UNIVERSITY OF CALIFORNIA, SAN DIEGO
UNIVERSITY OF CALIFORNIA SAN FRANCISCO
CONSENT TO PARTICIPATE IN RESEARCH

1. Study Title and Number

CHAMPION: **C**ombining **H**IV **A**nd **M**eth **P**revention and Treatment **I**nterventions **O**ptimized for HIV-**N**egative MSM, Study # 810684

2. Principal Investigators

Kiyomi Tsuyuki, PhD and MPH (MPI), Assistant Professor, Department of Medicine, UC San Diego

Glenn-Milo Santos, PhD and MPH, (MPI) Professor, Department of Community Health Systems, School of Nursing, UC San Francisco

3. Principal Investigator Phone Numbers, Research Team Numbers, and Emergency Contact Numbers

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Emergency Contact Number: 909.649.3396

4. Study Sponsor

NIH/NIDA is funding UC San Diego to conduct this research study.

5. Study Overview

This research study is being conducted to find how our mobile application (app) intervention, called CHAMPION app, can help people use PrEP and reduce methamphetamine (meth) use. The study will ask about your environment, sexual behaviors, substance use, and other social factors. We are inviting you to participate in a research study because you use meth and are taking PrEP.

This form explains the research so that you may make an informed decision about participating.

- Research is voluntary - whether or not you participate is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes, but change your mind later.
- If you say no, we will not hold your decision against you.
- You can say no even if the person inviting you is part of your healthcare team.
- Your decision will not affect your health care or other benefits you may be entitled to.
- Please ask the study doctor or study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.

- You may consult with friends, family, a personal doctor, or anyone else before deciding whether or not to be in the study.
- You will be given a copy of this consent form and the Participant's Bill of Rights.

Purpose: We want to see if our CHAMPION mobile application (app) intervention can help with daily PrEP use and help reduce meth use.

Study Procedures: First, we will check if you qualify for the study. If you do, you will either start our intervention right away for 6 months or wait 3 months to start our intervention, which you would take part of for 3 months. While in the study, you will be asked to use a mobile app, answer monthly online surveys, and provide dried blood samples (DBS) using a finger prick. You will also get access to PrEP information and resources.

The study lasts for 6 months. There are a total of 15 remote online visits during the study.

Possible Risks: You might feel uncomfortable or embarrassed by answering questions about yourself, including your PrEP use and meth use. There may also be some discomfort from finger prick for blood samples. There is a risk of your information being seen by someone who should not see it, but we use secure systems to protect your data.

All possible risks of study participation are listed in Section 9 of this document.

Possible Benefits: There is no guarantee of benefits, but you might reduce your meth use and improve your PrEP adherence. The study might also help society understand HIV risk and meth use better.

Alternatives: You could use online reminders to take PrEP, support groups, or other resources for PrEP adherence without joining this study.

More detailed information about this research study is provided below.

6. Whom can I talk to if I have questions?

If during your participation in the study you have questions or concerns, or if you think the research has hurt you, contact the research team at the numbers listed in Section 3 on the first page of this form. You should not agree to participate in this study until the research team has answered any questions you have about the study, including information contained in this form.

If before or during your participation in the study you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:

- UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

7. How many people will take part?

We plan to include 50 people in San Diego and 50 people in San Francisco in this study, making a total of 100 people.

8. What happens if I take part in the research?

If you agree join, here is what will happen:

Screening: During this visit, we will confirm your eligibility, get your consent, and collect your contact information. Please note that you may be ineligible for a number of reasons.

- **Assess Eligibility:** Study staff will confirm that you qualify for our study, including assessing you for meth use disorder (MUD - an eligibility criterion for our study) and verifying your use of PrEP based on a prescription record or pill bottle.
- **Informed Consent:** Study staff will get your informed consent to join the study using this form.
- **Contact Information:** Study staff will collect a list of ways to contact you (such as your email address, phone number, and alternative contacts we can reach out to in the event we cannot reach you). Study staff will not leave phone messages unless you give permission. The study staff will also not tell your relative or friend anything about this study, your participation in the study, or give any information about you unless you give permission. You will be reminded to complete behavioral assessments and mail your DBS in the study's mobile app platform, but study staff may contact you (using your email and/or phone number) if you have not completed the assessments on schedule. You also can choose not to give any information that you do not want to give.
- **Agreeing to Terms and Conditions of Radiant App:** By giving consent, you agree to the terms of use and privacy specifications for the app outlined by Radiant Digital.

