Participant ID#: _____

Louisiana State University Health Sciences Center - New Orleans

Consent to Participate in Research

STUDY TITLE:	Assessing the feasibility and preliminary impact of an mHealth app on reducing STI risk in Black MSM PrEP
PRINCIPAL INVESTIGATOR:	Meredith Clement, MD
EMERGENCY CONTACT:	Meredith Clement, 252-902-4961 (cell), or Clare Kelsey, 504-252-1698 (cell)
STUDY SPONSOR:	National Institute of Allergy and Infectious Diseases (NIAID)

1. Invitation to be Part of a Research Study

Dr. Meredith Clement and associates from the LSU-CrescentCare Sexual Health Center at the Louisiana State University Health Sciences Center in New Orleans (LSUHSC-NO) are conducting a research study. A research study is a scientific way to improve or develop new methods of health care. Studies are designed to answer specific questions on how to prevent, diagnose, or treat diseases and disorders. Dr. Meredith Clement disclosed that she is a paid medical monitor for FHI 360/has a financial relationship with FHI 360, an organization whose interests are related to this research study. This study is being funded by the National Institute of Allergy and Infectious Diseases (NIAID). The research team is asking you to be in this study because [you are in care for HIV pre-exposure prophylaxis (PrEP) and meet the eligibility criteria: you are an 18-35 year old Black man who has sex with men]. **Research studies are voluntary and include only people who choose to take part.** The researchers will explain this study to you and this consent form will help you decide if you want to participate. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.
- Even if you choose to participate, you can decide to stop participating at any time.

In this consent form, “you” always refers to the participant. If you are a legally authorized representative, please remember that “you” refers to the study participant.

2. Important Information about this Research Study

This section lists the key characteristics of this study and the basic reasons why you may or may not want to take part. It is only a summary. The sections following this summary have more details, including contact information for people who can answer any questions or concerns you may have. Please take time to read this whole document and ask questions before deciding if you want to take part in this research study.

- In order to participate, you must be:

- A cisgender man who has sex with cisgender men (MSM) including gay, bisexual, or other MSM
- Age 18-35 years
- Black race or multi-racial including Black race
- Prescribed, administered or otherwise taking PrEP via routine care or PrEP clinical trial
- Smartphone possession
- Client at the LSU-CC Sexual Health Center
- Able to read and write
- Fluent in English

Things you should know:

- The purpose of the study is to test the effect of a new smartphone application called "PCheck" on reducing the rate of STIs, compared to routine care through the LSU-Crescent Care Sexual Health Clinic. The PCheck app is designed to facilitate PrEP adherence and encourage STI prevention behavior. The app includes a calendar feature that allows users to document daily PrEP adherence, sexual encounters, STI prevention behaviors, mood, and stress levels. To encourage peer support and a sense of community, users can interact with community members anonymously through a message board, monitored by research staff. PCheck also allows users to securely send messages and medical documents to providers. Participants will be randomly assigned to use the app for 24 months, or participate in routine PrEP care, without using the app.
- If you choose to participate, you will be randomly assigned to one of two groups after you enroll: two-thirds of participants will use the PCheck app for two years, and the other third would not use the app and continue routine PrEP care as usual for two years. At the enrollment visit, those randomized to the app group will receive a training of the PCheck app. The group not assigned to the app would serve as a control group, or comparison group, so we can test the effect of the intervention on an otherwise similar population. All participants (those using the app and those in routine care) will complete STI testing every three months are part of routine PrEP care and complete a survey with demographic, social, and behavioral questions at every study visit. We would like to gain a better understanding of the factors that may put people taking PrEP at risk for STIs. There are no study drugs in this research.
- You will be in the study for 24 months, or two years, if you decide to stay for the whole study. Including the enrollment visit, there will be 9 study visits total (at day 1, 3 months, 6 months, 9 months, 12 months, 15 months, 18 months, 21 months, and 24 months) on which you would complete the survey. Study visits will be scheduled to happen on the same day as your routine PrEP appointments or STI testing, or at a time that is convenient for you.
- The main risks of being in the study are that you might become embarrassed or worried when entering personal information in the PCheck app or the survey. We take substantial measures to protect the privacy and confidential of this information. Additionally,

although all users on the PCheck app will use anonymous avatars any information shared in the community message board cannot be guaranteed to stay confidential.

