Assessing the acceptability and adoptability of HIV-1 pre-exposure prophylaxis (PrEP) technologies with and without contraceptive formulation among African American women in the southeastern United States

OMB# 0920-1091
Section A: Supporting Statement

October 1, 2019

CONTACT
Eleanor McLellan-Lemal, M.A.
Technical Monitor
Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention, EPI
1600 Clifton Road, NE, Mailstop E-45
Atlanta, GA 30333
Phone: 404-639-6147
Fax: 404-639-6127
E-mail: egm4@cdc.gov

TABLE OF CONTENTS

EXHIBITS

LIST OF ATTACHMENTS

Attachment 4	Written Informed Consent
Attachment 5	Human Subjects Centers for Disease Control Institutional Review Board Approval
Attachment 6	Data Security Plan
Attachment 7	Privacy Impact Assessment (PIA)

- **Goal of the study**: The goal is to examine the acceptability and adoptability of several promising biomedical HIV-1 prevention technologies that may or may not offer simultaneous protection against pregnancy among African American women residing in the southeastern United States.
- **Intended use of the resulting data**: Inform ongoing CDC efforts to target PrEP focused HIV prevention strategies for African American women and gauge acceptability of emerging HIV prevention options, including alternative PrEP administration. Findings will provide practical information that may be considered in future product development, in particular multipurpose technologies with HIV microbicides for women. Descriptions of participant perceptions and experiences may improve researchers' understanding of elements (social, behavioral, relationship, etc.) that may facilitate or deter African American women at risk for HIV infection to comply with study requirements, or adhere to study products in the context of clinical trials or their real world use.
- **Methods to be used to collect data**: Qualitative semi-structured interviews (n=75) with African American women will be conducted in three (3) sites: Atlanta, GA; Jackson, MS; and Baton Rouge, LA.
- **Population to be studied**: Self-identified African-American women born in the United States, who are 18 to 34 years of age, self-report to be HIV-uninfected or HIV status-unknown, were female at birth and currently identify as female, and engage in sexual relations with men.
- **How data will be analyzed:** Qualitative content analysis of interview and focus group transcripts. Statistical analysis of quantitative behavioral assessment data.

Supporting Statement

A. <u>Justification</u>

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 a research study entitled, "Assessing the acceptability and adoptability of HIV-1 pre-exposure prophylaxis (PrEP) technologies with and without contraceptive formulation among African American women in the southeastern United States" as a new information collection. This information collection request is to be conducted under the Generic clearance, *Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States* (OMB # 0920-1091, expiration 9/30/2021).

The effectiveness of biomedical intervention technologies to prevent HIV-1 infection depends on both the biological efficacy of the technology and the behavioral adherence to that technology. Research has shown that taking daily oral tenofovir disoproxil fumarate-containing pre-exposure prophylaxis against HIV-1 infection (PrEP, active ingredient tenofovir [TFV]) is an effective HIV-1 prevention tool for women; protection rates among discordant couples were 65-75%

among heterosexual men and 62% among women.[1] Uptake and use of oral PrEP among women, as well as long-term adherence, have been variable.[1,2] Multipurpose technologies (MPTs) that combine protection against multiple risks, such as unintended pregnancy, HIV-1 and other sexually transmitted infections (STIs), are believed to offer the best solution for addressing women's sexual and reproductive health needs.[3] A new generation of HIV-1 biomedical prevention technologies, including MPTs, may be more effective, easier to use (e.g., not coital dependent, do not interfere with sexual pleasure, reduce dosing frequency) and potentially provide additional health benefits.[4] This new generation of HIV-1 biomedical prevention technologies include vaginal delivery, long-acting injectables, and implantable devices. Yet, limited perceptibility, acceptability research, and clinical trials of HIV-1 PrEP technologies with and without contraceptive formulation are being conducting in the United States (US), including research focused on the most at-risk group, African American women, particularly those living in the southeastern US.

In general, feasibility research aimed at more broadly addressing the acceptability of a biomedical intervention has focused on qualities that make a product attractive, satisfactory, pleasing, or welcomed. The gap between research and practice has fostered, more recently, a rethinking about acceptability of HIV-1 biomedical prevention interventions, especially given the lack of information regarding the probability that a method will be used by a target population or within a particular setting.

