Mobile Messaging Intervention to Present New HIV Prevention Options for Men who have Sex with Men: Randomized Controlled Trial

OMB #0920-New

Section A: Supporting Statement

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- **Goals of the study:** The purpose of this research study is to test the efficacy of a smartphone-based sexual health and HIV prevention messaging intervention for men who have sex with men (MSM).
- **Intended use:** Data collected through this study will be used to evaluate a smartphone-based HIV messaging intervention for MSM.
- **Methods to be used to collect data:** Data will be collected through an online behavioral assessment, to be completed in 3-month intervals over the 9 month study period. Participants will be assigned to either an intervention group, who will receive the intervention upon enrollment, or a waitlist control group, who will receive the intervention materials after the study is complete.
- **The subpopulation to be studied:** 1,206 adult MSM living in Atlanta, Detroit and New York City. One-third of participants (n=402) will be HIV-positive, and at least 40% will be men of color ($n \geq 482$).
- **How data will be analyzed:** We will conduct bivariate analyses to describe associations between study outcomes and key demographics, and logistic regression analyses to test the effect of the intervention at each assessment time point, controlling for demographics.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's Division of HIV/AIDS Prevention, (DHAP) requests OMB approval for 2 years of data collection for a research study entitled, "Mobile Messaging Intervention to Present New HIV Prevention Options for Men who have Sex with Men: Randomized Controlled Trial" as a new information collection.

This study will test the efficacy of a smartphone-based prevention messaging intervention for men who have sex with men (MSM), known as M^3, through a randomized controlled trial. To our knowledge, this is the first intervention to integrate messaging related to both behavioral and emerging biomedical prevention strategies using a smartphone-based platform. Before this intervention can be disseminated to MSM more broadly, it needs to be rigorously evaluated, necessitating the proposed information collection. We will evaluate whether M^3 smartphone-based intervention is an effective HIV-prevention strategy by assessing whether exposure to the messaging intervention results in improvements in men's self-reported sexual health and HIV prevention behaviors, attitudes, and beliefs.

Sexual risk behavior among men who have sex with men (MSM) in the U.S. increased from 2005-2011, a group already disproportionally affected by HIV:[1] increases are especially alarming among young MSM[2] and MSM of color.[3] The 20-city National HIV Behavioral Surveillance system reported that in 2011, only 67% of men overall and 62% of young MSM had tested in the past 12 months.[4,5] At the same time, messaging on the range and complexity of HIV prevention options is becoming increasingly challenging as the field of HIV prevention moves from behavioral to biomedical risk reduction. It is estimated that 25% of MSM are at high risk for HIV infection and could be appropriately prescribed the breakthrough biomedical strategy of Pre-Exposure Prophylaxis (PrEP)[6] but only 2% of MSM in an

online survey were currently taking PrEP.[7] Reasons for poor uptake of PrEP include confusion and misunderstanding in the community about the efficacy of taking a pill to prevent HIV and concern about side effects.[8] As new information about biomedical prevention options continues to emerge from the scientific community, this information must be translated clearly and concisely to populations at highest risk for HIV infection. New and complex scientific information included in this study are: pre-exposure prophylaxis (PrEP); antiretroviral (ARV) adherence; condom efficacy; and frequency of HIV/STD testing. This complex HIV prevention landscape requires novel multi-component messaging for 1) HIV-positive MSM, 2) high-risk HIV-negative MSM, and 3) lower-risk HIV-negative MSM. Importantly, these three groups are distinct from each other with respect to the prevention messages that will be most appropriate for them. For example, ARV adherence is important for HIV-positive MSM, and PrEP is an important HIV prevention method for high-risk HIV-negative MSM but not for lower-risk MSM (who might benefit from condom and testing frequency messaging). Using new technologies to deliver messages related to these emerging prevention methods will enable easy tailoring of messages so that they will be relevant to MSM from each risk group. Further, research has demonstrated that utilizing current technology, such as Smartphones and tablets, is an increasingly promising approach for reaching MSM and for scaling up interventions addressing HIV risk reduction and medication adherence.[9] To our knowledge, no study to date has tested the efficacy of an intervention based on brief messages for MSM delivered via smartphone or tablet applications.