- You might benefit from being in the study by experiencing a greater sense of motivation to participate in PrEP care, but there are no major personal benefits to being in this study. This study may contribute to a better understanding of STD prevention among PrEP users, which may have a public health benefit.
- You could get these benefits without being in the study by continuing to attend your routine PrEP appointments.
- Taking part in this research study is voluntary; you do not have to participate. If you do take part, you can stop at any time.

3. Why is this study being done?

Past research shows that PrEP users who are Black men who have sex with men (MSM) between the ages of 18-35 are particularly at risk for STIs. Among BMSM, factors such as social isolation, medical mistrust, and experiences of racism and homophobia have been shown to drive sexual risk taking. These and other barriers to STI risk reduction practices have not been thoroughly characterized in PrEP users, particularly Black MSM.

Mobile health applications offering peer support are a promising solution to effect behavioral change and reduce STIs in Black MSM prescribed PrEP. Findings from this study will potentially be used to support a new method of reducing STI through app technology.

4. What will happen if I take part in this study?

Before you begin the study

Before you begin the study, you must verbally confirm that you meet eligibility criteria.

During the study

If you agree to take part in this study, you will be asked to complete the following.

For all participants, your typical PrEP clinic visit will not be affected, but at the end we will ask that you take a 30-45 minute online survey with demographic, social, psychological, and behavioral assessments. These surveys will be completed at your first study visit and then every three months (for a total of two years—a total of 8 follow up visits) when you return for your routine PrEP follow-up visits. The questionnaires will include questions about peer support and social networks, stigma, discrimination, depression/anxiety and other social factors, as well as questions regarding your behaviors while on PrEP. For example, we will ask about such things as number of sexual partners, history of sexually transmitted infection, and drug and alcohol use.

For all participants, we will review your medical records (if in care at CrescentCare) or use your self-reported STI diagnoses (if in care outside of CrescentCare) to track STIs over the course of the study. As part of routine PrEP care, all participants will complete STI (syphilis, gonorrhea,

chlamydia, HIV) screening every three months and screening for the Hepatitis C Virus will occur every 6-12 months.

Participant Retention

We will collect contact information (phone numbers, social media information, and email addresses) for all participants, which will be updated at each clinic visit. Providing social media contact information is optional. Social media contact information will only be used if you cannot be reached through other forms of contact information. Efforts will be made to contact you up to five times after any missed appointment or check-in. The research coordinator will send text reminders to encourage engagement with the app and remind participants of upcoming STI screening visits.

Sample Timeline

Visit 1, Day 1 (Screening and Enrollment)

This visit is estimated to take approximately 45-60 minutes. This includes the time it will take to complete the study questionnaire. During your clinic visit, the study team will speak with you regarding the study requirements and review your medical records to determine if you qualify for the study. Only eligible patients will be enrolled in the study. You will not randomly assign you to a study group (app group or routine care group) until after you are enrolled in the study. Once enrolled, you will be asked to provide contact information including your telephone number, address, and alternate contacts. We will request that you put the study team's contact information in your phone so that you know who is trying to reach you in the circumstance that follow-up phone calls are needed.

Using your choice of a clinic iPad or your own personal device, you will be asked to complete the first round of survey questions, listed below. If you choose to complete the survey on your device, the coordinator will email you a secure link to the survey.

Assessments:

- Demographic information (date of birth, sexuality, race, ethnicity)
- Socioeconomic information (referral source, employment, education, housing, income, PrEP payment source)
- Social support assessment
- Social isolation assessment
- Mental health assessments (depression, anxiety)
- Discrimination assessments (experience of racism and homophobia)
- Medical mistrust assessments
- Perceived stigma assessments
- PrEP questions (barriers to PrEP care, stigma, and adherence)
- Sexual practices assessment (number of partners, type of sex, condom use)
- Drug use (tobacco, alcohol, and drug use)
- STIs diagnosed outside of LSU-CrescentCare Sexual Health Clinic

These questions will be asked as part of validated tools/scales that assess mental well-being, feelings of stigma, social support/isolation, medical mistrust, or other possible contributors to sexual behavior. The survey data will be stored in a secure database. This information will be kept strictly confidential.

App-Specific Procedures

If you are assigned to the app group, we will train you in how to use the app. The training is anticipated to take 15-30 minutes and will include an overview of the app's features and how to use each, coaching about using the daily check-in feature to record mood, stress levels, recent sexual activity and condom use, guidance on creating an anonymous introductory post to the community board, and practice using each of the PCheck features.