Clinical trials of HIV-1 PrEP technologies with and without contraceptive formulation among women are mostly being conducted outside of the US; thus, it is critical that we have a better understanding to know if and how these products will benefit US African American women at risk. To date, limited research (perceptibility, acceptability, adoptability) has been conducted among African American women of North American ancestry (henceforward referred to as African American women) living in the southeastern US. There is a need for research that examines both of the following: 1) how well a biomedical intervention will be received (acceptability) as well as 2) the perceived extent to which new biomedical intervention might meet the needs of African American women and real-world organizational settings (adoptability).

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

Given that several innovative methods for delivering PrEP topically and systemically are being explored, input from African American women on biomedical prevention methods that they

[1] Seidman D, Carlson K, Weber S, Witt J, Kelly PJ (2016). United States family planning providers' knowledge of and attitudes towards preexposure prophylaxis for HIV prevention: a national survey. Contraception, 93(5:463-469.
[2] Sheth AN, Rolle CP, Gandhi M (2016). HIV pre-exposure prophylaxis for women. Journal of Virus Eradication, 2(3):149-155.
[3] Brady M, Manning J (2013). Lessons from reproductive health to inform multipurpose prevention technologies: don't reinvent the wheel. Antivir Res, 100 Suppl:S25-31.
[4] Thurman AR, Clark MR, Doncel GF. Multipurpose prevention technologies: biomedical tools to prevent HIV-1, HSV-2, and unintended pregnancies. Infectious Diseases in Obstetrics and Gynecology, 1-10.

believe to be the appropriate and practical option for them is critical. Thus, the aim of this qualitative study is to examine, among African American women residing in the southeastern US, the acceptability and adoptability of several promising biomedical HIV-1 prevention technologies that may or may not offer simultaneous protection against pregnancy.

This exploratory, qualitative approach will offer a unique source of in-depth information about perspectives and experiences that may influence African American women's perceptions about the acceptability and adoptability of specific HIV prevention biomedical technologies. In addition, this study will also add breadth to the limited published literature currently available. The sample will be recruited from three (3) sites from comparable metropolitan statistical areas in the southeastern US with moderate to high HIV-1 prevalence among targeted women: Atlanta, GA; Jackson, MS; and Baton Rouge, LA.

We are proposing a qualitative study that includes in-person, qualitative, semi-structured in-depth interviews (IDIs). All data collection will be carried out in Atlanta, GA; Jackson, MS; and Baton Rouge, LA. A total of 75 IDIs will be conducted (25 per site). Data collection will involve a 5-minute pre-screening in-person or telephone eligibility assessment collected via an interviewer-administered, computer-assisted personal interview (CAPI) and brief contact information will be requested from eligible women for interview scheduling purposes. After completing written informed consent process on the day of the interview, respondents will complete a 60-minute, audio-recorded IDI and a 6-minute interviewer-administered demographic and behavioral CAPI. CAPI data will be collected using Survey Gizmo. A study participation incentive of $40 in the form of cash or a gift card will be provided.

Descriptive statistics will be used to quantitatively describe the main features of the sample. Audio files will be transcribed and transcripts will be compiled into an NVivo dataset to support a qualitative text-based analysis. Descriptive statistics will also be generated in NVivo. Neither collection of biological samples nor testing of HIV-1 biomedical prevention technology will take place.

All study instruments have undergone pilot testing with nine respondents similar to those targeted for the study. The written informed consent and all information collection tools have been modified as appropriate. Institutional Review Board (IRB) approval has been obtained for these amended documents (**Attachment 5)**. Data collectors will be trained on all study procedures. **Exhibit A.2.1** identifies the information items to be collected.

Exhibit A2.1 Items of Information to Be Collected

Variables to be explored	Data collection tool and citation	Study Related Procedures	Target Population
Eligibility verification	Attachment 3a. Study Screener CAPI	In-person or telephone screening eligibility CAPI assessment	HIV-negative of HIV status unknown, African American women 18-34 years of age who have engaged in vaginal intercourse with a male in the past 12 months
Contact information: name, phone number, email	Attachment 3b. Contact Form	Contact form	African American women who meet eligibility criteria
Perceptions of PrEP use, decision making, challenges, barriers and facilitators to use, new prevention options	Attachments 3c In-depth Interview Guide Product Information Showcards	Semi-structured in-person, audio-recorded in-depth interviews	African American women who met eligibility criteria and were enrolled in the study
Eligibility verification, Demographics; HIV knowledge; HIV risk behavior; PrEP use; health seeking behavior; future prevention options	Attachment 3d. Demographic and Behavioral CAPI	Post-IDI respondent characteristics CAPI	African American women who completed an IDI

