Expanding PrEP in Communities of Color (EPICC)

OMB 0920-1423

Section A: Supporting Statement

December 9, 2024

CONTACT
Katrina Byrd, MD
Project Officer

Carla Galindo, MPH
Co-Project Officer

Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention
1600 Clifton Road, NE, Mailstop H24-5
Atlanta, GA 30329

Phone: 404-639-1902
E-mail: cgalindo@cdc.gov

TABLE OF CONTENTS

EXHIBITS

LIST OF ATTACHMENTS

4a. Aim 1 Provider Training Screener
4b. Aim 1 Provider Training Contact Information
4c. Aim 1 Provider Pre-Training Survey
4d. Aim 1 Provider Post-Training Survey
4e. Aim 1 Provider Patient Interaction (Baseline & Final)
4f. Aim 2a Cohort Screener (English/Spanish)
4g. Aim 2a Cohort Contact Information (English/Spanish)
4h. Aim 2a Cohort HIPAA Form (English/Spanish)
4i Aim 2a Cohort Baseline Survey (English/Spanish)
4j. Aim 2a Cohort App Setup (English/Spanish)
4k. Aim 2a Cohort Follow-up Survey (English/Spanish)
4l. Aim 2a Cohort Blood Collection Instructions (English/Spanish)
4m. Aim 2a Cohort Exit Interview Guide (English/Spanish)
4n. Aim 2b Provider Focus Group Screener
4o. Aim 2b Provider Focus Group Contact Information
4p. Aim 2b Provider Pre-Focus Group Survey
4q. Aim 2b Provider Focus Group Guide
4r. Aim 1&2 Clinic Assessment Baseline and Final
4s. Aim 1&2 Clinic Assessment every 6 months

Attachment 5- Consent Forms

5a. Aim 1 Provider Training Consent
5b. Aim 2a Cohort Consent (English/Spanish)
5c. Aim 2b Provider Focus Group Consent

Attachment 6- IRB Approval

6a. Florida State University IRB Letter of Approval
6b. University of North Carolina Chapel Hill IRB
6c. FHI 360 IRB
6d. Cook County HHS IRB
6e. Children's Hospital Montefiore IRB
6f. Children's Hospital of Philadelphia IRB
6g. Amity Medical Group IRB
6h. Five Horizons Health Services IRB
6i. Ybor Youth Clinic IRB
6j. Bliss Healthcare Services IRB
6k. Harris Health PrEP Clinic at Thomas Street IRB
6l. Wake County Health Department IRB

Attachment 7- Data Use Plan

Attachment 8 - Privacy Impact Assessment (PIA)

Attachment 9 – Provider Training Activities Outline

- **Goals of the study:** The goal of this study is to implement and evaluate the effectiveness of a clinic-based intervention that utilizes evidence-based education and support tools to 1) increase provider knowledge of and comfort with HIV preexposure prophylaxis (PrEP) modalities in clinical practice and 2) improve PrEP adherence among young men and non-binary persons who have sex with men (YMSM).

- **Intended use:** The information collected in this study will be used to 1) describe real-world PrEP use including factors influencing selection and change of PrEP regimens; 2) understand and describe barriers and facilitators impacting the implementation of new PrEP modalities in clinical practice; 3) evaluate the feasibility and acceptability of the EPICC+ mobile app among YMSM on PrEP; and 4) evaluate the feasibility and acceptability of implementing provider PrEP training.
- **Methods to be used to collect data:** In addition to administering quantitative assessments at pre-intervention, baseline and follow-up periods, the study will also collect data from in-depth interviews, focus groups, electronic health records, biological specimens, and a clinic assessment tool.
- **The subpopulation to be studied:** 400 young men and non-binary persons who have sex with men, ages 18-39 inclusive, with an active prescription for PrEP and receiving care at one of the seven participating clinic sites. Additionally, 30 health care providers will be asked to participate in a provider training and 48 providers will be asked to participate in post-intervention focus groups. Provider participants will be any clinic staff who discusses PrEP with a patient.
- **How data will be analyzed:** The study will use a pre-post design to compare provider knowledge retention at pre-, baseline and post-training levels. A pre-post design will also be used to track participant PrEP adherence. Survival analyses will be conducted to describe time to first discontinuation and time to first non-adherence. Patient qualitative interview and provider focus group data will be analyzed to describe intervention experiences and barriers and facilitators to intervention implementation.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) requests approval for 36 months of a data collection for a research study entitled "Expanding PrEP in Communities of Color (EPICC)."

The purpose of this study is to implement and evaluate the effectiveness of a clinic-based intervention that utilizes evidence-based education and support tools to 1) increase provider knowledge of and comfort with HIV preexposure prophylaxis (PrEP) modalities in clinical practice, and 2) improve PrEP adherence among young men and non-binary persons who have sex with men or persons with a penis, hereafter referred to as YMSM.

Young men who have sex with men bear a heavy burden of HIV in the United States (US), particularly YMSM of color. Since the start of the HIV epidemic, men who have sex with men (MSM) have been disproportionately affected, with MSM having the highest annual rates of HIV incidence each year. Among MSM, the highest HIV incidence is among 13-24- and 25–34-year olds[1].

Increasing PrEP use is a principal strategy of the Ending the HIV Epidemic initiative[2]. The use of PrEP for HIV prevention holds enormous promise given its >90% efficacy at preventing HIV acquisition. Unfortunately, PrEP uptake has remained exceedingly low among YMSM.[3-5] While there is now substantial evidence demonstrating that YMSM have high levels of PrEP awareness,[6,7] very few have ever used PrEP. Strauss et al. found that 68% of YMSM recruited from three cities (Atlanta, Chicago, and New York City) reported awareness of PrEP, however, only 9% reported having ever used PrEP.[8] Kuhns et al. similarly found that only 12% of YMSM recruited from two cities (Chicago, Houston) had ever used PrEP.[9] Black YMSM were found to have the lowest rates of uptake (4.7%) and whites the highest (29.5%). Black MSM are six times less likely to receive PrEP compared to their white

counterparts[10-12]. Even in demonstration projects providing free PrEP, uptake has remained low[13]. Complex reasons for lower uptake of PrEP among YBMSM include intersectional stigma as well as structural barriers occurring at individual, interpersonal, and societal levels. Interventions addressing these contextual barriers to PrEP uptake are urgently needed.

The challenges of daily pill taking for YMSM, particularly YMSM of color, suggest an urgent need to examine additional methodologies such as on-demand PrEP and injectables. A recent large internet survey of YMSM using geo-spatial networking apps found that unwillingness to use PrEP was significantly associated with concerns about ability to adhere to a daily regimen[14]. Data from 240 YMSM and young transgender women participating in an RCT of our theory-based, comprehensive smartphone app to support PrEP adherence (P3: Prepared, Protected, emPowered)[15] showed that, of those on or with a history of prior PrEP use at study entry (n=232), 72 (31%) report ever stopping for 7 or more days. The most common reason for stopping was forgetting to take a daily pill (46.3%). The findings of these and other[16] studies point to the urgent need for alternative dosing strategies. In order to make progress towards the goal of no new HIV infections, YMSM (particularly YMSM of color) need access to highly effective prevention interventions that are safe, highly acceptable, and easy to use[17].

The Expanding PrEP in Communities of Color (EPICC) protocol proposes to adapt and implement existing EBT to facilitate PrEP SDM, train providers on the use of evidence-based provider and patient education and support tools (EBT) and evaluate the impact within a longitudinal cohort of racially and geographically diverse YMSM. We refer to this combination of interventions as the EPICC+ intervention package, which includes provider training, EBT for providers, and a mobile app-based platform to support ongoing participant engagement and monitoring, as well as to provide additional adherence support.

PrEP choices have been increasing with new drugs and formulations that will become available in the next few years, including the long-acting injectable PrEP drug CAB-LA. Educating healthcare providers about PrEP best practices, including recommended use of new PrEP drugs, will ensure the delivery of quality PrEP services in accordance with CDC guidelines, and increase the number of PrEP users. Evidence based tools are available to support PrEP initiation and use but have been underutilized. These tools will be implemented to help healthcare providers screen patients for PrEP indications; counsel them about PrEP choices and factors that are important in their choice of PrEP regimen; guide their selection of a PrEP regimen; and support their adherence to, and persistence with, PrEP. Implementation science methods will be used to evaluate the effectiveness of the education module and support tools.

This research will also increase our understanding of provider and patient factors that influence the choice of a PrEP regimen; adherence and persistence with various regimens; changes in regimen; CAB LA tail coverage; sexually transmitted infections (STIs) while using PrEP; and the overall PrEP experience of providers and patients. Findings from this implementation study will be used to support expanded use of effective provider PrEP tools and increase understanding of PrEP use by MSM to inform the future revisions of CDC PrEP recommendations and interventions to increase PrEP use by persons in priority populations.

This project is in alignment with three of the four goals of the National HIV/AIDS Strategy[18]:

- Goal 1 Prevent New HIV Infections
- Goal 3 Reduce HIV=Related Disparities and Health Inequities

This project is also in alignment with the Prevent strategy of the U.S. Department of Health and Human Services (HHS) Ending the HIV Epidemic in the U.S. (EHE) initiative. The initiative aims to reduce

new HIV infections in the U.S. by 90% by 2030 by scaling up four key HIV prevention and treatment strategies: Diagnose, Treat, Prevent and Respond Quickly[2]. Increasing the number of persons with PrEP indications who initiate, adhere to, and persist with PrEP will help to accomplish the goals of EHE, which includes a pillar to prevent new HIV infections using PrEP.

This project will involve interaction with human participants and intends to collect new individually identifiable data and biospecimens from the participants. This project is considered human subjects research and will be covered by the Paperwork Reduction Act.

The following section of the U.S. Federal Code is relevant to this data collection: 42 USC 241, Section 301 of the Public Health Service Act authorizes conduct of "research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." [19]

2. Purpose and Use of the Information Collection

The purpose of the Expanding PrEP in Communities of Color (EPICC) project is to rigorously evaluate the use of evidence-based provider and patient education and support tools (EBT) in clinical settings to increase PrEP screening, counseling, initiation, adherence, and persistence by young men and non-binary persons who have sex with men (YMSM) and to understand reasons for selection of a preexposure prophylaxis (PrEP) formulation and switching patterns associated with the use of daily, 2-1-1, and injectable PrEP. This research project will involve interaction with human participants and intends to collect new individually identifiable data and biospecimens from the participants.

The project proposes to 1) adapt and implement existing EBT to facilitate PrEP shared decision making (SDM), 2) train providers on the use of EBT, and 3) evaluate the impact within a longitudinal cohort of racially and geographically diverse YMSM (cisgender males and non-binary persons, ages 18-39). We refer to this combination of interventions as the EPICC+ intervention package, which includes provider training, EBT for providers, and a mobile app-based platform (EPICC+ app) to support ongoing participant engagement and monitoring, as well as to provide additional adherence support.

This study will be carried out in seven clinics located in New York City, NY; Philadelphia, PA; Charlotte, NC; Raleigh, NC; Tuscaloosa, AL; Tampa, FL; and Houston, TX.

This study will consist of three distinct aims (Aim 1, 2a, and 2b) to adapt and implement the EBT and materials:

Aim 1: Will include 30 health care providers from the seven clinic sites, all involved in the direct delivery of PrEP services. Providers may include but are not limited to medical doctors, nurses, adherence counselors, pharmacists, and social workers. Health providers will be recruited via staff emails (**Attachment 3a**) and screened (**Attachment 4a**) and consented (**Attachment 5a**) for participation. The 30 providers within seven clinical sites will be asked to provide contact information as part of enrollment (**Attachment 4**). They will be trained through two virtual 6-hour training workshops on the use of newly developed EBT and updated PrEP clinical guidance to ensure providers' ability to engage in PrEP screening, counseling, initiation and to provide support for adherence and persistence. Provider participants will complete Pre- and Post-training Provider Surveys (**attachments 4c and 4d**), and patient interaction assessments (competency assessments) post-training and 3 months post-training (**Attachment 4e**).