2. Purpose and Use of the Information Collection

The purpose of the information collection is to test the efficacy of the M^3 mobile-messaging intervention through a randomized controlled trial. Information collected from this activity will be used to determine whether changes in sex and HIV prevention behaviors, attitudes and beliefs can be demonstrably linked to use of and interaction with this smartphone-based intervention. The trial will assess whether intervention participants' behaviors significantly change when compared to participants in the waitlist control arm, and whether these changes are sustained at the 6-month and 9-month follow-ups.

Twelve hundred and six MSM, including 402 HIV-positive MSM, 402 lower-risk HIV-negative MSM, and 402 higher-risk HIV-negative MSM will be recruited to the study and randomly allocated to either the M^3 intervention arm or a waitlist control. MSM recruited into the study will be diverse (at least 40% MSM of color) and living in Atlanta, Detroit, or New York City. Recruitment will be conducted in both online and offline venues in which MSM congregate, including web sites (such as Facebook), bars, community events, and street locations (**Attachment 3**). In addition, MSM can drop-in or be referred to the study via collaborating clinics and community centers. All potential participants will complete a brief two-phase screening process for eligibility (**Attachment 4a-b**), which includes an initial screening and collection of contact information, followed by reverification of eligibility prior to consent and data collection. If eligible via reverification, participants will complete the consent process prior to study enrollment (**Attachment 5**).

All participants will receive the same 36 core messages and 12 videos, covering the six intervention content domains (HIV testing, STI testing, PrEP, ART, Condoms, and Engagement in Care), with the aim of developing a messaging package that is both appropriate to the target population (e.g. MSM, particularly MSM of color) and broad enough to be relevant to all participants, regardless of their HIV serostatus or other sexual health risk factors. Messages and videos were developed based on prior research literature, and iterative formative work within the project (ie. Focus groups, in-depth interviews). Final messages will receive CDC communications review and CAB oversight review before deployment of the intervention.

A quantitative assessment will be used to collect information for this study, and will be delivered in-person at baseline and 9-months, and remotely at the 3-month and 6-month follow-ups (**Attachment 4c**). The assessment will be used to measure changes in condom use behavior, number of sex partners, HIV testing (HIV-negative MSM only), sexually transmitted disease (STD) testing, health care engagement, PrEP uptake and adherence (HIV-negative MSM only), and antiretroviral therapy (ART) uptake and adherence (HIV-positive MSM only) during the study period. In addition, we will collect information related to participant socio-demographics, smartphone use, and a small number of covariates that are theorized to mediate the relationship between receipt of the intervention and HIV risk and prevention behaviors in this population. The study protocol and all data collection instruments have been approved by Emory University IRB (**Attachment 6a-c**).

The primary focus of this research is to carry out a study that is internally valid. As such, we will employ convenience, as opposed to probability, sampling methods. Because we are not using random sampling methods to recruit participants to this study, the results will not be generalizable beyond the specific populations and geographic contexts in which they were obtained. Rather, the results will be used to demonstrate a causal relationship between receipt of the M^3 mobile-messaging intervention and improvements in sexual health and HIV prevention behaviors over time among participants in the study. CDC and/or its partners may also analyze these data and publish results in peer-reviewed journals. Additionally, it is anticipated that the data collected will be made publically available following completion of this study, in the form of summary tables and limited use datasets, in accordance with HHS policy.

3. Use of Improved Information Technology and Burden Reduction

All of the forms used to collect information for this study will be administered electronically (100% of responses), though participants will be required to present in person to complete an electronic assessment at baseline and at the final, 9-month assessment. Conducting all data collection activities through an online web application, SurveyGizmo, will allow us to build in computer-generated skip patterns, significantly cutting down on respondent burden. In addition, data collected through the web application can be used to automatically generate the study database, reducing data entry burden and potential data entry error.

