focused HIV prevention strategies for MSM and gauge acceptability of emerging HIV prevention options, including alternative PrEP dosing and administration.
- **Methods to be used to collect data**: Qualitative semi-structured interviews (n=60) and focus groups (12 groups with 5 respondents per group; n=60) with men who either refuse PrEP or unsuccessfully initiate a PrEP regimen. A 30-minute self-administered quantitative behavioral assessment (aka survey) with all respondents (n=300).
- **Population to be studied**: Biological males who report having sex with other men, are over 18 years of age, and are HIV-negative. At least 35% and no more than 65% will be men who identify as black/African American, Hispanic/Latino or identify as another race/ethnic minority.
- **How data will be analyzed:** Qualitative content analysis of interview and focus group transcripts. Statistical analysis of quantitative behavioral assessment data.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of HIV/AIDS Prevention, (DHAP) requests OMB approval for 1 year of data collection for a research study entitled, "**Understanding Decisions and Barriers about PrEP Use and Uptake Among Men Who Have Sex With Men**" as a new information collection.

Approximately half of all diagnosed HIV infections are among other MSM.[1] The FDA-approved PrEP regimen, daily Tenofovir/emtricitabine (aka Truvada®), has shown greater than 90% efficacy in reducing HIV infections among MSM when taken in accordance with its prescribed daily schedule.[2] In 2014, CDC published voluntary clinical practice guidelines for the use of PrEP in high-risk populations[3], and began national promotion of PrEP as an effective HIV prevention strategy for MSM in accordance with HHS indicators, which call for a 500% increase in PrEP uptake by 2020.[4] However, PrEP uptake has been slow.[5] Some studies report a wide range in the percentages of MSM (28-81%) interested in PrEP.[6] In addition, other studies indicate that specific cities have very low rates of PrEP.[7] Moreover, recent survey findings have shown that less than 1 in 10 MSM on PrEP are adherent to their PrEP regimen[8]; adherence is necessary to optimize efficacy.

Age, level of educational attainment, risky sexual behavior, and perceived risk of HIV are all key influencers on attitudes towards PrEP utilization.[9] MSM who do not consider themselves at risk for HIV in particular, and those with long-term partners/spouses who are also HIV negative,

question the need for PrEP as a preventative measure.[10] Lack of access to healthcare providers may pose an additional challenge to PrEP use for people without regular care.[11]

Studies are needed to better understand the decisions men make about their HIV prevention needs. Qualitative methods will be used to explore in-depth the "Whys" and "How's" of MSM's decisions to refuse or use PrEP, and barriers and challenges to successfully undertake a PrEP medication regimen. Quantitative methods will be used to understand the HIV risk behavior context, attitudes towards PrEP, health seeking behavior, and acceptability of new modes of PrEP delivery (that differ from current recommendation of daily PrEP and that are in development or discussion) and emerging biomedical HIV prevention options.

This request is authorized by Title III – General Powers and Duties of the Public Health Service, Section 301 (241.)a. Research and investigations generally (**Attachment 1**).

2. Purpose and Use of Information Collection

The purpose of this research is to explore decisions, barriers, and facilitators about pre-exposure prophylaxis (PrEP) use (PrEP is an FDA-approved regimen of Tenofovir/emtricitabine (aka Truvada®), shown to have greater than 90% efficacy in reducing HIV infections among MSM when taken in accordance with its prescribed daily schedule among MSM: 1) who were offered PrEP but refused it; 2) who were interested in or started a PrEP regimen but did not follow through; and (3) are not on PrEP but who are eligible for PrEP per CDC guidelines (condomless anal sex within last 3 months) but are not currently on PrEP.

This study will provide insight on individual and community level PrEP-related decision-making, and identify barriers and facilitators to successful PrEP initiation and PrEP acceptability. Findings will improve programming, in line with the CDC Division of HIV/AIDS Prevention goal of high-impact prevention to reduce HIV infections in the U.S.[12] Findings will assist the CDC and frontline public health programs in identifying and designing programs and intervention approaches that encourage, support, and maintain appropriate PrEP uptake among eligible MSM and anticipate future HIV prevention needs, including anticipated changes in PrEP delivery.

We are proposing a mixed method study that includes in-person qualitative semi-structured in-depth interviews (IDIs) and focus groups, as well as a self-administered, structured behavioral assessment. All data collection will be carried out in Atlanta, GA, Raleigh-Durham, NC, and Chicago, IL with the cooperation of designated local partners, such as community based organizations (CBOs), community health clinics, health departments, and other service providers in each of the selected cities. Data collection will occur in 2 phases.

