

**Request for Sub-collection under the Generic ICR:
Formative Research and Tool Development
OMB #0920-0840 Expires 01/31/2019**

**“Formative Tools for Addressing HIV Prevention
Preferences among Adolescent Men Who Have Sex with Men
(AMSM)”**

Supporting Statement Part A

October 16 2017

Supported by:

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

Richard Dunville, MPH
CDC/OID/NCHHSTP, Research Officer
(404) 769-3290
dgo2@cdc.gov

Table of Contents

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

EXHIBITS

- Exhibit A2.1:.....Items of Information to be Collected
Exhibit A12.1:.....Estimated Annual Burden Hours
Exhibit A12.2:.....Estimated Annual Burden Costs
Exhibit A14.1:.....Annual Cost to the Government
Exhibit A16.1:.....Project Time Schedule
-

List of Attachments

Attachment Number	Document Description
1	Data Collection Forms
1a	Survey Screener
1b	Screener Diagram
1c	Web Survey - Word File
1d	Web Screen Shots - AMSM
1e	Web Screen Shots - Trans
2	Consent and Assent Landing Page
3	Human Subjects Approvals
3a	NORC IRB Approval Letter
3b	NORC IRB Approval Amendment 1
3c	NORC IRB Approval Amendment 2
3d	NORC IRB Renewal Letter
3e	NORC IRB Approval Amendment 3
3f	CDC Project Determination
3g	Sensitive Questions
4	Web Recruitment Ads
4a	Web Recruitment Ads
4b	Snapchat Recruitment Ads
4c	Example Snapchat Video
5	Data Security Plan

- The purpose of the “Formative Tools for Addressing HIV Prevention Preferences Among Adolescent Men Who Have Sex with Men (AMSM)” pilot is to evaluate: 1) our ability to reach a viable number of AMSM and Trans youth, particularly Blacks and Latinos and youth 13-17 years old; 2) potential to recruit youth in areas disproportionately affected by HIV/AIDS; 3) ability to address the role of parental permission in the venues as dictated by state and local laws and relevant policies, including corporate policies; 4) potential for harm to participants (i.e., being identified as gay or bisexual to others); 5) potential for respondent bias; 6) calculate an average cost per respondent; 7) knowledge, attitudes, behaviors regarding: acceptability of HIV risk/prevention including risk behaviors, condoms, as well as biomedical interventions such as PrEP, PEP, etc.; 8) access, exposure, attitudes toward: sex education, HIV prevention services in school and community settings.
- The intended use of this data is to inform the design of a future surveys of AMSM and Trans youth and the development of tools and guidance to effect changes in education, health care, and youth services that can reduce AMSM’s vulnerability to HIV infection.
- The method that will be used for data collection is a web-based survey including fundamental aspects of sexual identity, behavior, protective factors, and acceptability of HIV prevention strategies using technology-based strategies for survey recruitment and completion.
- The subpopulation to be studied are up to 3500 individuals, including 1750 AMSM ages 13-18 and 1750 transgender youth ages 13-24.
- How data will be analyzed: Statistical analysis of quantitative demographic survey data and operational data.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Division of Adolescent and School Health (DASH) is requesting approval for a data collection entitled, “Formative Tools for Addressing HIV Prevention Preferences Among Adolescent Men Who Have Sex with Men (AMSM)” under the OMB

approved Generic Clearance, “Formative Research and Tool Development” (OMB #0920-0840 exp. 1/31/2019). Piloting this survey will add to CDC’s knowledge of alternative instrument and data collection design to inform future research studies. Survey data will also be used to inform the development of tools and resources for practitioners and community leaders who serve AMSM and Transgender youth.