3. Use of Information Technology and Burden Reduction

Variables of interest for this project are best explored in face-to-face, semi-structured, qualitative (open-ended) in-depth interviews. Telephone interviews/focus groups or visual remote interviews (such as via the web or Skype) are not optimal for developing the necessary rapport between interviewer 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 more often lack the controls necessary to minimize ambient sounds, as well as intrusions to the interview process. Thus, we will conduct all individual, semi-structured interviews in-person. After receiving permission from respondent(s), we will audio-record the interview. Recordings will be transcribed as soon as possible after the interview. 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. A computer-assisted structured demographic and behavioral assessments will be interviewer-administered (immediately after the interview) using SurveyGizmo on an iPad or laptop computer. This allows for privacy in responding to sensitive questions about risk behavior. Assessments will be done in-person after the qualitative data collection 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 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 the contract, and determined that this study is collecting unique information from this population. Biomedical HIV prevention options, including PrEP, are new and rapidly emerging. Knowledge about uptake or lack thereof, community norms, etc. are not available. There is very little research examining attitudes of HIV biomedical prevention technologies among African American women, in particular the acceptability and adoptability of such technologies. Therefore, our evaluation requires the collection of this new primary data. Given the non-generalizable nature of our study, exclusion of foreign-born Black women, and its limited geographical scope, there could be reasons for another Federal Agency to evaluate this using a similar or different research design.

5. Impact on Small Businesses or Other Small Entities

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

6. Consequences of Collecting the Information Less Frequently

The present study will provide the primary qualitative data needed to understand acceptability and perceived adoptability of HIV biomedical prevention technologies among HIV-negative African American women 18-34 years of age at risk for HIV infection in the US. If this evaluation were not conducted, it would neither be possible to identify barriers and facilitators to the uptake of these HIV biomedical prevention technologies nor to use this information to strengthen uptake of biomedical technologies to prevent HIV infection in this 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

Public comments were solicited for the Generic clearance in the Federal Register: 60-Day on 3/13/18, Volume 83, Number 49, Page Number 10853-55.

Data collection, management, and analysis will be overseen by Research Support Services, Inc. and IMPAQ International LLC. There were no other public contacts or opportunities for consultation on this study.

Alisú Schoua-Glusberg, Project Director Research Support Services, Inc. Address: 906 Ridge Ave. Evanston, IL 60202-1720 Phone: 847.864.5677 Email: alisu@researchsupportservices.com	Casey Tesfaye, Project Manager Research Support Services, Inc. Address: 906 Ridge Ave. Evanston, IL 60202-1720 Phone: 847.864.5677 Email: casey@researchsupportservices.com
Valerie Betley, IMPAQ Project Director, Data Analyst IMPAQ International Address: 10420 Little Patuxent Parkway Suite 300 Columbia, MD 21044 Phone: 443-259-5196 Email: vbetley@impaqint.com	Bryan Gale, Data Analyst IMPAQ International Address: 10420 Little Patuxent Parkway Suite 300 Columbia, MD 21044 Phone: 443-259-5186 Email: bgale@impaqint.com

9. Explanation of Any Payment or Gift to Respondents

We will provide study respondents with an incentive to encourage their participation and convey appreciation for contributing to this important study. Incentives will be in gift cards or cash as follows:

In-depth interview (with CAPI demographic and behavioral data collection) = $40

Study participation incentives have been shown to help increase participation rates and avoid biases resulting from the omission of those who decline participation because it would take them away from other tasks, in particular those that generate income. Moreover, the provision of incentives that considers the duration of participation and the procedures involved helps to demonstrate respect and appreciation for the participant's role in the research process. Limited empirical data are available on whether payment creates undue influence, exploitation, or biased enrollment; however, concerns on attempts to control over- and under incentivizing research participants are important to address.[5,6] The provision of incentives to recruit research participants has been shown for the most part to be "innocuous" for minimal risk study such as this one.[7]

Offering incentives is considered necessary to recruit minorities and historically underrepresented groups in research studies. Known barriers related to recruiting minorities include (1) lack of trust among minority communities towards the medical research process and research,[8] (2) a lack of competence among researchers to use culturally appropriate approaches for recruitment,[9] and (3) reluctance to participate due to inconvenience and a lack of time.[10]