Both participants recruited online and those recruited in person will be directed to the study webpage to complete the initial screening process to determine study eligibility (**Attachment 4d**). This will allow participants to complete the screening form at a place and time that is most convenient to them, and will enable us to instantaneously determine study eligibility. Men who meet the study eligibility criteria will be automatically transferred to the form that will be used to collect contact information (**Attachment 4e**); this is a seamless process. Participants are required to present in-person to rescreen for eligibility and for the 1st assessment survey (**Attachment 4f**). Although this assessment will be administered via a computer or tablet at the study location, requiring in-person participation during the first study visit will enable grantee staff to administer one-on-one informed consent, and to provide instruction in the use of study systems and applications. Participants are also required to present in-person for their 4^{th} assessment survey, after which they will be debriefed by grantee staff. In-person debriefing of participants, similarly, enables grantee staff to utilize participant body language in responding to questions about the study. Remote administration of the 2^{nd} and 3^{rd} assessment surveys will allow participants to participate from any internet-connected location. This limits the burden on the respondent by limiting the number of study activities that require transportation to and from the study sites.

4. Efforts to Identify Duplication and Use of Similar Information

The assessment surveys will collect information from MSM about their sexual behaviors, partnering dynamics, engagement in care, and HIV/STI prevention efforts in the 3 months prior to each assessment, all of which will be used to evaluate the efficacy of this particular mobile-messaging intervention. We are aware of two studies that have tested or are testing messages related to HIV prevention. The first of which was the formative phase of this study, which utilized focus groups and in-depth interviews to gauge preferences for the messages that comprise the current intervention (IC Title: Development of a Mobile Messaging Intervention for Men who have Sex with Men: Formative Study. OMB #0920-0840. Exp. 1/31/2019). The other is a study that is planning to test messages related to new HIV prevention options (IC Title: Act Against AIDS Campaign. OMB #0920-0572. Exp. 3/31/2018); however, it will be testing messages that differ in format, content, intended audience and intended delivery mechanism. Because the information collected here will be used to evaluate this specific smartphone-based intervention the Agency believes this information 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 this population. CDC conducted a review of similar studies prior to the issuance of the Cooperative Agreement, and determined that this study is collecting unique information from the populations. 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

This collection request does not involve burden to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

The present study will provide the primary quantitative data needed to assess the efficacy of a smartphone-based, sexual health messaging intervention for MSM. The length of data collection is 9 months, and data will be collected 4 times, at baseline, 3-month, 6-month and 9-month time points. Collecting assessment surveys less frequently than every 3 months would limit our ability to assess each participant's adherence to CDC recommendations for HIV and STI testing frequency for high-risk, HIV-negative MSM. The number of assessment surveys administered is the minimum required to assess any effects of the intervention and post-intervention decay.

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 FRN notice to solicit public comments was published in the Federal Register on 10/25/2016, Volume 81, Number 206, Page Number 73402. No public comments were received.

In addition, Emory University, Public Health Solutions, the University of Michigan and the University of Pennsylvania were consulted for the development of this study. There were no unresolved issues associated with the consultation process. The NCHHSTP IT Security Information System Security Officer (ISSO), consulted on Privacy-related issues as discussed in Section 10 of this document. Aside

from the official 60 day public comment period for the Generic data collection, there were no other public contacts or opportunities for public comment on this study.

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9. Explanation of Any Payment or Gift to Respondents

Participants will receive a $50 token of appreciation at each in-person assessment (baseline and 9-months) and an online $10 pharmacy gift card (e.g. CVS Pharmacy, Walgreens, Rite-Aid) for each assessment that is completed remotely (immediate intervention post-test and 3-month post-intervention follow up at 3 and 6 month study time points. Participants who complete all study activities will receive a combined total of $120 (two $50 tokens, and two $10 pharmacy gift cards) in appreciation of their time and efforts across the various study activities.