Adolescent MSM

Disparities in new HIV infection rates between black and white men who have sex with men (MSM) (ages 13 and above) are largely explained by disparities in the HIV care continuum, pointing to the need for improvement in HIV testing among black MSM, and linkage to and retention in care for those testing positive¹. This may particularly impact HIV disparities among adolescent men who have sex with men (AMSM) where a large portion of new HIV infections are concentrated, and racial disparities are especially pronounced. Although new HIV infections were relatively stable between 2008 and 2011, they increased 26% among young MSM aged 13–24 years old, and approximately 93% of all new HIV infections in 2011 among 13-19 year old males were from male-to-male sexual contact. A disproportionate number of these new infections are among black and Latino AMSM. In 2011 an estimated 58% of MSM aged 13–24 years with newly diagnosed HIV infection were Black and 20% were Latino. Young black MSM experienced the largest increase in new HIV infection of all racial/ethnic groups –from 3,762 diagnoses in 2008 to 4,619 diagnoses in 2011². Critically, a recent longitudinal study among MSM 18 years and older in Atlanta found black MSM were more likely to be diagnosed with HIV and other sexually transmitted infections as compared to white MSM. The study also found a significantly higher rate of HIV infection among those 18-24 years old, suggesting the need to target prevention efforts to black MSM younger than 18 years³.

Transgender Youth

A disproportionate share of transgender women (27.7%)⁴ and transgender men (11.8%)⁵ are living with HIV infection compared to the general adult population (<1%).⁶ These rates are even

¹ Rosenberg, The Lancet, Published online November 18, 2014 [http://dx.doi.org/10.1016/S2352-3018\(14\)70030-X](http://dx.doi.org/10.1016/S2352-3018(14)70030-X)

² CDC, HIV and Young Men Who Have Sex with Men; Retrieved December 1, 2014 from http://www.cdc.gov/healthyyouth/sexualbehaviors/pdf/hiv_factsheet_YMSM.pdf

³ Rosenberg et al., Race and Age Disparities in HIV Incidence and Prevalence Among MSM in Atlanta, GA; presented at CROI 2014

⁴ Herbst JH, Jacobs ED, Finlayson TJ, McKleroy VS, Neumann MS, Crepaz N. (2008, January). Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. *AIDS Behavior*.

⁵ Ibid.

⁶ Centers for Disease Control and Prevention. (2015, March 16). HIV/AIDS: Basic Statistics. *CDC*.

higher among transgender women of color.⁷ There are a number of possible reasons for disproportionate rates of infection among transgender women: sex with cisgender male partners^{8,9, 10, 11}; history of homelessness, incarceration, forced sex, survival sex, and unemployment^{12, 13, 14, 15}; high burden of negative mental health outcomes in transgender adolescent patients¹⁶; syndemic factors including low self-esteem, polysubstance use, victimization related to transgender identity, and intimate partner violence. The conflation of transgender women with MSM in HIV prevention ignores the unique vulnerabilities and gender identities of transwomen.¹⁷ This conflation also highlights the barriers to PrEP uptake, including a lack of trans-inclusive PrEP marketing, prioritization of hormone use, and medical mistrust due to transphobia. There is also a lack of evidence-based interventions to address HIV prevention with transgender youth.¹⁸ Culturally competent interventions must be developed with the needs of transgender youth in mind.

Though the increased risk for HIV infection among AMSM and transgender populations is well documented, particularly for Black and Latino youth, there is still a significant gap in research that can inform the development of culturally specific, evidence-based tools to engage AMSM and transgender youth in HIV-prevention behaviors. Review of existing research and interventions for AMSM (ages vary by study, but range from 15-30 years) concludes that little information is available about the

⁷ amfAR: The Foundation for AIDS Research (2014). Trans population and HIV: Time to end the neglect. Retrieved from: <http://www.amfar.org/issue-brief-trans-populations-and-hiv-time-to-end-the-neglect/>. As cited in Marquez S, Cahill S (2015, December 1). *Transgender women and pre-exposure prophylaxis for HIV prevention: What we know and what we still need to know*. Boston: National Center for Innovation in HIV Care, the Fenway Institute.

⁸ Operario D, Nemoto T, Iwamoto M, Moore T. (2011, December). Risk for HIV and unprotected sexual behavior in male primary partners of transgender women. *Archive of Sexual Behavior*.