Given the level of involvement required of qualitative participants in articulating their beliefs, knowledge, and experiences, not providing incentives or paying them lower than what is typically offered for similar data collection has the potential for offending targeted groups and their communities. Forty (40) US dollars is a generally approved amount for OMB-approved 60-minute qualitative interviews. This amount is consistent with what is offered by similar studies. Under the Generic clearance, the Local Effectiveness Assessment Project (LEAP), Part I and Part II studies provided the study participants with a $40 for in-depth interviews. Each participant will receive $40 in the form of cash or gift cards as an incentive for her participation and any inconvenience or personal transportation costs incurred taking part in the study. No study participation incentive will be provided for completing the 5-minute eligibility assessment. A review article examining issues influencing African American participation in research highlighted the importance of researchers offering incentives given participants' potential limited access to resources, in particular transportation, child care, and health services.[11] Additionally, a meta-analysis of 95 studies published between January 1999 and April 2005 describing methods

[5] Neale J, Black L, Getty M, Hogan C, Lennon P, Lora C, McDonald R, Strang J, Tompkins C and Usher J (2017).Paying participants in addiction research: Is cash king? Journal of Substance Use, 22(5):531-533.
[6] Largent, E.A. and H.F. Lynch (2017). Paying research participants: Regulatory uncertainty, conceptual confusion, and a path forward. Yale Journal of Health Policy, Law, and Ethics, 17(1):61.
[7] Grant, R.W. and J. Sugarman (2004). Ethics in human subjects research: do incentives matter? Journal of Medicine and Philosophy, 29(6):717-738.
[8] Rendina HJ, Whitfield TH, Grov C, Starks TJ, Parsons JT (2017). Distinguishing hypothetical willingness from behavioral intentions to initiate HIV pre-exposure prophylaxis (PrEP): Findings from a large cohort of gay and bisexual men in the U.S. Soc Sci Med, 172:115-123.
[9] Goodwin, P. Y., Williams, S. W., & Dilworth-Anderson, P. (2006). The role of resources in the emotional health of African American women: Rural and urban comparisons. In R. T. Coward, L.A. Davis, C.H. Gold, H. Smiciklas-Wright, L.E. Thorndyke, & F.W. Vondracek, (Eds.). Rural women's health: Mental, behavioral, and physical issues (pp. 179 — 196). New York: Springer.
[10] Mason, S. E. (2005). Offering African Americans opportunities to participate in clinical trials research: How social workers can help. Health & Social Work, 30, 296-304.

of increasing minority persons' enrollment and retention in research studies found that remuneration enhanced retention among hard-to-reach populations.[12] Based on these scientific research studies, providing remuneration to hard-to-find racial/ethnic minority respondents is critical to achieve acceptable response rates.

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

The CDC NCHHSTP Privacy and Confidentiality Review Officer and the NCHHSTP IT Security Information System Security Officer (ISSO), have assessed this package for applicability of 5 U.S.C. § 552a, and determined that the Privacy Act does apply to the overall information collection. This information collection is covered under the Privacy Act system of records notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC", which enables 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.

Personally identifiable information (PII) is being collected on the brief contact form (**Attachment 3b**). The nature of this study is to understand the possible acceptability of three HIV prevention biomedical intervention technologies (injection, implant, and intravaginal ring) and the perceived adoptability of such new biomedical intervention for African American women in real-world organizational settings. To ensure that respondents' health information is protected, we will take the following measures to separate 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 (i.e., name and telephone number) will be collected only from women who meet the study eligibility criteria via paper and pencil methods, and stored separately from responses to the CAPI questionnaires and in-depth interview audio files and prepared transcripts; and (3) we will train researchers who play a role in data collection and analysis in proper procedures for securing project data.

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 evaluation 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 (or such keys that link de-identified codes to personal information) will be limited to research staff with a data collection or analysis role in the project. Such data will be needed only for scheduling interviews with respondents, and will not be used for analyses. Transcripts will be completed on password-protected, standalone (non-networked) computers. Access to the transcript files on these computers will require a password, and will

[11] Huang H-h, Coker AD (2010). Examining issues affecting African American participation in research studies. Journal of Black Studies, 40(4):619-636.