Aim 2a: Will test the newly adapted EBT materials through a hybrid type 2 effectiveness implementation clinical trial to assess PrEP uptake and adherence to PrEP amongst 400 YMSM (effectiveness outcomes) and provider provision of PrEP and competence with EBT to increase PrEP services (implementation outcomes). All YMSM potential participants will complete an online screening survey via secure platform to obtain consent to be screened and verify all inclusion criteria (**Attachment 4f**). Screening may occur on the same day as enrollment or beforehand. Participants who are recruited by clicking on social media ads will be automatically redirected the online screening survey. Participants who are recruited via clinic recruitment will be sent the screening survey by study staff. Recruitment materials can be found in **Attachment 3b**. If the person is verified as eligible, this will trigger an automatic REDCap action to email the person who completed the screener an informed consent link that is stored within the study REDCap database. Study staff will confirm their eligibility and complete informed consent procedures (**Attachment 5b**). Participants will also be asked to complete a contact information form (**Attachment 4g**) and a HIPAA release form to allow access to participant medical records (**Attachment 4h**). After participants have completed the online consent process, REDCap will automatically send the participant a link to the baseline cohort survey (**Attachment 4i**).

After completing the baseline survey, a welcome email will be sent to the participant that includes an access code and instructions for downloading and setting up the EPICC+ application on their smartphone (**Attachment 4j**). The EPICC+ app is designed to be a safe space for users to explore fun and educational material related to sexual health, nutrition, relationships, careers, advocacy, finance and more. Users can opt to read articles on these topics, complete quizzes and other interactive games or even ask anonymous questions to health care providers to gain knowledge on topics important to them. Users of EPICC+ can also leverage tools to help them achieve their health and wellness goals, such as receiving medication reminders to help keep up their adherence to PrEP, as well as connect anonymously with a community of people who can offer a support and insight on issues or experiences, they may also have encountered. After the participant has downloaded the app, further use of the app is optional.

After the initial encounter, YMSM participants will be followed for 12 months, during which time PrEP uptake, adherence and persistence will be evaluated. Data collection includes follow-up surveys at 3, 6, 9, 12, 15, and 18 months to assess PrEP adherence; PrEP knowledge, usage, and choice; sexual risk behaviors; HIV status of partners; and substance use assessment (**Attachment 4k**). Every six months participants will be mailed a dried blood spot (DBS) specimen collection kit to measure PrEP metabolites and assess PrEP adherence (**Attachment 4l**). Aim 2a also includes exit interviews (**Attachment 4m**) with subset of patients (N=45) to understand factors that influence participants' selection of PrEP regimens, changes and/or discontinuations; perceptions of the counselling they received by providers at PrEP initiation and follow-up, receipt of tools or materials that influenced choice; and feasibility/acceptability of the EPICC+ app.

Aim 2b: Will conduct six post-trial virtual focus groups with 48 PrEP providers and clinical staff over a 2–4-month period to gather feedback on overall perceptions of the barriers and facilitators to EBT implementation at their clinical sites. Staff will be recruited (**Attachment 3c**) from the seven participating clinics and will be screened for participation in the virtual focus groups (**Attachment 4n**). Providers selected for participation will complete an informed consent in order to participate in the focus groups (**Attachment 5c**). A Provider Focus Group Contact Information Form (**Attachment 4o**) and Provider Pre-Focus Group Survey (**Attachment 4p)** gathering provider contact and demographic information will be collected from participating staff prior to the focus groups. Focus group participation is expected to take 120 min. (**Attachment 4q**). Additionally, clinic-level surveys to assess the

implementation of PrEP support services will also be conducted at each of the seven participating clinics at baseline and every six months (**Attachments 4r and 4s**).

The data collected in this study will be used to 1) describe real-world PrEP use including factors influencing selection and change of PrEP regimens; 2) understand and describe barriers and facilitators impacting the implementation of new PrEP modalities in clinical practice; 3) evaluate the feasibility and acceptability of the EPICC+ mobile app among YMSM on PrEP; and 4) evaluate the feasibility and acceptability of implementing provider PrEP training.

Study findings will be disseminated through community forums, academic and community conference presentations, and peer-reviewed publications.

3. Use of Improved Information Technology and Burden Reduction

Screening, consent, contact information collection, survey completion, focus group attendance and in-depth interview will be conducted online. This will allow participants to complete the study activities at a place and time that is most convenient to them. Focus groups and in-depth interviews will be audio-recorded. This limits burden on the interviewer (the interviewer does not have to take handwritten notes), allows researchers to capture participant responses more accurately, and allows the interviewer or focus group moderator focus on building and maintaining rapport with the respondent.

Quantitative data collection will be conducted with REDCap, a HIPPA compliant web-based system. Surveys will be optimized for participants to take them through a personal computer, mobile phone, or tablet. For participants who do not have any of these devices or prefer to not take the survey from their personal device, each clinic will have research space where participants can take the surveys on a tablet that the study will provide for that purpose.

4. Efforts to Identify Duplication and Use of Similar Information

Evidence-based provider and patient education and support tools (EBT) are available[20,21]but are not being routinely used in clinical settings to increase PrEP screening, counseling, initiation, adherence, and persistence by YMSM. To date, there has been a lack of research on the impact that existing EBT have on PrEP provision, or how tailoring these materials to meet the needs of providers and YMSM from diverse backgrounds could enhance their effects. Further, a literature review conducted by our team did not find any evidence for the development or evaluation of tools specifically crafted to address both the initial choice of PrEP modalities and modality switches that occur during usage. Given the expansion of PrEP options currently available, as well as likely additions in the coming years, additional research to develop and evaluate new EBT has both clinical and public health importance. Further, while EBT and educational materials for both providers and YMSM are available, these resources are not maximizing opportunities to engage in a shared decision-making (SDM) process[22.23]. Rather than developing new messages and materials to improve provision of PrEP de novo, we will use principles of human centered design (HCD) rooted in an implementation science framework to identify ways to make existing EBT more effective through promotion of SDM. Human-centered design (HCD) principles represent an innovative means by which to partner with health care sites in identifying the most important needs for the intervention for all parties. HCD refers to an iterative process of tailoring innovations and interventions to fit end-users[24]. In the present study, end-users include providers (who will be communicating the information to YMSM), and YMSM (who will be receiving and processing the information).