Participants who complete the baseline visit will be given a rechargeable prepaid MasterCard card containing the initial $50 token. As a token of appreciation for completing the final assessment survey, an additional credit of $50 will be added to their prepaid MasterCard card within 2 business days. Participants who complete the remotely-administered assessment surveys (3 months and 6 months) will receive an online pharmacy gift card valued at $10 for each remote survey completed. Online pharmacy gift cards will be delivered electronically, via an emailed coupon or discount code.

Other forms of tokens of appreciation were considered, such as tokens of appreciation that reinforce health messages and healthy behaviors (e.g. educational materials, health promotion products). This study is designed to test potential health knowledge and behavioral outcomes associated with use of the

intervention app. As such, educational materials and health promotion products risk confounding the experimental conditions of the study. Participants in the intervention arm are distinguished from those in the waitlist control arm by their exposure, or lack of exposure, to the intervention app. Given that the intervention app is composed of health information and health promotion materials, providing similar materials as a non-cash token of appreciation would substantially confound our waitlist control group.

A token of appreciation for remotely-administered assessment surveys is crucial to maintaining the integrity of the sample, specifically for the waitlist control participants whose overall opportunities for study engagement are fewer and more sporadic than for those in the intervention arm. Participants in the waitlist control arm, because they cannot receive the intervention app until they complete the study, have fewer modes and opportunities for engaging with study activities in the three month period between assessment surveys. While interactions with the intervention app will help keep intervention arm participants engaged in the study for the three months between assessment surveys, waitlist control participants will also need to remain engaged in the study, despite having fewer opportunities for engagement over the same time periods. For this reason, it is essential to provide a $10 online drug store gift card token of appreciation for the 3-month and 6-month follow-up assessment surveys, to be completed remotely. Without a token of appreciation for the two remotely-administered assessment surveys, waitlist control participants would need to remain engaged in the project for a 6-month period, completing 3 hours of surveys, with no means of engagement with the study other than taking surveys and receiving survey reminders. Intervention arm participants will have the intervention app, which provides a readily-accessible mode of engagement at any time the participant wishes to open it.

In his memorandum for the president's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions…" 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. Offering tokens of appreciation is necessary to recruit minorities and historically underrepresented groups in to research.

In a recent study of the effects of a Spanish-language HIV risk behavior intervention for Latino MSM living in South Carolina (HOLA en Grupos, OMB 0920-0942, exp. 3/31/2018), offering a token of appreciation improved participation among Latino MSM. HOLA en Grupos and comparison intervention participants were given a token of appreciation of $40.00 after completing the baseline assessment and $50.00 after completing the post-intervention 6-month follow-up assessment. Participants in both study conditions were given a token of appreciation of $40.00 for each of the 4 intervention sessions they attend. To facilitate retention, participants received $5.00 for contacting study staff to update their contact information if it changed during the study period. In total, participants who completed all activities received $250 over the intervention period. 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 incentives enhanced retention among this group.[i]

Incentives have been used in other HIV-related CDC data collection efforts, such as for National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014), the Transgender HIV Behavioral Survey (OMB 0920-0794, exp. 12/31/2010), and the Testing Brief Messages for Black and Latino MSM Study

(OMB 0920-14SY under 0920-0840, exp. 1/31/2019), all of which included hard-to-reach populations and had a similar length of time for completing the client interview as in this proposed research. In all of these other projects, tokens of appreciation were used to help increase participation rates.

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

Information collection procedures were reviewed by the NCHHSTP IT Security Information System Security Officer (ISSO) and other NCHHSTP personnel with expertise in privacy-related matters. NCHHSTP personnel also assessed this package for applicability of 5 U.S.C. § 552a, and made a preliminary determination that the Privacy Act does not apply to the overall information collection. The project will collect PII for potential respondents but CDC will receive coded data from the grantee, Emory University. CDC is not engaged in this research (Project Determination Approval #6885). The data collection is federally funded and sponsored but CDC does not own the data and the data are not under federal control. No names or PII will be received by CDC nor stored in a system of records at CDC.