[12] Yancey, A. K., Ortega, A. N., & Kumanyika, S. K. (2006). Effective recruitment and retention of minority research participants. Annu. Rev. Public Health, 27, 1-28.

only be allowed for staff working on this project and with a need to access. No PII will be included in the transcripts. 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 also be encrypted. No names or identifiers will be used when transcribing the data.

In conjunction with the data policy, members of contractor project 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 project 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 6**) 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 CDC Privacy Officer 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. CDC has completed a Privacy Impact Assessment of the data system used by the study contractor team (**Attachment 7**).

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

IRB

IRB approval was issued on May 24, 2019 and amendment with slight wording changes to informed consent and information collection tools based on pilot testing with nine respondents was approved on September 3, 2019 (**Attachment 5**).

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**
What sex were you assigned at birth, on your original birth certificate? (Screener Question S5)	Structured response eligibility question to determine that the potential participant was female at birth and currently identifies as female. Response options are: [ ] Female [1] [ ] Male [0] [ineligible] [ ] REFUSE TO ANSWER [8]
Do you currently describe yourself as male, female, or transgender? (Screener Question S6)	Structured response eligibility that the potential participant currently identifies as female. Response options are: [ ] Female [1] [ ] Male [2] [ ] Transgender [3] [ ] None of these [4] [ ] REFUSE TO ANSWER [8]
Just to confirm, you were assigned <Answer to S5> at birth and now describe as <Answer to S6>. Is this correct? (Screener Question S7)	Structured response eligibility that the potential participant was female at birth and currently identifies as female. Response options are: [ ] No [0] [ ] Yes [1] [ ] Don't know [7] [ ] REFUSE TO ANSWER
During the past 12 months, were tested for HIV? (Screener Question S10 and S10a *if response is yes*)	Structured response eligibility question to determine that the potential participant is HIV-negative or HIV status unknown. Response options are: [ ] No [0] [ ] Yes [1] [ ] REFUSE TO ANSWER *If yes*: What was your most recent HIV test

Potentially Sensitive Questions	Justification
	result? [ ] HIV Negative [1] [ ] HIV Positive [2] [ineligible] [ ] Never tested [3] [ ] Tested but didn't receive results [4] [ ] Indeterminate [5] [ ] REFUSE TO ANSWER [8]
During the past 12 months, that is since <interview date -12 months>, have you had vaginal or anal sex with a man at least 1 time without using a condom? [READ IF NEEDED: When we ask you about vaginal sex, we mean that a man puts his penis in a woman's vagina. Some women refer to this as regular sex. When we ask you about anal sex, we mean that a man puts his penis in a woman's butthole.] (Screener Question S11)	Structured response eligibility question to determine that the potential participant is engaged in condomless vaginal or anal sex in the last 12 months. Response options are: [ ] No [0] [ ] Yes [1] [ ] Don't know [7] [ ] REFUSE TO ANSWER [8]
Describe sexual health services that you have used? (IDI Question 6)	In-depth interview question to explore the types of sexual health services used among the target sample.
What steps, if any, do you take to protect yourself against sexual diseases or STDs? (IDI Question 7)	In-depth interview question to explore behavioral risk factors related to risk for HIV/STDs and PrEP biomedical intervention technology use/refusal.
What steps, if any, do you take to protect yourself against HIV? (IDI Question 10)	In-depth interview question to explore behavioral risk factors related to risk for HIV/STDs and PrEP biomedical intervention technology use/refusal.
Now, I am going to ask you about infections that can get from having sex. These are referred to as STDs (sexually transmitted diseases).In the past 12 months, were you diagnosed with an STI? (Post IDI Demographic and Behavioral Questionnaire, Question BC9)	Structured response question to measure sexual risk behavior. Response options are: [ ] No [0] [ ] Yes [1] [ ] REFUSE TO ANSWER [8]
Now, I am going to ask you some questions about your sexual experiences. Did you have more than one male sexual partner in the past 12 months? (Post IDI Demographic and Behavioral Questionnaire, Question BC11)	Structured response question to measure sexual risk behavior. Response options are: [ ] No [0] [ ] Yes [1] [ ] REFUSE TO ANSWER [8]
Did you have vaginal sex in the past 12 months? *If necessary,* By vaginal sex, we mean when a man puts his penis inside a woman's vagina. (Post IDI Demographic and Behavioral Questionnaire, Question BC12)	Structured response question to measure sexual risk behavior. Response options are: [ ] No [0] [ ] Yes [1] [ ] REFUSE TO ANSWER [8]

Potentially Sensitive Questions	Justification
Did you have anal sex in the past 12 months? *If necessary*, By anal sex, we mean when a man puts his penis inside a woman's butt. (Post IDI Demographic and Behavioral Questionnaire, Question BC13)	Structured response question to measure sexual risk behavior. Response options are: [ ] No [0] [ ] Yes [1] [ ] REFUSE TO ANSWER [8]

Understanding the slight possibility of emotional response or anxiety on the part of the respondent, all 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.