⁹ Nemoto T, Bodeker B, Iwamoto M, Sakata M. (2014, April). Practices of receptive and insertive anal sex among transgender women in relation to partner types, sociocultural factors, and background variables. *AIDS Care*.

¹⁰ Operario D, Nemoto T, Iwamoto M, Moore T. (2011, April). Unprotected sexual behavior and HIV risk in the context of primary partnerships for transgender women. *AIDS Behavior*.

¹¹ Sevelius JM, Keatley J, Salma N, Arnold E. (2016, March 10). 'I am not a man': Trans-specific barriers and facilitators to acceptability among transgender women. *Global Public Health*.

¹² Nadal KL, Davidoff KC, Fujii-Doe W. (2014). Transgender women and the sex work industry: roots in systemic, institutional, and interpersonal discrimination. *Journal of Trauma and Dissociation*.

¹³ Operario D, Soma T, Underhill K. (2008). Sex work and HIV status among transgender women: systematic review and meta-analysis. *J Acquir Immune Defic Syndr*, 48, 97–103.

¹⁴ amfAR: The Foundation for AIDS Research. (2014). Trans population and HIV: Time to end the neglect. Retrieved from: <http://www.amfar.org/issue-brief-trans-populations-and-hiv-time-to-end-the-neglect/>

¹⁵ Garofalo R, D. J., Osmer E, Doll M, Harper GW. (2006). Overlooked, misunderstood and at-risk: Exploring the lives and HIV risk of ethnic minority male-to-female transgender youth. *Journal of Adolescent Health*, 38, 230-236.

¹⁶ Reisner SL, V. R., Leclerc M, Zaslow S, Wolfrum S, Shumer D, Mimiaga MJ. (2015). Mental health of transgender youth in care at an adolescent urban community health center: A matched retrospective cohort study. *Journal of Adolescent Health*, 56(3), 274-279.

¹⁷ Sevelius J, Keatley J., Calma N, Arnold E. (2016). 'I am not a man': Trans-specific barriers and facilitators to PrEP acceptability among transgender women. *Global Public Health*.

¹⁸ Garofalo R, J. A., Kuhns LM, Cotten C, Joseph H, Margolis A. (2012). Life Skills: Evaluation of a theory-driven behavioral HIV prevention intervention for young transgender women. *Journal of Urban Health*, 89(3), 419-431.

acceptability of and preferences for various HIV prevention interventions. In particular, little is known about AMSM attitudes and behaviors that could aid access to, acceptability of, and adherence to promising biomedical HIV prevention interventions (i.e., pre-exposure prophylaxis medications or PrEP, non-occupational post-exposure prophylaxis or nPEP, microbicides, and earlier detection of infection)¹⁹. Further, there are outstanding questions about frequency and timing of HIV testing, barriers to retention in care for HIV-positive AMSM, and testing for other STDs, that, if answered, could improve HIV prevention efforts. Even less is known about the acceptability of these interventions among transgender youth.

Within the relative dearth of information on young MSM, even less is known about AMSM (i.e., MSM 18 years old and younger). For various reasons including less connection to a “gay” community, evolving sexual identity, greater internalization of sexual minority stigma, lack of disclosure to others, misclassification of gender, need for parental consent, and lack of transportation²⁰, reaching AMSM is often difficult by traditional methods. Adolescent sexual development further compounds challenges in recruiting and engaging AMSM, because common definitions of MSM in the literature (e.g., in terms of identity or same-sex behavior) may not yet apply to AMSM. Therefore, most research focuses on those older than 18 years and many studies that access young MSM in bars or social venues include only young adults over 18. This creates some problems when drawing conclusions about AMSM who are underrepresented in current research while also existing at the intersection of both sexual minority status and a unique life course stage.