Enrollment: During the enrollment, you will complete the baseline procedures, including an online survey, collecting a DBS, and reviewing participation guidelines. Study procedures will be conducted during virtual visits at your home.

- **Online Survey:** You will get a link to an online survey about PrEP, meth use, and other topics. It take about 60 minutes.
- **Blood Sample Collection:** We will show you how to collect a DBS sample at home, using a finger-prick kit. We will mail you a kit with instructions to do this at home.
- **Randomization*:** You will be randomly assigned to one of two groups (described below):
    - ***Group 1 (Intervention):*** You will get access to the CHAMPION app and continue your usual PrEP care (with the doctor that currently prescribes you

PrEP) for 6 months starting today.
Group 2 (Waitlist): You will get some information and resources on the CHAMPION app, and continue your usual PrEP care (with the doctor that currently prescribes you PrEP) for 3 months starting today. Then, at month 3, you will get access to the rest of the CHAMPION app components for 3 months.
**Randomization means that you are put into a group by chance. It is like flipping a coin, you will have a 50/50 chance of being placed in either group. Neither you nor the research staff choose which group you will be in. You might be put into a group that receives a delayed access to an intervention (i.e., be on a waitlist) and have shorter time of having access to this intervention as another group.*

- **Review Participation Guidelines:**
  - **Intervention arm orientation:** If you are randomly assigned to the intervention arm, a study staff member will give you a unique username and password for the mobile app, and take you on a brief tour of the mobile app modules, how to access them, and the optimal frequency of using each module. You will have the opportunity to ask any questions about the mobile app. Please use as many of the mobile app features as possible. You may use the mobile app on a computer, smart phone, or both.
  - **Control arm orientation:** If you are randomly assigned to the waitlist control arm, a study staff member will give you a unique username and password for a stripped version of the mobile app that only has the direct messaging component to access the online survey link that will be available via a link on the mobile app. You will also have access to basic resources on PrEP, including information on taking and accessing PrEP.
- This initial visit will last about a total of 120 minutes.

The following is the schedule of study follow-ups:

Weekly Counseling Debriefs (Once a week for 7 weeks from today):

- For the first seven weeks, following the completion of each CBT4CBT counseling module, you will attend a weekly debrief over Zoom with a study staff member. These sessions, lasting approximately 15–30 minutes, will provide an opportunity to discuss the content of the videos.

Monthly Online survey (Each month for 6 months; Month 1, Month 2, Month 3, Month 4, Month 6):

- You will complete another online survey about PrEP, meth use, and sexual behavior.
- The survey will take about 60 minutes to complete.

Blood Sample Collection: (Month 3 and Month 6):

- You will collect another blood sample as described above.

9. What are the risks and possible discomforts?

You may experience the following risks or discomforts for participating in this study.

Risks of Loss of Confidential Information: There is also a risk that information about you could be released to an unauthorized party. To minimize this risk, we will use secure methods to protect your data such as using a code instead of your name on your information. We also use a secure HIPAA compliant platform that requires you to log-in for access. However, it is possible that others may read your text messages or see the CHAMPION mobil app, and result in loss of privacy. The CHAMPION app will save your information and login information, which will be protected at Radiant Digital (the app developer). Radiant Digital uses multiple security controls to protect the confidentiality of data. This research is also covered by a Certificate of Confidentiality from the National Institutes of Health—which will be explained in detail later in this form.

Risks of Collection of Dried Blood Spot (DBS): DBS is a safe and easy way to collect blood samples. Also, DBS cards do not display data in a public manner. However, some people might experience irritation from DBS fingerstick. To help prevent infection, you will be asked to use different fingers each time and to wash your hands before collection. The collection kit will include alcohol swabs to clean your finger before taking the sample. If you get an infection from the finger prick, contact your health care provider for help.

Risks of Survey Questions about Sensitive Issues: Some questions might feel very personal or make you uncomfortable. If you don't want to answer a question, you can skip it. If the questions upset you a lot, we can help you to find a counselor or refer you to a clinic. You can also reach out to the study staff for support.

Possible Unknown Risks: There might be risks we don't know about right now. These unknown risks could be minor and only last while you are part of the research, or they could be serious and last a long time, and in rare cases, even be life-threatening. If we find out anything new that could affect your health or make you think about whether you want to keep participating, we will let you know.

10. How will information about me be protected?

All staff will use UCSF-IRB authorized software (Redcap and Qualtrics) for data entry. The data will be stored in password protected software that automatically updates patches and other security items. The data will be de-identified with personal health information. A study code will be given to each participant. The data will be stored at UCSF with cloud-based back-up.

While we cannot promise complete confidentiality, but we will do our best to keep your information safe. Only people who need to see your information, documents, or samples will have access. This might include:

a. Members of the research team and other staff at UCSD, San Francisco Department of Public Health, UCSF, and the University of California who are involved in the research or in keeping your rights and safety. Representatives from federal and other agencies check to make sure the study is done correctly and that your rights and safety are protected.
b. Representatives from the group that is funding the study.

Identifying Information Confidential:
Your study information will be labeled with a code instead of your name or other details that could identify you. The document that links your personal details (like your name and address) to the code will be kept separate from the rest of the study information. The results of this study may be shared once it is finished, but we will keep your name and other personal details private. We think the study will take about 2 years to complete, but it might take more or less time depending on different things. If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential. But we cannot guarantee total privacy. Some information from your medical records may be collected and used for this study. People involved with your future care and insurance may become aware that you participated in this study. They may see information added to your medical record. Study tests and information obtained from you will be part of your research records. This information may be added to your medical record. Your personal information may be given out if required by law. Information from this study may be published or presented at scientific meetings. If it is, your name and other personal information will not be used.

Health Insurance Portability and Accountability Act (HIPAA):
You will need to sign a separate UC HIPAA Research Authorization form. This form allows us to use and share your health information for the study. Your permission does not expire automatically.

Federal Certificate of Confidentiality:
Your specimens and information about you are protected by a federal Certificate of Confidentiality. This means that we cannot be forced to release your specimens or information about you for any legal proceeding, even if a court of law asks.

The Certificate allows us to use your specimens and information about you for purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect specimens and information we share with them.

There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
- You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).
- A federal agency audits or evaluates research that it funds.
- Researchers are required to report possible intent to harm yourself or others, child abuse, elder abuse, or infectious disease cases.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. In addition, if researchers are made aware that a subject has certain communicable diseases including sexually transmitted diseases/infections (STDs/STIs), hepatitis, and HIV, this must be reported. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

11. Will I need to pay to participate in the research?
There will be no cost to you for participating in this study. However, you may need to pay for items such as parking and transportation for your medical visits related to PrEP. You and/or your health plan/insurance company will need to pay for all costs of caring for your condition while in this study.

12. What if I agree to participate, but change my mind later?
You can stop participating at any time for any reason, and it will not affect you negatively. Your choice will not impact any medical care or services you get from UC San Diego Health, UCSF or SFDPH. You will not lose medical care or any legal rights.

If you stop participating, we may not be able to remove the information we have already collected about you or samples we have already collected from you.

If you decide later that you do not want your samples used for future research, you may tell this to the study staff or principal investigator know. They will try their best to stop any further research with your samples. But, if your samples have already been tested, the information from these tests might be anonymous and cannot be taken out of the research database.

13. What will happen to information and/or biospecimens collected from me?
The information and samples we collect, which include details like your name or date of birth, might be used to answer other research questions or shared with other researchers.

Before doing this, we will remove any personal details so that you cannot be identified. Once this is done, we will not ask for your permission again for using or sharing your information. In addition, this de-identified information might also be stored in a data repository called the National Addiction & HIV Data Archive Program (NAHDAP) for other researchers to use.

The samples we collect, like blood or saliva, might be used for this research or other research, and shared with other organizations. You will not get any money or benefits from how these samples or information are used. Your specimens or information obtained from your specimens may be used for commercial use. If this happens, you will not share in any profits.

The information from your samples and study will be added to a database in NAHDAP with data from the other study participants. This database may be used for future research. While these databases will be accessible online, only anonymous information will be in the public database. Personal details like your name, address, or telephone number will not be included in the public database.

Even though we take steps to protect your privacy, it is possible that in the future, someone could find a way to link your genetic information back to you. For example, someone could compare information in a database with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). There is also a chance that the security of the computer systems used to store your information could be broken.

While we work hard to keep your identity private and your information confidential, we cannot promise that it will always stay hidden.

14. What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- Engaging in the mobile health app intervention.
- Completing online study assessments.
- Attending 7 weekly counseling debriefs.
- Collecting DBS blood samples and returning it via mail to study staff.

15. Will I be compensated for participating in the research?

Yes, if you decide to join this research, you will be paid for your time and effort. You will get $15 for completing the screening visit, $30 for completing the enrollment visit, $5 for each weekly counseling for 7 weeks ($35 total), $20 for each month for completing your online survey and $15 for completing your month 3 and month 6 DBS sample collection. In total, you could earn up to $230 for participating in the study.

16. What else is important for me to know?

You will not receive any personal health-related information from this research, and you will not get a summary of the research results.

It is important to tell the Principal Investigators, Kiyomi Tsuyuki and Glenn-Milo Santos, if you feel you have been injured or harmed because you took part in this study. You can tell them in person or contact them at 415-502-0955.

Details about this research will be posted on www.clinicaltrials.gov, as required by U.S. Law. This information will not include anything that can identify you. At most, the website might have a summary of the results. You can check this website any time. We are in the process of submitting the study to clinical trials for review.

17. What are my rights when providing electronic consent?

California law gives you certain rights when you give electronic consent:

- You can ask for a copy of the consent document in a paper format, not just online.
- You can choose to give your consent in a paper format, if you prefer.
- If you change your mind about giving electronic consent, you can ask to cancel it and then provide consent in a paper format. However, a copy of your electronic consent will still be kept for legal purposes. If you wish to withdraw your electronic consent just let the study team know.

This electronic consent only applies to agreeing to join this research study. We will use Docusign to secure the participants signature and participation. Docusign sends the signed consent form copy to the participant in a secure environment and provides a signed consent form for our study.

18. Additional Choices to Consider

The study team would like to ask if they can contact you about joining future studies. You can still join this study even if you do not agree to future contact. You can also change your mind later. Please put your initials below to show your choice:

_____YES, you may contact me

_____NO, you may NOT contact me

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CONSENT TO PARTICIPATE IN RESEARCH

Participant

I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I agree to participate in the research described in this form.

Printed Name of Participant

Signature of Participant Date

Person Obtaining Consent

I document that:

- *I (or another member of the research team) have fully explained this research to the participant.*
- *I have personally evaluated the participant's understanding of the research and obtained their voluntary agreement.*

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Witness (if applicable)

I document that the information in this form (and any other written information) was accurately explained to the participant. The participant appears to have understood and freely given consent to join the research.

Printed Name of Witness

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CONSENT TO PARTICIPATE IN RESEARCH

Signature of Witness Date

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CONSENT TO PARTICIPATE IN RESEARCH

Experimental Participant's Bill of Rights

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.

2. Provided an explanation of the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.

5. Informed about of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. Told of the types of medical treatment, if any, available if complications should arise.

7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.

9. Provided a copy of the signed and dated written consent form and a copy of this form.

10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777

Radiant Digital
CHAMPION App Platform Addendum

Terms and Conditions of Use for Radiant App

These terms include conditions of use of the CHAMPION app developed by Radiant Digital in conjunction with the study team:

1. **Platform required:** To install the CHAMPION app, you will need to be a registered user of the iOS App Store or Google Play (depending on mobile device). The app is intended to run on the current and immediately previous versions of the platform operating systems.
2. **SMS Opt-In:** By consenting to participate in the study you are agreeing that you can elect to receive SMS communications in conjunction with the study. If you wish to opt-in to receiving SMS communications, please notify your coordinator. You do not have to elect to receive these SMS messages to participate.
3. **SMS Opt-Out:** You can opt-out of receiving SMS messages at any time by contacting your coordinator or the study Principal Investigator at 909.649.3396.
4. **SMS Frequency:** We anticipate that you could receive up to 7 SMS messages per week from CHAMPION. These may include engagement, encouragement, or reminder messages.
5. **SMS Rates:** Message and data rates may apply.
6. **Privacy:** The privacy of your information is protected per the conditions outlined in the Consent to Participate in Research. Mobile numbers will not be shared or sold.

_____
Phone/SMS Number of Participant

_____ _____
Printed Name of Participant | Signature of Participant

_____ _____
Printed Name of Person Obtaining Consent | Signature of Person Obtaining Consent