Because the information collected here will be used to evaluate use of evidence-based provider and patient education and support tools (EBT) resources to maximize opportunities for providers and patients to engage in a shared decision-making (SDM) process in a clinical setting, the Agency believes this information is not capture 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[25] 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 information collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Collecting assessment data less frequently would make it impossible to fully evaluate the feasibility and acceptability of the EPICC+ intervention (i.e., provider training, EBT for providers, and a mobile app-based platform (the EPICC+ app) over the course of the PrEP Choice Study; barriers and facilitators impacting the implementation of new PrEP modalities in clinical practice; as well as patient factors associated with selection and change of PrEP regimens, adherence and persistence given access to trained medical providers and EBTs to support PrEP uptake and adherence.

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

This data collection does not involve any special circumstances and 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

The 60-day FRN notice to solicit public comments was published on Tuesday, June 27, 2023 Volume. 88, Number. 122 , Page 41623 (**Attachment 2a**). CDC received no public comments.

In addition, study partners at Florida State University, FHI-360, and the University of North Carolina-Chapel Hill were consulted for the development of this study in 2021, 2022 and 2023. There were no unresolved issues associated with the consultation process.

Lisa Hightow-Weidman, MD, MPH Primary Investigator Professor, College of Nursing Florida State University Vivian M. Duxbury Hall 98 Varsity Way Tallahassee, FL 32306-4310 Email: lhightowweidman@fsu.edu	Henna Budhwani, PhD, MPH Co-Investigator Professor, College of Nursing Florida State University Vivian M. Duxbury Hall 98 Varsity Way Tallahassee, FL 32306-4310 Email: hbudhwani@fsu.edu

Allysha Maragh-Bass, PhD Co-Investigator Scientist, Behavioral, Epidemiological and Clinical Sciences, FHI 360 359 Blackwell Street Suite 200 Durham, NC 27701 AmaraghBass@fhi360.org	MacKenzie Cottrell, PharmD, MS Co-Investigator Assistant Professor Division of Pharmacotherapy and Experimental Therapeutics UNC-Chapel Hill Email: mlcottre@email.unc.edu
Audrey Pettifor, PhD Co-Investigator Professor, Department of Epidemiology Gillings School of Global Public Health 2101-D Mcgavran-Greenberg Hall Campus Box #7435 Chapel Hill, NC 27599 Email: apettif@email.unc.edu	Sylvie Naar, PhD Co-Investigator Professor Center for Translational Behavioral Science Florida State University College of Medicine 2010 Levy Ave Building B Suite B0266 Tallahassee, FL, 32310 Email: sylvie.naar@med.fsu.edu
Lina Rosengren-Hovee, MD, MPH, MS Co-Investigator Assistant Professor, Division of Infectious Disease UNC-Chapel Hill Department of Medicine CB# 7030, Bioinformatics Building 130 Mason Farm Road, 2nd Floor Chapel Hill, NC 27599-7030 Email: lina_roho@med.unc.edu	Kate Muessig, PhD Co-Investigator Associate Professor Gillings School of Global Public Health UNC-Chapel Hill 135 Dauer Drive Chapel Hill NC, 27599 Email: kmuessig@med.unc.edu
Andrés Martinez, PhD Co-Investigator Statistician Clinical Sciences, FHI 360 359 Blackwell Street Suite 200 Durham, NC 27701 amartinez@fhi360.org	Crissi Rainer, MPHc Study Coordinator College of Nursing Florida State University Vivian M. Duxbury Hall 98 Varsity Way Tallahassee, FL 32306-4310 Email: crainer@fsu.edu
Elizabeth Tolley, PhD Co-Investigator Director of Behavioral, Epidemiological and Clinical Sciences, FHI 360 359 Blackwell Street Suite 200 Durham, NC 27701 Btolley@fhi360.org	Aimee Rochelle, MPH mHealth Manager College of Nursing Florida State University Vivian M. Duxbury Hall 98 Varsity Way Tallahassee, FL 32306-4310 Email: arochelle@fsu.edu
Jonathan Morgan, BS Program Administrator Florida State University College of Medicine Center for Translational Behavioral Science 2010 Levy Ave., Bldg. B, Suite 0266 Tallahassee, FL Email: jm22e@fsu.edu	

9. Explanation of Any Payment or Gift to Respondents

Tokens of appreciation for participation are an important tool used in research and are particularly important for the population in this study. This study seeks to recruit, enroll, and follow a hard-to-reach population, while also asking highly sensitive questions about issues such as sexual behavior, HIV and STI status, and medication adherence. To enhance our ability to recruit 400 young men who have sex with men who are using PrEP and retain at least 80% of that sample, we will provide participants with tokens of appreciation for completing follow up surveys and blood collection activities. Amounts per assessment vary based on estimated survey duration. A subset of participants who are selected and complete qualitative exit interviews will receive additional tokens of appreciation for this activity.

To enhance our ability to retain healthcare providers in the provider training and study activities, we will provide provider participants with tokens of appreciation for completing study activities including surveys and patient interaction assessments. The study team draws on their experience engaging providers in similar research projects including the Tailored Motivational Interviewing Implementation Intervention Effectiveness Trial in Multidisciplinary Adolescent HIV Care Settings study.[48] Amounts are described below.

<u>Aim 1 Provider Trainings</u>

- $50 for pre-training survey
- $50 for post-training survey and patient interaction
- $50 for 3-month post-training patient interaction

Healthcare provider participants can receive up to $150 for completing all Aim 1 study activities.

<u>Aims 2a and 2b: Cohort Participants</u>

- $50 for baseline survey and app download
- $50 for attending the cohort app setup visit
- $25 for 3-month follow-up survey
- $50 for 6-month follow-up survey
- $25 for 9-month follow-up survey
- $50 for 12-month follow-up survey
- $25 for 15-month follow-up survey
- $50 for 18-month follow-up survey

Cohort participants can receive up to $325 total for completing the app download and all seven surveys during the 18-month follow up period.