All of these coinciding changes have implications for clinical practice and HIV prevention programs. It is therefore not likely that HIV prevention efforts aimed at adult populations will adequately address the unique needs of adolescents. Experts argue that AMSM 18 years old and younger deserve a distinct approach and that to accurately understand risk and resiliency in this group requires inclusion of participants under the age of 18²¹. Likewise, the experience of being AMSM can isolate AMSM from traditional efforts geared at a general adolescent population. The experience of being adolescent, MSM, and a racial/ethnic minority calls for distinctive set of programmatic strategies. However, the information to inform such strategies and tools to facilitate their development and implementation are largely missing.

¹⁹ Bauermeister et al., 2013, *Current HIV Research*, 11:7, 520; Mustanski et al., 2011, *J Sex Research*, 48:2-3, 218-253

²⁰ Kuhns et al, *J Urban Health*. 2014 Aug 16

²¹ Mustanski et al., 2011, *J Sex Research*, 48:2-3, 218-253

For the reasons outlined above, there is a need for new tools and guidance for the variety of public health practitioners trying to work with this population to prevent HIV. This project will increase understanding of the unique individual, interpersonal, and social characteristics of AMSM to provide needed input to improve HIV prevention efforts; the preferences and behaviors of AMSM, and especially AMSM of color, to inform acceptability and adherence to promising HIV prevention strategies; and translate these findings into HIV prevention tools and guidance for preventing HIV among AMSM that are nationally scalable.

This request is being conducted in coordination with 0920-17AZH. Both requests are funded through the same contract mechanism and share the goal of increasing DASH's understanding of adolescent sexual minority males HIV prevention preferences, in order to develop tools for youth service providers. This request and 0920-17AZH use different methods in order to obtain complimentary but distinct information about the risk behaviors, identity, and HIV prevention preferences of sexual minority males aged 13-19 and transgender youth aged 13-24. The previously submitted request (0920-17AZH) is for the collection of qualitative information which will provide an understanding of the inter- and intra-personal processes that underlie respondents' decision-making around HIV prevention preferences. Quantitative data collection via this request is needed to estimate this populations' risk profile and attitudes towards HIV prevention and risk reduction. Specifically, this request is for formative testing of a quantitative survey of adolescent sexual minority males aged 13-19 and transgender youth aged 13-24. Additionally, one of the aims of this formative quantitative survey is to investigate novel and efficient recruitment methods for including this population in survey research, which cannot be conducted with the limited sample size of qualitative data collection. From this request we will learn the percentages of sexual minority males aged 13-19 and transgender youth aged 13-24 nationwide who endorse key HIV prevention modalities and their correlates, which we cannot quantify via the limited number of focus groups in 0920-17AZH.

This request is managed by our contractor NORC at the University of Chicago. The package (0920-17AZH) submitted already is for online and in-person focus groups of sexual minority males aged 13-19 and transgender youth aged 13-24. This submission is managed by NORC's subcontractor, The Fenway Institute out of Boston. The submissions use different participant recruitment methods, data collection methods, and the participants recruited for one request are not simultaneously recruited for the other

request. Though the submissions share the same goal, they have completely different methods and are designed to elicit complimentary but distinct information.

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

2. Purpose and Use of Information Collection

The purpose of this study is to conduct a pilot survey with AMSM and transgender youth. This project consists of research among AMSM 13-18 years old and transgender youth 13-24 years old to characterize: 1) effective methods of and venues for recruitment in research and HIV prevention activities; and 2) fundamental aspects of sexual identity, behavior, and protective factors. The proposed information collection is one component of a multi-year project. Future components, which will apply findings to the development of culturally appropriate HIV prevention tools and strategies, will be addressed in separate information collection requests.

This formative research will be conducted using a national web-based survey with respondents recruited via social media and other websites, including Facebook, Twitter, Kik, Tumblr, Instagram, Google, and SnapChat. Our study population will consist of (1) adolescents born male ages 13 to 18 who report attraction to or sexual history with males and (2) transgender youth ages 13 to 24. Ads will be designed to effectively attract a large proportion of youth of color to respond to the survey. Various ads will be posted using different strategic targeting options on the listed social media apps and websites in order to assess the effectiveness of each site, ad, and recruitment strategy. This research design was chosen based on the exploratory nature of our study purpose. The data collection instrument is included with this submission (**Attachments 1a-c**).