The grantee, Emory University, will be responsible for collecting all data for this study. All participants will be assigned a unique identification number for the study. Respondent interview data will not be attributable directly to the participant but associated only via the unique study ID. Contact information in the form of email addresses and/or telephone numbers will be collected for the purposes of providing tokens of appreciation as incentives after in-person and on-line assessments, and will be stored securely and separately from responses to screening, interview, and assessment questions.

CDC's Privacy Office is conducting a Privacy Impact Assessment (PIA) on this information collection request. NCHHSTP will comply with all Privacy Act requirements or other privacy-related requirements determined to be applicable. As indicated, NCHHSTP will employ the Change Request mechanism to update the information collection request submitted to OMB with respect to PIA outcomes.

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 research team. Terms of the CDC Cooperative Agreement authorizing data collection require the grantee to maintain the privacy of all information collected. Accordingly, individuals' data will be kept private and protected to the extent permitted by law.

This study will collect several types of sensitive information—including participant HIV status, ART and PrEP use, HIV and STI testing, and sex behaviors—from men who have sex with men (MSM), we are sensitive to the need to protect personal health information. To ensure respondents' health information is protected, several measures will be taken by the grantees to separate personally identifiable information (PII) from study-related data. All participants will be assigned a unique identification number for the study. Each participant will sign a consent form indicating that the data received and analyzed by CDC will not contain PII, and each person's data will be identified only by study participant ID. Signed consent forms will be kept separate from all other study data, in locked file cabinets at the study sites. Private contact information (i.e., phone numbers and email addresses) will be maintained on the study server, separated from the study data (i.e., screener, baseline survey and follow-up survey data), and only accessible via a separate username and password. The Emory Project

Coordinator will manage access to the participant contact information and will limit access to study staff directly involved in this research on a need-to-know basis. Outside of the consent forms, all study-related information will be stored off-site on secure webservers by SurveyGizmo.com, with whom Emory has established a formal agreement for secure business practices.

Contact information will be destroyed six months after completion of the study unless participants indicate that project staff may keep it on file for future studies or programs, or they request a copy of the primary results of this study. Regardless, six months after the study is completed, study ID numbers for all participants will be de-linked from contact information in the participant database. Additionally, any data made publically available after completion of the study will be de-identified and will not be linkable to participant contact information.

The M-CUBED intervention application will be self-contained, designed in a way that prevents the application from accessing the contents of participants' personal device. While it is not uncommon for mobile applications to request access to information, data or files that are stored elsewhere on the phone, the intervention application for M-CUBED will not require or request any such access. The application will not have access to files or information stored outside of the application itself, nor will the application request access to files or data stored elsewhere on the participant device. The M-CUBED intervention application will generate de-identified data, linked to participants' study ID, about each participant's use of the application. The intervention application will not collect or transmit information about participant's use of their device's operating system, other applications, or any other actions that occur outside of the M-CUBED intervention application.

Further, the M-CUBED intervention application will not collect data passively from the participant's files, device operating system or other applications. Although it is not uncommon for mobile applications to collect data from other concurrently running applications, the intervention application for M-CUBED will not require or request such access. In cases where participants may leave the M-CUBED intervention application open, the M-CUBED app will not collect data from other applications.

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

IRB Approval

This study has been reviewed and approved by the Emory IRB (**Attachment 6**).

Sensitive Questions

This is an initiative to learn about preferences and needs for risk level-specific HIV prevention messaging for MSM. As such, our study entails collection of sensitive HIV-related information. All study staff will be trained to provide respondents with referrals for prevention and care, such as mental health organizations, as needed. Sensitive questions will be asked to identify the risk level of participants. We will inform all participants that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimates of Annualized Burden Hours

All potential participants will complete a brief, two-phase screening process for eligibility (**Attachment 4a-b**), which includes initial screening and reverification of eligibility prior to consent and data collection. The recruitment and analysis plan calls for a total of 1,206 completes over a 2-year clearance period. The figures in this section have been annualized accordingly for the 2-year clearance period.