Returning self-collected blood specimens:
Participants will be asked four times (at baseline, 6, 12 and 18 months after enrollment) to self-collect blood specimens via finger prick and mail the specimen (dried blood spot) to a specified lab. To encourage retention and completion of blood specimens, participants will receive larger tokens for return of blood collection at the later time points. Participants will receive the following compensation for completing and mailing in their blood collection:

- $50 at baseline
- $50 at 6-months
- $50 at 12-months
- $50 bonus for returning all three initial specimens: baseline, 6-month, and 12-month
- $75 at 18-months

Participants can receive up to $275 total for returning blood specimens at all four time points during the 18-month follow up period.

Cohort participants who complete all the above listed study activities (app download and surveys and specimen collections) can receive a total of $600.

Exit interviews:
A subset of cohort participants (N=45), will be invited to complete an exit interview. If the participant accepts the invitation, they will receive $50 for completing the interview.

These tokens of appreciation for completing study activities support study participation and the completion of study activities. The amounts are set by the study Principal Investigators (PIs) based on typical amounts in similar prior studies, consideration of the study budget, and with care being taken that these tokens of appreciation are low enough not to be considered coercive. The PIs and study team draw on their experience engaging YMSM in similar research projects including the P3: Prepared, Protected, and emPowered study[26], HealthMpowerment studies[27,28] and studies conducted within the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)[29,30].

The Office of Information and Regulatory Affairs Office of Management and Budget has issued the following guidance for justifying the use of incentives as part of Information Collection Requests (ICRs), "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."[31] The use of tokens of appreciation in the proposed research is appropriate according to this guidance. One of the primary goals of this study is to implement an intervention to improve PrEP adherence among young men who have sex with men. This study seeks to recruit, enroll, and follow a stigmatized population, while asking highly sensitive questions about issues such as PrEP use, HIV and STI's, and sexual behaviors.

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

The NCHHSTP Associate Director Science Office has reviewed this project and determined that the Privacy Act applies to this information collection activity. A Privacy Impact Assessment has been conducted (**Attachment 8**).

The recipient, Florida State University (FSU) and their partners, will be responsible for collecting all data for this study. Data sent to CDC will not contain participant names or contact information, and each person's data will be identified only by a study participant identification number.

The terms of the CDC Cooperative Agreement authorizing data collection require the recipient to maintain the privacy of all information collected. Section 301(d) of the Public Health Service (PHS) Act, as amended by Section 2012 of the 21st Century Cure Act, P.L. 114-255 (42 U.S.C. 241(d), states that the Secretary shall issue Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. This study meets those requirements. The Certificate of Confidentiality further protects the privacy of subjects by limiting the disclosure of identifiable, sensitive information. With this Certificate, the research team cannot be forced (for example, by court subpoena) to disclose identifying information

from study participants for any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

To ensure the protection of personal privacy of research participants and confidentiality of individually identifiable information, publicly accessible study data will be stripped of all directly identifying information such as the name, social security number or other information that is unique to an individual. Data will also be stripped of indirect identifiers including uncommon race, ethnicity, extreme age, unusual occupation, and other details; however, because the data may be released on an individual level, and because the data contains sensitive, personal information such as sexual risk behaviors, CDC will take all precautions to safeguard confidentiality of study participants. A restricted data set necessitates the use of a data sharing agreement between CDC and the requesting entity. The data sharing agreement ensures that CDC's guiding principles of accountability, privacy and confidentiality, stewardship, scientific practice, efficiency, and equity are adhered to. In order to ensure participant confidentiality, the data sharing agreement sets restrictions on the use of data; a prohibition on efforts to determine the identity of any individual, group or organization whose data appears in the dataset; a prohibition on linking the data with individual identifiable data from other datasets; a prohibition on disclosing the identity of data subjects; and order to immediately disclose to the CDC project officer if an individual identity is discovered.

To preserve and share data in a manner that enables validation of results by recipients (e.g., allowing for replication of published findings and conclusions), analytical datasets and statistical code will be retained by the FSU Research Team until analyses are complete. Per the University's data retention and disposal policy, data will be retained for up to 3 years following study closure by the FSU Research Team; at that time, users must delete all data stored on their servers. Regarding the public access dataset, CDC will store complete de-identified data on a secure server that is accessible through the Division of HIV Prevention, HIV Research Branch for 6 years; after which time, the data will be archived according to guidance set forth by CDC Records Management Policy, Policy # CDC-GA-2005-07 (updated 9/14/2021).

All information provided by participants will be kept confidential and private as permitted by law. To maintain participant confidentiality, all surveys, case report forms (CRFs), medical record data, biological specimens and other study records will be identified by a coded number (a participant identification number) and kept separately from the documents containing participant's names and other identifying information (i.e., informed consent forms, contact information forms, as well as the linking document which pairs the participant identification number with the name of the study participant). The study will safeguard against the risk of the linking information being stolen by keeping such information in REDCap, a HIPAA compliant secure platform, to which only essential study personnel who have completed CITI certification for human subjects' research ethics training (http://citiprogram.org) will have access. Further, several safeguards have been created to ensure the security and integrity of the data. The intervention content, questionnaires, and personal information will be secured with role-based security that will provide different types of users with different access privileges. Separate data collection modules, located in different firewalled servers, have been created to collect personal identifying information, questionnaire data, and to run the study app.

Numerous features are included to ensure app security and privacy. All relevant app communications (e.g., those between participants or those between participants and staff) will be secured via industry

standard encrypted SSL communications links. These connections will ensure that all communications are inaccessible to unauthorized third parties. Furthermore, the app can be updated regularly to address any unforeseen security updates to the software libraries underlying the secured communication links. Beyond encrypting communication, users will need to log in with a username and password to access the app, even if the use of their phone is "unlocked." This will allow the user to share their phone generally with others without granting access to EPICC app. These software security solutions will provide the layers of both communications' security and physical access security to ensure that only authorized users have access to the information stored on the phone as well as the information being shared over communications links.