In phase 1, we will conduct 45-minute semi-structured qualitative, in-depth interviews (n=60), 12 one-hour focus groups with 5 MSM per group (n=60), and a 30-minute computer-assisted, self-administered, structured behavioral assessment via SurveyGizmo (n=120). Phase 1 respondents will be evenly divided into two groups of MSM: 1) those who were offered PrEP but refused ('PrEP refusers'), and 2) those who agreed to start PrEP but did not follow through, or who started but stopped within a week ('unsuccessful initiators'). Phase 1 respondents will

participate in one qualitative data collection activity (either an interview or a focus group) and will complete the self-administered structured behavioral assessment.

In phase 2, we will implement the 30-minute self-administered behavioral assessment with MSM who are eligible for PrEP through self-reported risk behavior ('PrEP-eligible') (n=180) but are not currently on PrEP.

Combined, phase 1 and phase 2 will result in a total of 300 respondents.

All study instruments will be pilot tested prior to implementation. Data collectors will be trained on all study procedures. All MSM will meet the same HIV risk and age eligibility requirements at screening for participation. Respondents for the qualitative phase will be asked additional eligibility questions about PrEP use. Respondents will be screened at the time of recruitment, and if enrolled, will be re-screened prior to data collection. Screening verification will identify if MSM change eligibility during the time period between enrollment and participation (up to one month).

Exhibit A2.1 Items of Information to be Collected

Variables to be explored	**Data collection tool and citation**	**Study Related Procedures**	**Target Population**
Perceptions of PrEP use, decision making, challenges, barriers and facilitators to use, new prevention options	Attachment 3d. Focus Group Moderator Guide	Small in-person groups	HIV-negative PrEP refusers/ unsuccessful uptake MSM
Eligibility reverification, Demographics; HIV knowledge; HIV risk behavior; PrEP use; health seeking behavior; future prevention options	Attachment 3e. & 3g Behavioral Assessment	Self-administered survey	HIV-negative PrEP refusers/unsuccessful uptake, PrEP eligible high risk MSM
Perceptions of PrEP use, decision making, challenges, barriers and facilitators to use, new prevention options	Attachment 3c. In-depth Interview Guide	Semi-structured in-person interviews	HIV-negative PrEP refusers/ unsuccessful uptake MSM
Eligibility criteria [HIV status, sex risk, PrEP use]	Attachment 3a. Screener	Short eligibility screener	HIV-negative MSM
Eligibility criteria [HIV status, sex risk, PrEP use]	Attachment 3b. Eligibility Verification	Short eligibility verification	HIV-negative PrEP refusers/ unsuccessful uptake MSM

Contact information: name, phone number, email	Attachment 3f. Contact Form	Contact form	HIV-negative MSM

3. Use of Improved Information Technology and Burden Reduction

Variables of interest for this project are best understood in face-to-face interviews and focus groups. Telephone interviews/focus groups or visual remote interviews/focus groups (such as via the web or Skype) are not optimal for developing the necessary rapport between interviewer/facilitator and respondent(s) for a successful qualitative interview on a sensitive or controversial topic. Body language and facial cues are critical to understand where additional probing may be needed or should stop, and telephone or web interviews limit the interviewer's ability to assess both. In addition, telephone and visually remote interviews/focus group more often lack the controls necessary to minimize ambient sounds, as well as intrusions to the interview process. Thus, we will conduct individual, semi-structured interviews and small focus groups in person. After receiving permission from respondent(s), we will audio-record the interview/focus group. Recordings will be transcribed as soon as possible after the interview/focus group. Audio-recording limits the burden on the respondent and allows the interviewer to focus on building and maintaining rapport with the respondent, as well as ensuring the completeness of responses during transcription. Focus groups will be led by a facilitator and a note-taker. The role of the note-taker is to identify the speaker (via a code or by number 1 through 5) for the purpose of differentiating responses in the transcripts, reducing the burden on the facilitator, and allowing the group discussion to flow with limited interruption. Note-takers will also observe non-verbal group dynamics. Structured behavioral assessments will be self-administered (immediately after the focus group or interview in phase 1) using SurveyGizmo on an iPad or laptop computer. This allows for privacy in responding to sensitive questions about risk behavior. Assessments will be completed in-person after the qualitative data collection or immediately after recruitment (in phase 2 only) on study iPads or laptops that are compliant with federal data security protocols.

4. Efforts to Identify Duplication and Use of Similar Information

The interviews will collect key information that the Agency believes is not captured elsewhere. The Agency believes no other survey data collection effort has been conducted or has been planned to collect similar information for these populations. CDC conducted a review of similar studies prior to the issuance of this contract, and determined that this study is collecting unique information from this population. There is very little research on PrEP decision making among MSM. Also, biomedical HIV prevention options, including PrEP, are new and rapidly emerging. Knowledge about uptake or lack thereof, community norms, etc. are not available. Therefore, our evaluation requires the collection of this new primary data. There would be no reason for another Federal Agency to evaluate this.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be impacted by this study. The Contractor will partner with health departments, community based organizations (CBOs), and HIV clinics to aid in recruiting potential respondents by identifying eligible MSM and providing them with a recruitment materials.

6. Consequences of Collecting the Information Less Frequently

The present study will provide the primary qualitative and quantitative data needed to understand decisions about PrEP use among HIV-negative MSM at the greatest risk for HIV infection in the U.S. If this evaluation were not conducted, it would not be possible to identify barriers and facilitators of PrEP uptake and to use this information to strengthen PrEP uptake and prevention of HIV infection in these vulnerable populations. The length of data collection is 2-3 months and data will only be collected once.

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

This data collection effort does not involve any special circumstances.

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

A 60-day notice to solicit public comments was published in the Federal Register on 10/10/2017, Volume 82, Number 194, and Page Number 46996-46997 (**Attachment 1**). One public comment received from the New York City Department of Health and Hygiene that was support of the proposed study (Att. 2a).

In addition, Emory University's Rollins School of Public Health, the Emory University HIV Community Advisory Board, and Research Support Services, Inc., were consulted for development of this study. There were no unresolved issues associated with the consultation process. Aside from the official 60-day public comment period in the Federal Register, there were no other public contacts or opportunities for public comment on this study.

Alisu Schoua-Glusberg, Project Director Research Support Services, Inc. Address: 906 Ridge Ave. Evanston, IL 60202-1720 Phone: 847.864.5677 alisu@researchsupportservices.com	Casey Tefaye, Project Manager Research Support Services, Inc. Address: 906 Ridge Ave. Evanston, IL 60202-1720 Phone: 847.864.5677 casey@researchsupportservices.com
Paula Frew, Team Lead Emory University's Rollins School of Public Health Address: 1518 Clifton Rd, Atlanta, GA 30322 Phone: 404-712-8546 pfrew@emory.edu	Elizabeth Gall, Data Analyst IMPAQ International Address: 10420 Little Patuxent Parkway Suite 300 Columbia, MD 21044 Phone: 443-259-5216 egall@impaqint.com

Valerie Betley, Data Analyst IMPAQ International Address: 10420 Little Patuxent Parkway Suite 300 Columbia, MD 21044 Phone: 443-259-5196 vbetley@impaqint.com	

9. Explanation of any Payment or Gift to Respondents

We will provide MSM who participate with a token of appreciation to encourage their participation, and convey appreciation for contributing to this important study. Depending on the activities they participate in, the tokens will be in cash as follows:

In-depth interview and behavioral assessment = $60 token
Focus group and behavioral assessment = $75 token
Behavioral assessment only = $20 token

The minimum a respondent can receive is $20 for about 30 minutes of activity and the maximum $75 for 90 – 120 minutes of activity. Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates and the use of tokens of appreciation is expected to enhance survey response rates without biasing responses.[13,14] In addition, HIV has a stigma that other health issues do not, which makes it difficult to recruit respondents for research when compared to other diseases, (e.g. cancer, diabetes, obesity). In one study on research respondent recruitment in Hispanic/Latino communities, researchers noted that the stigma related to HIV/AIDS is a major barrier in subject recruitment for HIV/AIDS behavioral research.[15] Offering tokens of appreciation is considered necessary to recruit minorities and historically underrepresented groups in research studies. Barriers related to recruiting minorities include (1) lack of trust among minority communities towards the medical research process and research,[16] (2) a lack of competence among researchers to use culturally appropriate approaches for recruitment,[17] and (3) reluctance to participate due to inconvenience and a lack of time.[18] In a recent study of community based organizations (CBO) providing HIV prevention interventions to black/African American men who have sex with men (BMSM), study recruiters found it difficult to meet study sampling goals because many of the men were reluctant to provide their names and contact information due to concerns about being seen giving personal details to an HIV prevention program.[19] Concern with potential social labeling and HIV-related stigma also may have contributed to BMSM's hesitation. In the study cited, some agreed to participate in the evaluation because of the token of appreciation offered.[20] Additionally, a meta-analysis of 95 studies published between January 1999 and April 2005 describing methods of increasing minority persons' enrollment and retention in research studies found that remuneration enhanced retention among hard-to-reach populations.[21] Based on these scientific research studies, providing remuneration to hard-to-find racial/ethnic minority respondents is critical to achieve acceptable response rates.