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**.** Partnering agencies at each site will assist our recruiting efforts by distributing flyers (**Attachment 2: Recruitment Flyer)** to potentially eligible clients at agency points of contact, by posting flyers for agency clients to see, and by sharing flyers through social media. Partnering agencies will be asked to identify potential venues and settings frequented by African American women 18-34 years of age. Study staff will assess venues and settings to select those most appropriate for reaching our target population, and request permission to post flyers and undertake active recruitment, as appropriate. We will also encourage snowball sampling by generally encouraging a non-incentive-based recruitment by word-of-mouth. Recruitment in venues or settings (e.g., beauty salons, laundromats, parks, community centers) and word-of-mouth referrals may also be used. Respondents will be directed to contact study staff for telephone or in-person screening.

Overall, we anticipate screening a total of 150 respondents (~50 per site, at various locations, and anticipate the screening process to take 5 minutes per respondent for a total of 12.5 burden hours (**Attachment 3a: CAPI Eligibility Screening Assessment)**. Of the 150 respondents screened, we anticipate a 60% will meet the study eligibility criteria. We anticipate that recording a respondent's contact information to take 2 minute per respondent for a total of 3 burden hours for about 90 eligible respondents (**Attachment 3b: Contact Form**). We anticipate that a total of 75 respondents (25 per site) will take part in the study data collection. After completing written informed-consent (**Attachment 4: In-depth Interview Informed Consent)**, study participation will consist of a 60-minute semi-structured in-depth interview (**Attachment 3c: IDI Guide** and **Product Information Showcards),** and a 6-minute demographic and behavioral computer-assisted personal interview (**Attachment 3d: CAPI Demographic and Behavioral Questionnaire)**. The total number of burden hours is 98 as shown in **Exhibit A12.1**.

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.Screening CAPI	150	1	5/60	12.5
General Public-Adults	Attachment 3b. Contact Form	90	1	2/60	3
General Public-Adults	Attachment 3c. In-depth Interview Guide and Product Information Showcards	75	1	1	75
General Public-Adults	Attachment 3d. Demographic and Behavioral CAPI	75	1	6/60	7.5
Total					**98**

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in **Exhibit A12.2**. 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 (mean) hourly wage rate for adults ($23.24).

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.CAPI Eligibility Screening Assessment	12.5	$23.24	$290.50
General Public-Adults	Attachment 3b. Contact Form	3	$23.24	$69.72

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public - Adults	Attachment 3c. In-depth Interview Guide and. Product Information Showcards	75	$23.24	$1,743.00
General Public - Adults	Attachment 3d. CAPI Demographic and Behavioral Questionnaire	7.5	$23.24	$174.30
Total				**$2,556.40**

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

There are no other costs to respondents for participating in this interview.

14. Annualized Cost to the Government

As shown in **Exhibit A14.1**, the annualized cost to the government is $533,600.89.

Exhibit A14.2: 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)	$13,829.60
	CDC, Technical Monitor (GS-13, 0.20 FTE)	$15,141.00
	CDC, Contracting Officer (GS-14, 0.20 FTE)	$27,659.20
	CDC, Contracting Officer (GS-13, 0.30 FTE)	$33,308.10
	CDC, Contracting Officer (GS-12, 0.20 FTE)	$15,141.00
	Subtotal, Direct Costs	**$105,078.90**
Cooperative Agreement or Contract Costs	Contract Cost: Research Support Services (RSS)	$428,521.99
	ANNUALIZED COST	**$533,600.89**

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**. Data collection is estimated to begin September 1, 2019.

Exhibit A16.3: Project Time Schedule

Activity	Timeline
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 describing the key results from this study. The report will include non-generalizable, descriptive comparisons in key findings across the three sites 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

The expiration date and OMB control number will appear on the first page of the instrument (top-right corner). The PRA disclosure statement will be included at the bottom of the first page of the instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.