All audio recordings (of interviews or focus groups) will be downloaded and stored on a password-protected, encrypted computer and transferred to encrypted servers. Transcription of audio files will be conducted using a HIPAA-compliant transcription service. Any names mentioned in the audio files will be redacted during transcription. Interview transcripts will be stored in REDCap. Biomedical data will be collected by study staff from electronic health records (EHR) and entered on case report forms in REDCap.

Public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. Data on individual participants will not be released to the public. Any data made publicly available after the completion of the study will be de-identified and will not be linked to participant contact information The Data Use Plan outlines the procedures for public access to study data (**Attachment 7**). All study data will be retained by the FSU Research Team until analyses are complete and for up to three years following study closure by the FSU Research Team. At that time, users must delete all data stored on their servers.

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

The study protocol, the data collection instruments, and all accompanying documents have been reviewed and will be approved by the Florida State University IRB (**Attachment 6a**). For purposes of this study and information collection, the study research partners/clinics will defer to the Florida State University IRB (**Attachments 6b – 6l**).

Sensitive Questions

All participants will be told during the informed consent process about the nature of sensitive data that will be collected in the study (i.e., sexual activity, prevention methods, drug use, etc.). Participants will be informed that they may decline to answer any question at any time. Further, they will be told that their participation is voluntary and that they can chose to stop participating at any time without any consequences. Sensitive questions are needed given the nature of the study to understand participant's need for PrEP, PrEP choice(s), barriers, and facilitators to use, context around PrEP use, discontinuation, etc. to improve medical care, tools and resources available to support patients with PrEP uptake, adherence, and persistence.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimates of Annualized Burden Hours

For the Aim 1 provider training, we estimate that screening (**Attachment 4a**) and the collection of contact information (**Attachment 4b**) will each take five minutes. It is expected that 50% of providers screened will meet eligibility and decide to enroll in the study. Pre-training and post-training surveys will take approximately 15 minutes each to complete (**Attachments 4c and 4d**). Patient interaction assessments (**Attachment 4e**) delivered at baseline and 3 months will take approximately 15 minutes each to complete. For Aim 2a, the effectiveness-implementation trial, it is expected that 50% of YMSM screened will meet study eligibility. The initial screening (**Attachment 4f**) will take five minutes to complete, and the collection of contact information (**Attachment 4g**) will take five minutes. The HIPAA form (**Attachment 4h**) will take approximately five minutes to complete. The baseline assessment will take approximately 45 minutes to complete (**Attachment 4i**). The follow-up assessments will take approximately 45 minutes to complete and will be administered quarterly for a total of six times during the 18-month follow up period (**Attachment 4k**). Study staff will assist participants to setup the EPICC+ app, a process that will take 30 minutes (**Attachment 4j**). Participants will be mailed a dried blood spot (DBS) specimen collection kit that will take approximately 30 minutes to read, collect the specimen, and ship (**Attachment 4l**). The patient exit interview takes approximately 60 minutes to complete and will be delivered one time to a subset (N=45) of YMSM participants (**Attachment 4m**). For the Aim 2b provider focus groups, it is expected that 50% of providers screened will meet eligibility and decide to enroll in the study. We estimate it will take approximately five minutes to conduct the screening (**Attachment 4n**), five minutes to collect contact information (**Attachment 4o**) and another five minutes to conduct the pre-focus group survey (**Attachment 4p**). Providers will attend one focus group that is expected to take 120 minutes to complete (**Attachment 4q**). Clinic-level assessments at baseline and study end are estimated to take 120 minutes to complete (**Attachment 4r**). Clinic-level assessments conducted at six-month intervals between the baseline and study end points are expected to take 90 minute to complete (**Attachment 4s**).

Overall, this study will enroll up to 478 participants. Total study enrollment for Aim 1 is 30; over the three-year study period, the estimated annual enrollment is 10. Total enrollment for Aim 2a is 400; over the three-year study period, the estimated annual enrollment is 134. For Aim 2b, total study enrollment is 48, and the estimated annual enrollment is 16. Additionally, a clinic staff member at each of the seven participating clinic sites will complete a clinic assessment form every 6 months throughout the study period.

There are no costs to the participant other than their time. The total number of burden hours is 3,535 across 36 months of data collection. The total estimated annualized burden hours are 759. Total burden for each activity has been rounded up to whole hours.

Exhibit 12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hrs)	Total Burden (in hrs)
Health Practitioners	Aim 1 Provider Training Screener	20	1	5/60	2
Health	Aim 1 Provider Training	10	1	5/60	1

Practitioners	Contact Information				
Health Practitioners	Aim 1 Provider Pre-Training Survey	10	1	15/60	3
Health Practitioners	Aim 1 Provider Post-Training Survey	10	1	15/60	3
Health Practitioners	Aim 1 Provider Patient Interaction (Baseline and Final)	10	2	15/60	5
General Public – Adults	Aim 2a Cohort Screener (English/Spanish)	267	1	5/60	22
General Public – Adults	Aim 2a Cohort Contact Information (English/Spanish)	134	1	5/60	11
General Public – Adults	Aim 2a Cohort HIPAA Form (English & Spanish)	134	1	5/60	11
General Public – Adults	Aim 2a Cohort Baseline Survey (English/Spanish)	134	1	45/60	101
General Public – Adults	Aim 2a Cohort Follow-up Survey (English/Spanish)	134	3	45/60	302
General Public – Adults	Aim 2a Cohort App Setup (English/Spanish)	134	1	30/60	67
General Public - Adults	Aim 2a Cohort Blood Collection Instructions (English/Spanish)	134	2	30/60	134
General Public - Adults	Aim 2a Cohort Exit Interview (English/Spanish)	15	1	60/60	15
Health Practitioners	Aim 2b Provider Focus Group Screener	32	1	5/60	3
Health Practitioners	Aim 2b Provider Focus Group Contact Information	16	1	5/60	1
Health Practitioners	Aim 2b Provider Pre-Focus Group Survey	16	1	5/60	1
Health Practitioners	Aim 2b Provider Focus Group Guide	16	1	2.0	32
Health Practitioners	Aims 1&2 Clinic Assessment (Baseline & Final)	9	1	120/60	18
Health Practitioners	Aims 1&2 Clinic Assessment (every 6 months)	9	2	90/60	27
Total					759

12B. Estimated Annualized Burden Costs

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 2021 (http://www.bls.gov/oes/current/oes_nat.htm) was used to estimate the hourly wage rate for the general public and clinic staff for the purpose of this request. This cost represents the total burden hours to respondents multiplied by the average hourly wage rate for general public adults ($28.01) and Health Practitioners and Technical Occupations ($43.80). Annualized burden costs are $22,775.43.

Exhibit 12.2: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Respondent Costs
Health Practitioners	Aim 1 Provider Training Screener	2	$43.80	$87.60
Health Practitioners	Aim 1 Provider Contact Information	1	$43.80	$43.80
Health Practitioners	Aim 1 Pre-Training Provider Survey	3	$43.80	$131.40
Health Practitioners	Aim 1 Post-Training Provider Surveys	3	$43.80	$131.40
Health Practitioners	Aim 1 Patient Interaction Rating Scale (Baseline and Final)	5	$43.80	$219.00
General Public - Adults	Aim 2a Cohort Screener (English/Spanish)	22	$28.01	$616.22
General Public - Adults	Aim 2a Cohort Contact Information Survey (English/Spanish)	11	$28.01	$308.11
General Public - Adults	Aim 2a Cohort HIPAA Form English & Spanish	11	$28.01	$308.11
General Public - Adults	Aim 2a Cohort Baseline Survey (English/Spanish)	101	$28.01	$2,829.01
General Public - Adults	Aim 2a Cohort Follow-up Survey (English/Spanish)	302	$28.01	$8,459.02
General Public - Adults	Aim 2a Cohort App Setup (English/Spanish)	67	$28.01	$1,876.67
General Public - Adults	Aim 2a Cohort Blood Collection Instructions (English/Spanish)	134	$28.01	$3,753.34
General Public - Adults	Aim 2a Cohort Exit Interview (English/Spanish)	15	$28.01	$420.15
Health Practitioners	Aim 2b Provider Focus Group Discussion Screener	3	$43.80	$131.40
Health Practitioners	Aim 2b Provider Focus Group Contact Information	1	$43.80	$43.80
Health Practitioners	Aim 2b Provider Pre-Focus Group Survey	1	$43.80	$43.80
Health Practitioners	Aim 2b Provider Focus Group Guide	32	$43.80	$1,401.60
Health	Aims 1&2 Clinic Assessment	18	$43.80	$788.40

Practitioners	Baseline & Final			
Health Practitioners	Aim 1&2 Clinic Assessment every 6 months	27	$43.80	$1,182.60
Total		750		**$22,775.43**

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 annual cost to the government for the data collection is estimated to be $1,112,799.00 (Exhibit 14.1).

Exhibit 14.1: Annualized Cost to the Government

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government	CDC, Physician Project Officer (GS-13 0.30 FTE)	$ 30,436
	CDC, Co-Project Officer (GS-13, 0.10 FTE)	$ 9,708
	CDC, Project Coordinator (GS-12, 0.40 FTE)	$ 32,655
	Subtotal, Direct Costs	**$ 72,799**
Cooperative Agreement Costs	**Annual Cooperative Agreement #PS21-003 Costs**	**$ 1,040,000**
	ANNUALIZED COST TO THE GOVERNMENT	**$ 1,112,799**

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 will focus on questions related to the study objectives. The study will use a pre-post design to compare provider knowledge retention at pre-, baseline and post-training levels. A pre-post design will also be used to track participant PrEP adherence. Survival analyses will be conducted to describe time to first discontinuation and time to first non-adherence. Patient qualitative interview and provider focus group data will be analyzed to describe intervention experiences and barriers and facilitators to intervention implementation.

Data collection will occur over a period of 36 months. Assuming OMB approval on December 2023, data collection will be carried out January 2024-December 2026, and the final data set and report will be submitted in April 2027. We are requesting approval for 3 years of data collection. The project timeline is detailed in exhibit 16.1.

Exhibit 16.1: Project Time Schedule

Activity	Time Schedule
OMB Approval Date	December 2023
Develop data collection tools, sampling and data plans, study protocol	September 2021-January 2023
Recruitment	1-18 months after OMB Approval
Data Collection	1-36 months after OMB Approval
Data analysis finalized and report drafted	40 months after OMB Approval
Final de-identified data set submitted to CDC	40 months after OMB Approval

In compliance with the CDC policy on data management and access, we will develop final, de-identified (names, other personally identifiable information, and locations will be removed) quantitative and qualitative datasets for this study along with the corresponding data documentation, which will be made publicly available within 18 months of the end of data collection. It is anticipated that the data collected through this study will be shared as summary data tables and restricted use dataset(s). A data use plan for information collected during this study has been developed. The plan describes in detail how data access will be provided and the provisions for protection of privacy, security, intellectual property, or other rights (**Attachment 7**).

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

1. Centers for Disease Control and Prevention. HIV Surveillance Report, 2016. Volume 28. November 2017. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html Accessed [April 12, 2020].
2. HIV.gov. What is ‘Ending the HIV Epidemic: A Plan for America’? Available at: https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview. Last Accessed: December 5, 2020.
3. Hosek S, Rudy B, Landovitz R, et al. An HIV Pre-Exposure Prophylaxis (PrEP) Demonstration Project and Safety Study for Young MSM ages 18-22 in the United States (ATN 110). International AIDS Society. Melbourne, Australia 2015.
4. Anderson PL, Glidden DV, Liu A, et al. Emtricitabine-tenofovir concentrations and pre-exposure prophylaxis efficacy in men who have sex with men. Science Translational Medicine 2012;4.

5. Pulsipher CA, Montoya JA, Plant A, Curtis P, Holloway IW, Leibowitz AA. Addressing PrEP disparities among young gay and bisexual men in California. Los Angeles, CA: UCLA HIV/AIDS Policy Research Center at UCLA/APLA Health; 2016.
6. Bauermeister JA, Meanley S, Pingel E, Soler JH, Harper GW. PrEP awareness and perceived barriers among single young men who have sex with men. Current HIV Research 2013;11:520-7.
7. Strauss BB, Greene GJ, Phillips G, et al. Exploring patterns of awareness and use of HIV pre-exposure prophylaxis among young men who have sex with men. AIDS and behavior 2017;21:1288-98.
8. Strauss BB, Greene GJ, Phillips G, 2nd, et al. Exploring patterns of awareness and use of HIV preexposure prophylaxis among young men who have sex with men. AIDS & Behavior 2017;21:1288-98.
9. Kuhns LM, Hotten AL, Schneider JA, Garofalo R, Fujimoto K. Use of pre-exposure prophylaxis (prep) in young men who have sex with men is associated with race, sexual risk behavior and peer network size. AIDS & Behavior 2017;21:1376-82.
10. Ya-lin AH, Zhu W, Smith DK, Harris N, Hoover KW. HIV preexposure prophylaxis, by race and ethnicity—United States, 2014–2016. Morbidity and Mortality Weekly Report 2018;67:1147.
11. Jenness SM, Maloney KM, Smith DK, et al. Addressing gaps in HIV preexposure prophylaxis care to reduce racial disparities in HIV incidence in the United States. American journal of epidemiology 2018.
12. Control CfD, Prevention. HIV prevention pill not reaching most Americans who could benefit—especially people of color 2018. 2018.
13. Rolle C-P, Rosenberg ES, Siegler AJ, et al. Challenges in Translating PrEP Interest Into Uptake in an Observational Study of Young Black MSM. Journal of acquired immune deficiency syndromes (1999) 2017;76:250-8.
14. Holloway IW, Tan D, Gildner JL, et al. Facilitators and Barriers to Pre-Exposure Prophylaxis Willingness Among Young Men Who Have Sex with Men Who Use Geosocial Networking Applications in California. AIDS Patient Care STDS 2017;31:517-27.
15. LeGrand S, Knudtson K, Benkeser D, et al. Testing the Efficacy of a Social Networking Gamification App to Improve Pre-Exposure Prophylaxis Adherence (P3: Prepared, Protected, emPowered): Protocol for a Randomized Controlled Trial. JMIR Res Protoc 2018;7:e10448.
16. Rolle CP, Rosenberg ES, Siegler AJ, et al. Challenges in Translating PrEP Interest Into Uptake in an Observational Study of Young Black MSM. J Acquir Immune Defic Syndr 2017;76:250-8.
17. Fauci AS, Redfield RR, Sigounas G, Weahkee MD, Giroir BP. Ending the HIV Epidemic: A Plan for the United States. JAMA 2019;321:844-5.
18. HIV.gov. National HIV/AIDS Strategy (2022-2025). Available at: http://www.hiv.gov/federal-response/national-hiv-aids-strategy/national-hiv-aids-strategy-2022-2025. Last Accessed: May 5, 2022.
19. Reginfo.gov. ATTACHMENT 2 Section 301 of the Public Health Service Act [42 U.S.C. 241]. Available at: https://www.reginfo.gov/public/do/DownloadDocument?objectID=92941901. Last Accessed: May 5, 2022.
20. US Public Health Service. “Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update. Clinical Providers’ Supplement”. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdchiv-prep-provider-supplement-2017.pdf. Last accessed: December 15, 2020.
21. US Public Health Service. “Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update. A Clinical Practice Guideline”. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdchiv-prep-guidelines-2017.pdf Last accessed: December 15, 2020.
22. Elopre L, McDavid C, Brown A, Shurbaji S, Mugavero MJ, Turan JM. Perceptions of HIV Pre-Exposure Prophylaxis Among Young, Black Men Who Have Sex with Men. AIDS Patient Care STDS 2018;32:511-8.

23. Elwyn G, Frosch D, Rollnick S. Dual equipoise shared decision making: definitions for decision and behaviour support interventions. Implement Sci 2009;4:75.
24. Beres LK, Simbeza S, Holmes CB, et al. Human-Centered Design Lessons for Implementation Science: Improving the Implementation of a Patient-Centered Care Intervention. J Acquir Immune Defic Syndr 2019;82 Suppl 3:S230-S43.
25. Grants.gov. RFA-PS-21-003 PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices. Available at: https://www.grants.gov/web/grants/view-opportunity.html?oppId=328319. Last accessed: May 5, 2022.
26. LeGrand S, Knudtson K, Benkeser D, et al. Testing the Efficacy of a Social Networking Gamification App to Improve Pre-Exposure Prophylaxis Adherence (P3: Prepared, Protected, emPowered): Protocol for a Randomized Controlled Trial. JMIR Res Protoc 2018;7:e10448.
27. Hightow-Weidman LB, Legrand S, Muessig KE, et al. A Randomized Trial of an Online Risk Reduction Intervention for Young Black MSM. AIDS Behav 2019;23:1166-77.
28. Muessig K, Golinkoff JM, Hightow-Weidman L, et al. Increasing HIV Testing And Viral Suppression Via Stigma Reduction In A Social Networking Mobile Health Intervention Among Black and Latinx Young Men And Transgender Women Who Have Sex With Men (Healthmpowerment). . JMIR Res Protoc 2020;In Press.
29. Hightow-Weidman LB, Muessig K, Rosenberg E, et al. University of North Carolina/Emory Center For Innovative Technology (Itech) For Addressing The HIV Epidemic Among Adolescents and Young Adults in the United States: Protocol and Rationale for Center Development. JMIR Res Protoc 2018;7:E10365.
30. Hightow-Weidman L, Muessig K, Claude K, Roberts J, Zlotorzynska M, Sanchez T. Maximizing Digital Interventions for Youth in the Midst of Covid-19: Lessons from the Adolescent Trials Network for HIV Interventions. AIDS Behav 2020.
31. Office of Information and Regulatory Affairs OoMaB. Questions and Answers When Designing Surveys for Information Collections. Washinton, DCJan 2006 (Last Modified Oct 2016).