You can use the app as much as you wish throughout the study. There is no set expectation for how frequently you should use the app, although we will encourage everyone to use it regularly to thoroughly test it. The app will send notification reminders to "check in" (in other words, use the daily check-in feature to track your mood, stress, and behaviors related to STI-prevention over time). The notification settings can be adjusted or turned off in your phone settings.

For participants receiving the app intervention, we will also schedule a follow-up call within two weeks after enrollment to encourage engagement, to talk through any difficulties that arise with using the app and to troubleshoot. During the 24 months of enrollment, we will contact anyone at the 1, 2, 4, and 12 week marks after they stop showing usage on the app to encourage re-engagement and address any technical or other barriers.

To encourage engagement with the app, we will post short quizzes on the app's landing page and reminders about them on the community message board. We will pilot once-a-day trivia questions, and adjust the frequency of trivia postings pending on participant engagement and/or feedback. Each set of trivia questions will take a couple minutes to complete and will ask 1-2 questions such as general knowledge about STIs, sexual health and wellness, and/or general New Orleans-specific or LGBTQI+ history. All participants who complete four of the quizzes for the week will be entered into a raffle for an additional $10 loaded onto their Clincard (a visa gift card you will receive as compensation for your participation).

For app users, we will extract data directly from the PCheck app, including app usage and data from the app's check-ins, adherence, and STI prevention features. Data extracted from the app will not have your name or personal information on it. In other words, data on sexual encounters and PrEP adherence will remain de-identified in study documents. However, in order to contact individuals showing low app usage, we will connect usage data extracted from the app to participants' contact information to reach out to individuals and encourage app engagement, as described above. The data extracted from the app will be anonymous in the analysis.

Follow-up Study Visits (9)

All participants, whether in the app group or routine care group, will attend follow-up study visits, which will last approximately 30-45 minutes and occur every 3 months (at month 3, 6, 9, 12, 15, 18, 21, and 24). All study visits will be scheduled as part of your routine PrEP follow-up visits if you are in PrEP care at CrescentCare, or at a time that is convenient for you. If receiving PrEP services outside of CrescentCare, you will be given the option to come into the CrescentCare clinic to complete the survey on the clinic iPad or receive the secure survey link via email to complete at your convenience on your own device. You will be asked to complete a similar survey to the one completed at enrollment, with stable factors removed (for example, age, race, and ethnicity). If you are randomized to group using the app, you will also be asked to complete questions about the app such as how easy it is to use, frequency of use, and technical difficulties. The quarterly surveys will be completed on your choice of clinic iPad or your own personal device. The CRC will email you a link to the survey in REDCap if you choose to complete it on your own device. If the CRC cannot meet you at the STI clinic visit (for example, if you attend the appointment at an unscheduled time or do not have time to complete it at the visit), then the CRC will send the secure survey link via email and you can complete it on your own time.

5. What should I know about genetic research?

Not Applicable

6. How many people will take part in this study and how long will it last?

In total, 120 clients from the LSU-CrescentCare Sexual Health Center in New Orleans will take part in this study.

If you complete the entire study, your participation will last 24 months.

7. What are the risks of taking part in this study?

Known risks and discomforts

The known risks and discomforts from the study procedures are as follows.

Risk of Questionnaire

You may become embarrassed, worried, or anxious when entering personal information about your sexual practices, social support and other social factors (mental health, sense of stigma, etc) drug, tobacco and alcohol use, and other information into the iPad or PCheck app. You may refuse to answer any of the questions (these can be skipped) and you may take a break or stop your participation in survey completion at any time. In the instance where you have any sense of overwhelming emotional response to the survey, the study team will follow the standard operating procedures regarding emergency psychiatric issues. If you are not felt to be an immediate danger to yourself or others, you will be referred to a mental health specialist.

Risk of PCheck App Usage

Users of the PCheck app will be encouraged to interact with other app users anonymously via the community message board. Although participants will be asked to not share any information disclosed in the community message board with outside parties, any information shared in the community message board cannot be guaranteed to stay confidential. Participants using PCheck do not have the capability to message other participants via the app; the messaging feature is set up to only allow users to communicate with their care team. All information shared by users with their care team via the app is strictly confidential. At the end of the study, all users' accounts will be deactivated.

Risk of Loss of Confidentiality

Every effort will be made to keep your information confidential, however, this cannot be guaranteed. Study records that identify you will be kept confidential as required by law. Only people who are involved in the conduct, oversight or auditing of this study will be allowed access to your records.

8. Are there any benefits to participating in this study?

Possible benefits to you

You will contribute to a better understanding of how to improve our STI prevention efforts, but there are no direct personal benefits to being in this study. If randomized to use the app, you might experience a sense of positive social support from interacting with peers via the community message board, experience improvement STI risk reduction practices, and/or lead healthier lives as a result of less frequent STIs. All participants might be motivated to participate in PrEP care more consistently due to compensation for surveys and reminders from the CRC to complete visits and surveys. Therefore, greater participation in care may translate into health benefits.

Possible benefits to others or society

This study may help researchers learn more about how mobile phone apps can be utilized to prevent STIs among BMSM PrEP users, which could potentially have a public health benefit.

9. What other choices do I have if I don't take part in this study?

The alternative is not to participate in this research study.

10. How will my information be kept confidential?

All of your data will be password-protected and stored on secure servers at LSUHSC and University of Virginia (UVA). We will collect contact information (phone numbers, social media contact information, and email addresses) for all participants, which will be updated at each study visit or check-in. Laboratory results will be reported in your electronic health record and transferred to password-protected files.

You will be assigned a random unique identification number. A separate password-protected file will be created linking the random IDs to the medical record number, PCheck app username, and contact information of participants so that data and STI test results can be subsequently linked to that participant. The log linking study participant names and study ID numbers will be destroyed when study activities are complete. All physical information (e.g. informed consent forms) will be kept in locked filing cabinets at LSUHSC.

The PCheck platform requires a password to access and has other security features to protect member information such as biometric login options. The password is unique for each member and members will only be able to change it by calling a PCheck staff member. In the app, you have the option to use biometric features (FaceID/TouchID) on your smartphone to log into the app for additional security. The app will remind you to check-in or notify you if have new messages via pop-up notifications, but these notifications will not show any content. You can also disable notifications in your phone settings at any time. For example, a notification would only say “new message” or “check-in” alongside the PCheck app icon (the letter “P” and a checkmark). All information in the PCheck app is encrypted and transmitted securely. All communications and transactions between the PCheck servers and apps are encrypted — not just sensitive information.

In the app, you will have access to a documents feature that will allow you to capture and upload images to share with study personnel and providers. During the image capture process, images will not be stored to your phone and will only store within the PCheck app. PCheck users, study staff, and provider participants will have access to the anonymous community board. All users will choose a personalized avatar and pseudonym as their profile name and will be instructed to not disclose any identifying information. The community board content is monitored daily by study staff. Access to use the PCheck app is authorized only by study personnel. Information entered into the PCheck app is visible only to authorized study personnel and the PCheck app development team. The PCheck app development team only have access to information that participants or providers enter in the app. This information includes profile name, self-reported data to daily check-ins, encounter logs, messages, and documents exchanged between participants and care team, and system activity. PCheck will use this information to monitor and enhance the user experience and support positive health outcomes. This information is not shared with outside parties.

We will make every effort to maintain your privacy but we cannot guarantee complete confidentiality. For example, there is always a risk of someone breaking into a computer system where your information may be stored. Federal or state law also may require us to disclose your records. Loss of confidentiality is a potential risk of taking part in this study.
The following people or groups may review your study records for purposes such as quality control or safety:

- The study sponsor, the National Institute for Allergy and Infectious Diseases, and/or a representative of the sponsor
- Representatives of LSUHSC-NO and the LSUHSC-NO Institutional Review Board
- Other organizations or agencies if required by law.

The results of the study may be released to the funding agency the National Institute for Allergy and Infectious Diseases. If any publications and/or presentations result from this study, they will not identify you by name.

11. Will my information/specimens be used for future research?

We will not use or share any of your information collected as part of this study for future research.

12. Will there be any costs to me for taking part in this study?

There will be no costs to you for taking part in this study. **If you take part in this study, you will not have any expenses beyond the routine costs for patients enrolled in PrEP care**.

As part of routine STI testing in PrEP care, your provider will bill you and/or your insurance company (or healthcare plan) for the costs of any standard medical care you receive during your participation in the study. You will be responsible for any co-payments and deductibles.
If you are randomized to the app group, the PCheck app is provided free of cost. We will also compensate via Clincard an additional $20 for travel when required. For example, we will load an additional $20 onto your Clincard if we ask you to come into the clinic for a study visit, on a date that you did not have a previously scheduled routine care appointment.

We do not have money to pay for any disability, damages such as lost wages, or similar outcomes that you may experience.

13. Will I be paid or for taking part in this study?

You will receive $60 for the first study visit and $40 for each subsequent survey completed as part of your participation in this study. The total amount of compensation for all study visits and questionnaire completion is $380, which includes your initial visit and 8 follow-up visits to span one year. You will receive a $60.00 gift card for Visit 1 and $40.00 will be added to the same gift card for visits 2 through 9. The gift card will be activated by the research coordinator within 48 hours of your survey completion for each visit. If you are assigned to the app study group and win the weekly raffle, an additional $10 will be loaded onto your Clincard. If the gift card is lost or stolen, you will have to contact the research coordinator. If your participation in the study ends for any reason, you will be compensated for all study surveys completed up until that point.

The study team will release your name, address, social security number and amount of payment to Accounting Services. If the total payment for your participation in research is greater than $600 in a year, Accounting Services will report this amount to the Internal Revenue Service as income as required by law.

14. Who can profit from study results?

Not Applicable.

15. What should I do if I get sick or injured during the study?

Not Applicable.

16. Who can I contact if I have questions about this study?

The research team:

You may contact the following individuals with any questions or concerns about the research or your participation in this study.

Principal Investigator

Name: Meredith Clement, MD

Address: 2021 Perdido St, New Orleans LA, 70112

Phone #: 504-568-5204

24-Hour Phone #: 252-902-4961

Research Coordinator

Name: Clare Kelsey

Address: 2021 Perdido St, New Orleans LA, 70112

Phone #: 504-252-1698

Office of the Chancellor, LSU Health Sciences Center - New Orleans:

You may contact the Office of the Chancellor by phone at (504) 568-4801, if

- you have questions about your rights while taking part in this study, or
- you have any concerns or suggestions, and
- want to talk to someone other than the researchers about the study.

Public information about this study:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

The National Clinical Trials number for this study is NCT 05395754.

17. What will happen if I cannot complete the study?

There are several reasons why you may not complete the study.

The researchers or the study sponsor might decide to stop the study at any time.

The researchers may end your participation in this study, without your permission, for a number of reasons including:

- Your safety and welfare are at risk.
- You do not follow instructions.

- You miss scheduled visits.
- You fail to complete study activities.
- Your HIV test becomes positive

You also may decide on your own to stop participating in the study. If you are thinking about withdrawing, let the researcher know so he/she may remove you from the study safely. You also should seek medical advice for alternative treatments. The researcher will inform you of any significant new findings during the study that may impact your willingness to continue participation.

If you decide to stop being in the study, or the study is stopped, or you are removed from the study, the researcher will ask you to:

- Meet for a final close-out visit or evaluation at your next routine care appointment
- Complete an exit telephone interview

You are not required to complete these tasks but some of them may be for your own safety.

Information collected about you up to the point of withdrawal will remain part of the study. You may not remove this data from the study database. We will keep this information confidential.

18. Your Participation in this Study is Voluntary

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason or no reason at all. No matter what you decide, there will be no penalty to you and you will not lose any services, benefits or rights you would normally have. Your routine clinical care will not be disturbed by your decision to participate, or not participate, in the study. If you want more information about your rights as a research participant, please visit https://www.lsuhsc.edu/administration/academic/ors/participant_information.aspx.

If you are a LSUHSC-NO student or faculty/staff member, you may choose not to be in the study or to stop being in the study before it is over at any time. Your decision will not affect your grades or job status at LSUHSC-NO. You will not be offered or receive any special consideration if you take part in this research study.

19. Your Consent

By signing this document, I acknowledge or am aware that:

- The researcher(s) discussed the study with me and answered all my questions.
- I will receive a copy of the consent form.

- I do not waive any of my legal rights by signing this consent document.
- I can contact the study team or the Chancellor's Office using the contact information provided above if I have any questions or concerns after signing the consent form.

Signature of Participant:

I agree to take part in this study.

_____

Participant Signature Printed Name Date

Signature of Person Obtaining Consent:

I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.

_____

Signature of Person Obtaining Consent Printed Name Date