Data collected will be used to promote the following research themes: understanding vulnerability and how to reduce it; understanding protective factors and how to promote them; understanding age cohort differences; understanding racial/ethnic differences; translating research findings into tools and guidance to effect changes in education, health care, and youth services that can reduce AMSM's vulnerability to HIV infection. Paradata will also be used to understand the feasibility of recruiting this population using social media and other websites, both to reduce costs and improve representation of minority

groups. Key variables to be explored are described in Exhibit A2.1.

Exhibit A2.1: Items of Information to be Collected

Variables to be explored	Data collection tool and citation	Study Related Procedures	Target Population
Ad impression rate, cost-per-click, cost-per-complete, click-through-rate, eligibility rate, breakoff rate, survey timing	n/a – Paradata	Social media and web ad reports and Voxco	AMSM and transgender youth
Eligibility criteria; attraction; identity; brief sexual history; age	3a. AMSM Screener and Flowchart	Web-based eligibility screener	AMSM and transgender youth
Demographics; HIV knowledge; HIV risk behavior; sexual history; gender identity; HIV prevention strategies; social media use; perceptions of PrEP and nPEP	3c. AMSM Survey	Web-based survey	AMSM and transgender youth

3. Use of Improved Information Technology and Burden Reduction

Voxco is a computer aided interviewing (CAI) system that has functionality to administer the web survey with minimal user-errors such as missing data or incorrect skip patterns. Use of a web survey will also reduce the time needed to complete the questionnaire. Transfer of data collected electronically will eliminate the need for data entry, reducing cost to the government and allowing for more rapid analysis of findings.

All social media apps and websites used will generate automated paradata reports that will allow project staff to monitor the effectiveness of the recruitment method and the composition of the recruited sample. Combined with data from the portal, project staff will be able to calculate response rates and make adjustments to the recruitment effort as needed.

4. Efforts to Identify 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 the contract, and determined that this study is collecting unique information from these populations. Most research to date has focused on those older than 18 years and many studies recruit from bars or social venues, thus limiting the sample to young adult MSM. This creates some problems when drawing conclusions about AMMS who are underrepresented in current research while also existing at the intersection of both sexual minority status and a unique life course stage. Therefore, our project requires the collection of this new primary data.

5. Impact on Small Businesses or Other Small Entities

This data collection effort does not involve any small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

The proposed pilot project involves a one-time data collection, starting with a soft launch of the pilot survey (4 weeks) followed by a 12-month full launch of the pilot survey. There are no legal obstacles to reducing burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

For sub-collection requests under a generic approval, Federal Register Notices are not required and none were published. The 60-Day federal register notice was published for this collection on Thursday, June 25, 2015, Vol. 80, No. 122, pp. 36540 (See Att2). No comments were received.

9. Explanation of any Payment or Gift to Respondents

We will provide all respondents who participate with a \$10 electronic gift card at the end of the survey to encourage their participation, and convey appreciation for contributing to this

important study. 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 modest tokens of appreciation is expected to enhance survey response rates without biasing responses^{22,23,24}. In addition, homosexuality and gender non-conforming behavior is highly stigmatized, especially among youth of color, making it difficult to recruit participants for research compared to less targeted projects. Offering tokens of appreciation is considered necessary to recruit minorities and historically underrepresented groups in to research studies. Multiple studies on research participant recruitment in Hispanic communities have noted that the stigma related to GBT issues, and the relationship between HIV/AIDS and homosexuality, is a major barrier in subject recruitment for this type of behavioral research^{25,26}. However, timely monetary incentives have been shown to improve participation rates among minority groups, as a tangible recognition of the participants' time and effort²⁷. Respondents will receive the token of appreciation regardless of whether they skip any questions.