Men will be recruited either online through web advertisements or in-person through venue-based sampling and outreach, print advertisements, recruitment from local MSM-serving HIV organizations, or word of mouth (**Attachment 3**). In the first phase of screening, men will consent to screen and complete a brief screening online screening questionnaire (**Attachment 4a**). Eligible men will be asked to provide contact information (name, phone number and email address) through a separate online questionnaire (**Attachment 4b**). In the second phase of screening, men will be asked to verify their eligibility before enrolling in the study. Those who remain eligible will complete the corresponding informed consent (**Attachment 5**), the baseline assessment (**Attachment 4c**) and randomization procedures. Participants in the intervention and control groups will receive the same instruments, and the same information will be collected from all participants, regardless of the group to which they are randomized.

It is expected that 50% of men screened will meet study eligibility and provide contact information, that 75% will schedule and show up for an in-person appointment, and that 95% of these men will remain eligible after reverification. We anticipate initial screening will take 4 minutes (**Attachment 4a**), providing contact information will take 1 minute (**Attachment 4b**), and reverification will take 4 minutes (**Attachments 4a**) to complete. The assessment will take about 90 minutes (1.5 hours) total to complete (**Attachments 4c**), and will be administered at baseline, 3-month, 6-month and 9-month follow-ups (4 total responses). The total number of burden hours over the 24-month data collection period is 7,574 hours. The total annualized burden estimate is 3,788 hours. Exhibits 12.1 and 12.2 provide further details about how the estimates of annualized burden hours and costs were calculated.

We acknowledge that the burden estimates presented may slightly overestimate total participation, as the estimated annual number of respondents (n=603) to the assessment instrument (**Attachment 4c**) does not take participant attrition into account between baseline and follow-up administration of the survey.

Exhibit 12.1: 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	Participant Screening (Eligibility) (Att. 4a)	1,693	1	4/60	113
General Public-Adults	Contact Information Form (Att. 4b)	847	1	1/60	14
General Public-Adults	Participant Screening (Verification) (Att. 4a)	635	1	4/60	42
General Public-Adults	Assessment (Att. 4c)	603	4	1.5	3,618
				Total	**3,787**

12.A. Estimated Annualized Burden Cost

The annualized costs to the respondents are described in Exhibit 12.2. The United States Bureau of Labor Statistics' employment and wages estimates from May, 2015

(http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this request. The estimated annualized burden cost is $87,979.45. This cost represents the total burden hours of general respondents multiplied by the average hourly wage rate ($23.23).

Exhibit 12.2: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General Public- Adults	Participant Screening (Eligibility) (Att. 4a)	112.87	$23.23	$2,621.97
General Public- Adults	Contact Information Form (Att. 4b)	14.12	$23.23	$328.01
General Public- Adults	Participant Screening (Verification) (Att. 4a)	42.33	$23.23	$983.33
General Public- Adults	Assessment (Att. 4c)	3,618	$23.23	$84,046.14
				Total $87,979.45

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

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

14. Annualized Cost to the Federal Government

The estimated annualized cost to carry out the data collection activities is **$1,317,692**. This estimate includes the cost of recruitment, screening, conducting the assessments, analysis and reporting, as well as the total cost of the tokens of appreciation ($50 per completed in-person assessment, $20 per completed online assessment [$140 total per participant]; $15 for scheduled participants who are ineligible at re-screen [n=26 anticipated] for a total of $87,979/year). The CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC Project Determination and local IRB reviews; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. Data will be collected by members of contractor project staff.

Exhibit 14.1: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, Project Officer (GS-14 0.40 FTE)	$53,594
	CDC Scientist(GS-13, 0.40 FTE)	$43,028
	CDC Scientist(GS-13, 0.20 FTE)	$15,648
	CDC Project Coordinator (GS-12, 0.60 FTE)	$45,423
	Subtotal, Direct Costs	**$157,693**
Cooperative	**Cooperative Agreement #PS15-002 Costs**	**$1,160,000**

Agreement Costs		
	ANNUALIZED COST TO THE GOVERNMENT	**$1,317,692**
	TOTAL 24-MONTH COST TO THE GOVERNMENT	**$2,635,384**

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

Our analysis plans for assessing the efficacy of the intervention include a tabular analysis to examine baseline variables across the randomized controlled trial (RCT) arms to determine whether characteristics were evenly distributed via random assignment. Specifically, we will examine differences in various demographic variables (e.g., age, income, education level) and our primary outcome variables (e.g., HIV testing, condom use) across the intervention and control groups using regression analyses. Observed differences across experimental groups will be statistically controlled in the final outcome analysis.