Remuneration has been used in other HIV-related CDC data collection efforts such as the National HIV Behavioral Surveillance (OMB 0920-0770, exp. 3/31/2017), and the Testing Brief Messages for Black and Latino MSM Study (OMB 0920-14SY under 0920-0840, exp. 1/31/2019). Both asked questions similar to those included in the proposed research, and have a similar length of time for completing participation. In these other projects, tokens of appreciation were used to increase participation rates. Other studies have also found that tokens of appreciation improve response rates.[22]

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

The Privacy Officer for CDC/ATSDR has assessed this package for applicability of 5 U.S.C. § 552a and determined that the Privacy Act does apply to the overall information collection as PII is being collected. PII is collected to contact participants for scheduling study activities. Access to these data is restricted to specific job tasks and individuals who perform those tasks. Access to PII in study data collected for the purposes of analysis is limited to the study investigators and data manager. However, personally identifiable information (PII) will not be transmitted to the CDC or retrievable by a personal identifier.

A privacy impact assessment (PIA) was conducted to ensure the protections of the collected information (**Attachment 8**). This information collection is covered under the Privacy Act system of records notice (SORN) # 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.

The Contractor will be responsible for collecting all data for this study. To ensure that respondents' health information is protected, we will take the following measures to separate personally identifiable information (PII) from study-related data: (1) all respondents will receive unique identification codes, which will be stored separately from PII on a password protected computer and or locked file cabinet; (2) contact information collected for the purposes of recruiting (i.e., name and telephone number) will be collected and stored securely and separately from responses to screening and or interview questions; and (3) we will train researchers who play a role in data collection and analysis in proper procedures for securing project data and protecting participant confidentiality. We will inform respondents that their responses will be kept private to the extent permitted by the law. All respondents interviewed will be informed that the information collected will not be attributable directly to the respondent and will only be discussed among members of the study team. Terms of the CDC contract authorizing data collection require the Contractor to maintain the privacy of all information collected.

Access to all data that identify respondents (name, phone number, email) will be limited to study staff with a data collection role in the project. Such data will be needed only for scheduling interviews with respondents, and will not be used for analyses. Transcripts of interviews and focus groups will be stripped of identifiers and will be completed on password protected, standalone (non-networked) computers. Access to the transcript files on these computers will

require a password, and will only be allowed for study staff working on this project and with a need to access, such as data analysts. No PII will be included in the transcriptions. If the respondent divulges PII during the interview, the transcriber will convert the PII to bracketed non-PII descriptor information (i.e., [Daughter's Name]). Although transcripts will *not* contain PII, all transcripts will be encrypted. No names or identifiers will be used when transcribing the data.

In conjunction with the data policy, members of study staff are required to:

- Ensure project data are secured against improper disclosure or unauthorized use of information.
- Access information only on a need-to-know basis when necessary in the performance of assigned duties.
- Notify their supervisor, the Project Director, and the organizational Security Officer if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner.
- Report immediately to both the Project Director and the organizational Security Officer all contacts and inquiries concerning information from unauthorized staff and non-research team personnel.

The security procedures implemented by the study staff cover all aspects of data handling for hard copy and electronic data. Transcriptions (stripped of PII) will be stored on encrypted flash drives. Additional information about the security protocols for all materials and transcripts can be found in the Data Security Plan (**Attachment 7**) submitted with this document. We will investigate immediately if any item is delayed or lost. When not in use, all completed hardcopy documents will be stored in locked file cabinets or locked storage rooms. All project related documents and audio recordings will be destroyed when no longer needed for the project.

SurveyGizmo was selected as the data collection platform for the quantitative behavioral assessment because of the anti-hacking measures, firewalls, and constant security scans, the parent company completes on behalf of subscribers. SurveyGizmo automatically encrypts all survey data, and requires unique passwords to access as well as decrypt collected data. Data will be stored on SurveyGizmo servers for 24 hours prior to download. All downloaded data will be eradicated from the SurveyGizmo servers.

The NCHHSTP IT Security Information System Security Officer (ISSO) consulted on the system security described in this section. The data system for this collection resides with the contractor at an external third party data center and underwent a Privacy Impact Assessment (PIA) during the SA&A process (Enterprise Systems Catalog, IT Record ID: 2567)**.**

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

IRB

The study protocol was reviewed by Emory University's IRB on May 30, 2017 (**Attachment 5a**) and approved by the CDC IRB on July 20, 2017 (**Attachment 5b**).

Sensitive Questions

This study will collect information on sensitive behaviors related to HIV risk and prevention. We plan to ask the following questions that may be sensitive to respondents:

Potentially Sensitive Questions	**Justification**
In the past 12 months, that is since [mm/yyyy], have you had sex with a man? (Screener 1 and 2, Question S11)	Questions to determine eligibility for PrEP (per CDC guidelines)
In the past 3 months, that is since [mm/yyyy], have you had anal sex with a man without using a condom? (Screener 1 and 2, Question S12)	
I want you to think about a recent sexual experience where you did not use a condom and answer the next questions about that experience (SSI, Question 14).	In-depth interview question to explore behavioral risk factors related to risk for HIV/STDs and PrEP use/refusal.
In the past 3 months, with how many men other than your most recent primary partner did you have any anal sex? (BA, Questions SX2)	Structured response question to measure sexual risk for HIV/STD acquisition.
In the past 3 months, that is since [month and year], have you had ANY anal sex with [Response to SXP1] in which a condom was not used from start to finish? Think of the times in the past 3 months that you had anal sex with [Response to SXP1] and did not use a condom from start to finish. Were you the top (you put your penis in his butt), the bottom (he put his penis in your butt), or both? Think of the times in the past 3 months that you had anal sex with [Response to SXP1] and did not use a condom from start to finish. Were you ever drunk or buzzed on alcohol within 2 hours before or during sex? Think of the times in the past 3 months that you had anal sex with [Response to SXP1] and did not use a condom from start to finish. Did you ever use non-prescription drugs within 2 hours before or during sex?	Structured response questions to measure sexual risk factors with primary male partner and non-primary male partner for HIV/STD acquisition. Response options are: 1 Yes 0 No 77 I don't know 99 I'd prefer not to answer

How long ago was the last time you had any anal sex with [Response to SXP1]? That is, with or without a condom, and with or without ejaculation. During the most recent time you had anal sex with [Response to SXP1], were you the top (you put your penis in his butt)? This would be with or without a condom and with or without ejaculation. Was a condom used from start to finish when you were the top? During the most recent time you had anal sex with [Response to SXP1], were you the bottom (he put his penis in your butt}? This would be with or without a condom and whether or not you ejaculated. Was a condom used from start to finish when you were the bottom?	
Did you use any drug within two hours before or during the most recent time you had anal sex with [Response to SEX5]? Which drugs? (Check all that apply) Injected Methamphetamine or other amphetamine, injected (meth, speed, crystal, crank, ice); Methamphetamine or other amphetamine, smoked or snorted (meth, speed, crystal, crank, ice); Downers (Valium, Ativa, Xanax); Pain killers (Oxycontin, Percocet); Hallucinogens (LSD, mushrooms, Peyote, Mescaline); Ecstasy (E, X, MDMA) Club drugs (GHB, ketamine, special K); Marijuana (pot, weed); Poppers (amyl nitrate); PCP (angel dust, wet, wicky sticks) Synthetic marijuana (herbal incense, spice, K2); Crack, injected; Crack, smoked or snorted; Cocaine, injected; Cocaine, smoked or snorted; Heroin, injected; Heroin, smoked or snorted; Heroin and cocaine injected together (speedballs); Other	Structured response questions measuring substance using behavior related to HIV/STD risk.

Please specify which other drugs you used.	

Understanding the slight possibility of emotional response or anxiety on the part of the respondent, all study staff will be trained to provide respondents with city-specific hotlines for HIV and mental health care organizations as needed. We will inform all respondents that they may skip any question or stop participation at any time for any reason. This study has been reviewed and approved for human subject's protections (**Attachments 5a and 5b**).

12. Estimates of Annualized Burden Hours and Costs

12A. Estimated Annualized Burden Hours

Partnerships with health departments, universities, and community based organizations and HIV and STD testing sites and health clinics and agencies will be made in each recruitment site**.** Recruitment will consist of partnering agency sites distributing flyers or palm cards to potentially eligible MSM. Partnering agency staff will be trained on the study eligibility criteria for this purpose. Respondents will then be directed to contact study staff for screening. In phase 2 of the study, recruitment will be solely for the 30 minute behavioral assessment and potentially eligible men will be screened at time of recruitment by study staff at partnering agencies or at community events (such as gay Pride festivals). We anticipate screening a total of 600 respondents, at various locations, and anticipate the screening process to take 5 minutes per respondent for a total of 50 burden hours (**Attachment 3a)**. Of the 600 respondents screened, we anticipate a 50% response rate. We anticipate that recording a respondent's contact information to take 1 minute per respondent for a total of 5 burden hours for the 300 respondents (**Attachments 3f**). Respondents recruited on site at partnering agencies or community events for the behavioral assessment will be immediately enrolled if eligible and be administered the behavioral assessment post enrollment; therefore, contact information will not be collected for these individuals. For phase 1 activities, we will conduct a 1 hour focus group or a 45 minute semi-structured in depth interview plus a 30-minute behavioral assessment. The total number of burden hours is 335.

Exhibit A12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public- Adults	Attachment 3a. & 3g. Screener	600	1	5/60	50
General Public- Adults	Attachment 3f. Contact Form	300	1	1/60	5

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
General Public- Adults	Attachment 3c. In-depth Interview Guide	60	1	45/60	45
General Public - Adults	Attachment 3d. Focus Group Moderator Guide	60	1	1	60
General Public - Adults	Attachment 3b. & 3g. Eligibility verification (verification of continuing eligibility)	300	1	5/60	25
General Public- Adults	Attachment 3e. & 3g Behavioral Assessment	300	1	30/60	150
Total					**335**

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A12.B. The United States Department of Labor Statistics May, 2016 http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for the general public for the purpose of this request. This cost represents the total burden hours to respondents multiplied by the average hourly wage rate for adults ($23.86).

Exhibit A12.2. Estimated Annualized Burden Costs

Type of Respondent	Form Name	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
General Public- Adults	Attachment 3a. & 3g. Screener	50	$23.86	$1,193
General Public- Adults	Attachment 3f. Contact Form	5	$23.86	$119.3
General Public- Adults	Attachment 3c. In-depth Interview Guide	45	$23.86	$1,073.7
General Public - Adults	3d. Focus Group Moderator Guide	60	$23.86	$1,431.6

Type of Respondent	Form Name	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
General Public - Adults	Attachment 3b. & 3g. Eligibility Verification (verification of continuing eligibility)	25	$23.86	$596.5
General Public- Adults	Attachment 3e. & 3g. Behavioral Assessment	150	$23.86	$3,579.0
Total				$7993.10

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

There are no costs to respondents for participating in this survey.

14. Annualized Cost to the Government

The annualized cost to the government is $474,082.84.

Exhibit A14.1: Annualized Cost to the Government

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government	CDC, COR (GS-14 0.10 FTE)	$13,829.6
	CDC, Contracting Officer (GS-14, 0.20 FTE)	$27,659.2
	CDC, Contracting Officer (GS-13, 0.30 FTE)	$33,308.1
	CDC, Contracting Officer (GS-12, 0.20 FTE)	$15,141.0
	Subtotal, Direct Costs	**$89,937.9**
Cooperative Agreement or Contract Costs	Contract Cost: Research Support Services (RSS)	$384,144.94
	ANNUALIZED COST	**$474,082.84**

15. Explanation for Program Changes or Adjustments

This is a new information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

A final meeting to present the findings from the study will be held in person at CDC in Atlanta at least two weeks before the end of the contract. Tabulation will include descriptive characteristics of study respondents collected in the first part of the interview (e.g., demographics, city, age, and race/ethnicity). The project timeline is detailed in exhibit A16.1.

Exhibit A16.1: Project Time Schedule

Activity	Data collection to begin March 1, 2018
Data collection tools, sampling and data pans, study protocol development	2-3 months before OMB approval
Recruitment	1 month after OMB approval
Data Collection	2-3 months after OMB approval
Data analysis finalized and reports drafted	4 months after OMB approval
Final data set and final reports submitted to CDC	5 months after OMB approval

The Contractor will write (1) report for each PrEP site (n=3) describing local results from this study, and will write one (1) report describing the overall results for CDC. A final data set will also be provided. CDC will prepare results for dissemination in manuscript and presentation format at the completion of the study period.

We anticipate that multiple manuscripts will be published in peer reviewed journals, presented at national conferences, and provided on conference websites. Links to these publications will be available through the CDC website. In addition, per CDC guidelines, demographic and text data will be publically available by special use request after study completion and dissemination of findings.

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

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

REFERENCES

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