The use of a token of appreciation for participation in this study is appropriate because the project seeks to administer a pilot web survey with a hard-to-reach and highly selective population and ask participants highly sensitive questions about issues such as sexual behavior (Kulka, 1995). We anticipate that increased response rates will lead to improved willingness of youth to participate and to achieve a more accurate representation of the underlying population of interest.

Remuneration has been used in other HIV-related CDC data collection efforts such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 05/31/2020), the Transgender HIV Behavioral Survey (OMB 0920-0794 exp. 12/31/2010), and the Medical Monitoring Project (OMB 0920-0740, exp. 6/30/2018) all of which ask questions similar to those in our study (Shaw et al., 2001).

²² Abreu, D. A., & Winters, F. (1999). Using monetary incentives to reduce attrition in the survey of income and program participation. *Proceedings of the Survey Research Methods Section of the American Statistical Association*.

²³ Shettle, C., & Mooney, G. (1999). Monetary incentives in U.S. government surveys. *Journal of Official Statistics*, 15, 231-250.

²⁴ Göritz, Anja S. (2006). Incentives in web studies: Methodological issues and a review. *International Journal of Internet Science*, 1(1), 58-70.

²⁵ Shedlin, M. G., Decena, C. U., Mangadu, T., & Martinez, A. (2011). Research participant recruitment in Hispanic communities: Lessons learned. *Journal of Immigrant and Minority Health*, 13 (2), 352-360.

²⁶ Kuhns, L. M., Vazquez, R., & Ramirez-Valles, J. (2007). Researching special populations: retention of Latino gay and bisexual men and transgender persons in longitudinal health research. *Health Education Research*, 23(5), 814-825.

²⁷ Yancey, A. K., Ortega, A. N., & Kumanyika, S. K. (2006). Effective recruitment and retention of minority research participants. *Annual Review of Public Health*, 27, 1-28.

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 has determined that the Privacy Act does apply to the overall information collection. The project will collect PII (email addresses and telephone numbers) for respondents. 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 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.

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.

As the nature of this study is to better understand barriers to HIV prevention, we are sensitive to the need to protect health information. We will train researchers who play a role in data collection and analysis in proper procedures for data handling. We will be prepared to describe these procedures in full detail and to answer any related questions raised by respondents via a toll-free phone line.

Access to all data that identify respondents will be limited to research staff with a data collection or analysis role in the project. Such data will be needed only for providing the gift code for incentives and will not be used for analyses. All data will be stored on secure, protected servers and PII will be destroyed at the conclusion of the project. Any data sent to CDC will not contain personal identifiers.

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

- Comply with procedures to prevent improper disclosure, use, or alteration of private information. Staff may be subjected to disciplinary and/or civil or criminal actions for

knowingly and willfully allowing the 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 Directors 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 electronic data. Data files will be stored on encrypted, secure servers. Additional information about the security protocols for all materials can be found in the Data Security Plan (**Attachment 5**) submitted with this document. Unless otherwise required by CDC, these files will be destroyed when no longer needed for the project.

The NCHHSTP IT Security Information System Security Officer (ISSO), Mr. Ralph Vaughn, consulted on the system security described in this section. The data system for this collection will reside at an external third party data center (NORC) and has undergone a Privacy Impact Assessment (PIA) during the SA&A process (Enterprise Systems Catalog, IT Record ID: 2721).

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

IRB Approval

This study has been reviewed and approved by NORC's IRB (**Attachments 3a - 3e**). IRB approval includes a waiver of parental permission for youth ages 13-17. The CDC National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention determined that CDC's role does not constitute engagement in the research and thus CDC human subject review action was not required (**Attachment 5f**).

In order to minimize risk to the respondent, contact information collected for the purposes of providing the incentive (i.e., email address and/or telephone number) will be collected and stored securely and separately from responses to screening or interview questions. No linking variables will be able to connect survey response data to phone numbers or email addresses.

Sensitive Questions

This study is an initiative aimed to assess barriers and facilitators of HIV prevention. As such, our study entails measurement of sensitive HIV-related information. For example, questions related to gender and sexual attraction are included. Gender identity is an inclusion criteria for identifying eligible respondents and sexual attraction is a way to identify eligible respondents who may not identify as a sexual minority and have not had sex with a man. Further explanation and justification for the sensitive questions are in **Attachment 1g**.

Understanding the slight possibility of emotional response or anxiety on the part of the respondent, all respondents will be routed to CDC resources (<http://www.cdc.gov/lgbthealth/youth-resources.htm>). If respondents report nonconsensual sex, they will be provided a link to <https://www.childwelfare.gov/aboutus/find-help/>. We will inform all respondents during assent/consent that they may skip any question or stop participation at any time for any reason. Each screen of the survey will offer respondents the opportunity to select 'Prefer not to answer'. This study has been reviewed and approved for Human Subjects Protections (**Attachments 3a-e**).

12. Estimates of Annualized Burden Hours and Costs

We predict that 4375 respondents will need to be screened in order to reach our target of 3,500 respondents. The screening process is anticipated to take 3 minutes per respondent for a total of 219 burden hours (**Att. 1a**). Of the 4375 respondents screened, we anticipate an 80% eligibility rate for a total of 3500 study participants. The web survey for AMSM (**Att. 1b**) will be administered to 1750 respondents providing 1 response with an estimated 20 minutes for a total of 583 burden hours. The web survey for transgender youth (**Att. 1e**) will be administered to 1750 respondents providing 1 response with an estimated 30 minutes for a total of 875 burden hours. We anticipate that the web survey will take a total of 1458 burden hours for all 3500 study participants (**Attachment 1c**). The total number of burden hours is 1677.

Exhibit A12.1: Estimated Annual Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
AMSM ages 13-18 & Transgender youth ages 13-24	Screening Att. 1a	4375	1	3/60	219
AMSM ages 13-18	AMSM Survey Att. 1d	1750	1	20/60	583
Transgender youth ages 13-24	Transgender Web Survey Att. 1e	1750	1	30/60	875
Total					1677

12B. Estimated Annual Burden Costs

The total costs to the respondents are described in Exhibit A12.2. The total estimated cost of the burden to respondents is approximately \$12,158.25. Estimates for the average hourly wage for respondents are based on Department of Labor (DOL) data from May 2016 providing national wage estimates for persons under 20 (<http://www.dol.gov/whd/regs/compliance/whdfs32.pdf>). This cost represents a basic wage for under age 20 and an average wage for the 20-24 year old respondents providing an average minimum hourly wage rate of \$7.25.

Exhibit A12.2: Estimated Annual Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
AMSM ages 13-18 Transgender youth ages 13-24	1a. Web Screener	219	\$7.25	\$1587.75
AMSM ages 13-18	1d. Web Survey	583	\$7.25	\$4,226.75
Transgender youth ages 13-24	1e. Web Survey	875	\$7.25	\$6,343.75
Total				\$12,158.25

*Numbers may not sum precisely due to rounding.

7.25

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

There are no costs to respondents for participating in this survey other than their time.

14. Annualized Cost to Federal Government

The estimated cost to carry out the data collection activities annually for this project is **\$784,358**. This estimate includes the cost of recruitment, web survey design and programming, analysis and reporting, as well as the total cost of the tokens of appreciation (\$10 per completed survey, for a total of \$35,000).

Exhibit A14.1: Annual Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, COR (0-5, 0.25 FTE)	\$20,328
	CDC, Contracting Officer (GS-12, 0.1 FTE)	\$7,426
	CDC, Contracting Officer (GS-12, 0.1 FTE)	\$7,426
	Subtotal, Direct Costs	\$35,180
Cooperative Agreement or Contract	Contract Cost for specific task: NORC @ the University of Chicago	\$749,178
	Subtotal, Cooperative Agreement or Contract Costs	\$749,178
	TOTAL COST TO THE GOVERNMENT	\$784,358

Expense Type	Expense Explanation	Annual Costs (dollars)
Costs		

15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Findings from the soft launch of the pilot study will be provided via e-mail and discussed at regularly scheduled weekly meetings. Tabulation will include descriptive characteristics of study respondents as reported in the web survey (e.g., demographics, sexual and gender identity, age, race/ethnicity) as well as productivity of each app/website and ad combination.

Findings from the full launch of the pilot study will be also provided via e-mail and discussed at regularly scheduled weekly meetings. The data analysis plan will include the following elements:

Aim 1: To understand AMSM’s knowledge of HIV risk behavior, and attitudes toward HIV vulnerability among AMSM, and to examine racial-ethnic and other demographic (age, region, sexual identity) differences in knowledge and attitudes

Outcomes: Understanding of HIV risk, how to prevent infection; sense of self-efficacy or fatalism regarding HIV infection; knowledge regarding how and where to access HIV prevention education, condoms, lubricant

Analysis: Descriptive bivariate statistics (chi-square and t-tests) and multivariable regressions (categorical and linear) will be conducted to compare differences in proportions and mean health outcomes and determinants between groups of AMSM (Latino, Black, White; 13-15, 16-18; gay, bisexual, other; rural/suburban/urban; region of country).

Aim 2: To understand sexual identity, and demographic differences in these areas

Outcome: Sexual identity, behavior, attraction

Analysis: Descriptive bivariate statistics (chi-square and t-tests) and multivariable regressions (categorical and linear) to compare differences in sexual identity development, behavior and attraction among groups of AMSM.

Aim 3: To understand risk and protective factors, and demographic differences in these areas

Outcome: Possible measures include: discrimination and rejection, self-esteem, parental acceptance, internalized stigma, racial-ethnic identity, social isolation, social support.

Analysis: Descriptive bivariate statistics (chi-square and t-tests) and multivariable regressions (categorical and linear) to compare differences in sexual identity development and protective factors among groups of AMSM.

Aim 4: To understand AMSM's access to sex education and other HIV prevention activities in school and community settings

Outcome: Knowledge, attitudes, beliefs and behaviors related to HIV prevention education

Analysis: Descriptive bivariate statistics (chi-square and t-tests) and multivariable regressions (categorical and linear) to compare differences in knowledge of HIV prevention resources, including condoms, among groups of AMSM.

Aim 5: Knowledge of and attitudes toward PrEP and other biobehavioral prevention interventions

Outcome: Knowledge, attitudes, beliefs and behaviors related to biobehavioral prevention approaches

Analysis: Descriptive bivariate statistics (chi-square and t-tests) and multivariable regressions (categorical and linear) to compare differences in knowledge and attitudes toward biobehavioral prevention approaches among groups of AMSM.

Aim 6: To understand the role of parental involvement in HIV prevention and testing.

Outcome: AMSM's attitudes and beliefs regarding parental involvement in HIV prevention and testing.

Analysis: Descriptive bivariate statistics (chi-square and t-tests) and multivariable regressions (categorical and linear) to compare differences in attitudes and beliefs regarding parental involvement in HIV prevention and testing.

The project timeline is detailed in exhibit A16.1.

Exhibit A16.1: Project Time Schedule

Activity	Time Schedule
Data collection tools, sampling and data	2-3 months before

Activity	Time Schedule
plans, study protocol development	OMB submission
Pilot data collection (n=500)	1-2 month after OMB approval
Pilot data analysis finalized and report submitted	3 months after OMB approval
Full data collection (n=3000)	3-15 months after OMB approval
Analysis plan developed	5 months after OMB approval
Analysis plan implemented for quantitative data	17 months after OMB approval

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

We do not seek approval to eliminate the expiration date.

18. Exemptions to Certifications for Paperwork Reduction Act Submissions

There are no exemptions to the certification.