Poisson and logistic analysis of variance (ANOVA)-like regression models will be used to examine the effect of the M^3 mobile-messaging intervention on the primary outcome measures that are common across the three HIV-risk groups (high-risk HIV negative; low-risk HIV negative; HIV positive): 1) Number of condomless anal sex partners; 2) Percentage of condomless anal sex acts; and 3) STD testing. Our primary analytic comparisons will use the 6-month assessment (3-months post-intervention completion) time point and will include both simple, two-arm comparisons and stratified comparisons by HIV-risk group and city. These will yield summary rate ratios (continuous outcomes) or risk/odds ratios (dichotomous outcomes) across the design strata. All analyses will be conducted using the intent-to-treat approach.

We will additionally conduct a number of secondary analyses to assess intervention effects. We will conduct subgroup analyses for the outcome measures specific to each risk group (i.e., HIV testing and health care engagement for HIV-negative MSM; Pre-Exposure Prophylaxis (PrEP) uptake/adherence for high-risk HIV-negative MSM; Antiretroviral Therapy (ART) uptake/adherence and HIV care engagement for HIV-positive MSM), using Poisson or logistic regression analysis. To assess whether the effect of the intervention varied by HIV-risk, we will fit models that include an interaction term for intervention arm and HIV-risk group. Pre-post analyses using paired data from the baseline and 6-month assessments will be used to further understand changes in risk. To assess the durability of the intervention effect, we will conduct generalized estimating equation analyses (GEE) and conditional logistic regression analyses which control for within-person correlation across all assessment time points. Finally, we will conduct dose-response analyses to assess between-participant variations in app usage frequency.

Logistic regression analysis will be used to examine the effect of the intervention to reduce unprotected anal sex (UAS) with male partners among intervention participants compared with the wait-listed controls at three and six months post-intervention. We will use an intent-to-treat approach to examine the hypothesized reductions. We will also examine the hypothesized effect of the intervention on additional intermediate outcomes such as increased communication with partners, reduced number of sex partners, and decreased UAS because of unavailability of a condom.

Data collection will occur over a period of 24 months, beginning in May of 2017 (2 months after OMB approval), analyses will be carried out in June - August 2019 (24-27 months after OMB approval), and the final data set and report will be submitted in September 2019 (28 months after OMB approval). We are requesting approval for 24 months of data collection. The project timeline is detailed in exhibit 16.1.

Exhibit 16.2: Project Time Schedule

Activity	Time Schedule
Recruitment	1 month after OMB approval
Data Collection	2-24 months after OMB approval

[1] Centers for Disease Control and Prevention. HIV Testing and Risk Behaviors Among Gay, Bisexual, and Other Men Who Have Sex with Men — United States. MMWR 2013a; 62(47); 6 of 44, 958-962. Available at: http://www.cdc.gov/mmwr/preview/mmwr.html/mm6247a4.htm. Accessed 9/29/2014.

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Complete field work	24-25 months after OMB approval
Validation	24-26 months after OMB approval
Data analysis finalized and report drafted	24-27 months after OMB approval
Final data set and final report submitted to CDC	28 months after OMB approval

Results from this data collection will primarily be used to assess the efficacy of the M^3 mobile messaging intervention. In addition, 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.

It is anticipated that the data collected through this study will be shared as 1) summary data table(s) and 2) restricted use dataset(s) (i.e. available under certain use restrictions). Supporting documentation will be provided along with shared data. If needed, a data use and/or data sharing agreement will be developed. The agreement(s) will describe in detail how data access will be provided and the provisions for protection of privacy, security, intellectual property, or other rights.

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: