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FRIENDS RESEARCH INSTITUTE, INC.

Research Center
Friends Community Center, 6910 Santa Monica Blvd., Los Angeles, CA 90038

CONSENT TO PARTICIPATE IN RESEARCH

TITLE:	Getting Off: A Theory-based mHealth Intervention for Methamphetamine-using MSM
LAY TITLE:	Getting Off App
PROTOCOL NO.:	1R01DA045562 WIRB® Protocol #20182737
SPONSOR:	Friends Research Institute
FUNDER:	National Institute on Drug Abuse
INVESTIGATOR:	Cathy J. Reback, PhD 6910 Santa Monica Blvd. Los Angeles, California 90038 United States
STUDY-RELATED PHONE NUMBER(S):	Cathy J. Reback, PhD 323-463-1601

INTRODUCTION

You are being asked to participate in a research study conducted by Cathy J. Reback, Ph.D. and Jesse B. Fletcher, Ph.D. from Friends Research Institute. The study site is Friends Community Center, at 6910 Santa Monica Boulevard in Hollywood, a division of Friends Research Institute, Inc. This study is sponsored by the National Institute on Drug Abuse. You have been asked to participate in this study because you: 1) self-identify as a male who has sex with men; 2) are between the ages of 18 and 65; 3) are a resident of Los Angeles County; 4) have used methamphetamine in the past year; 5) own an Android or iPhone smartphone, that uses the iOS or Android platform, with a current data plan; and, 6) are willing to download an experimental app and have at least 2 GB of available storage memory on your smartphone. Approximately 300 participants will participate in the study. Your participation in this study is entirely voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

PURPOSE OF THE STUDY

The purpose of this study is to:

- Determine if the computerized mobile app, *Getting Off,* a treatment intervention for methamphetamine-using men who have sex with men, can reduce methamphetamine use and high-risk sexual behaviors and, if appropriate, increase your PrEP uptake and adherence or HIV care and medication adherence.

PROCEDURES

If you volunteer to participate in this study, you will be asked to do the following things:

1. Assessment:
   Complete a private audio computer-assisted self-interview (ACASI) assessment. The ACASI will include questions about demographic information (age, race, etc.), your alcohol and drug use, sexual risk behaviors, HIV prevention or care, family and social support, general health, emotions, and psychiatric status. If you feel uncomfortable as a result of these questions, you may refuse to answer. There are no consequences for not answering questions.

2. Confidential Locator Information Form:
   We will ask you to agree to permit a member of the study team to contact the family members(s) and/or friend(s) that you indicate on a separate Locator Form for follow-ups or medical emergencies. A member of the study team will contact the people whose name(s) you give only if you have missed an appointment.

3. Complete a Urine Drug Screen, Sexually Transmitted Infections (STIs), and HIV-Antibody Fingerstick Blood Test collection kit:
   We will collect the following specimens:

   - Urine: We will ask you to give a urine sample that will be tested for methamphetamine and other drugs. The sample will also be used to test for gonorrhea and Chlamydia.

   - Rectal Swab: You will be given a kit with instructions and we will ask you to privately swab your rectum to collect rectal secretions to be tested for gonorrhea and Chlamydia.

   - Throat Swab: You will be given a throat swab to be tested for gonorrhea and Chlamydia.

   - Blood Draw: A trained phlebotomist, a person who is trained and certified to withdraw blood, will collect a sample of blood from a vein to test for syphilis. Using a new, sterilized needle, about 30 ml of blood (about 2 tablespoons) will be taken from your vein.

- Fingerstick Blood: A blood sample via fingerstick will be taken to test for HIV. If you know that you are HIV positive and can show documentation (such as your HIV medication, diagnosis form, or lab results) to verify your HIV-positive status you will not be given a HIV-antibody test.

The kits that we will use to collect the test samples will be mailed to a certified testing laboratory, Molecular Testing Labs (MTL). Blood draw samples will be collected by a courier to a separate certified testing laboratory, Foundation Laboratory (Foundation). Your information, including name and mailing address, will be entered by study staff into an online ordering portal where MTL will process the shipment. Similarly, this information will be submitted to Foundation via paper requisition form that will accompany blood draw specimens.

You will be notified if you test positive for HIV or any STIs once the results are received. If you test positive for HIV or any STIs, we will help you find appropriate treatment. Positive test results will be sent with your personally identifying information such as your name and address to the Los Angeles County Department of Public Health as required by law.

4. Test for Viral Load or Pre-Exposure Prophylaxis (PrEP) Medication Adherence (if applicable):
    - If HIV positive, you will be asked to allow study staff to collect a second sample of blood to be tested for viral load. If you are able to provide recent (within 3 months) lab results with your viral load, you will not be asked to provide a second blood sample.

    - If HIV negative and on PrEP, you will be asked to allow study staff to collect a second blood sample to be tested for PrEP medication adherence.

5. Download the *Getting Off* app onto your smartphone.

6. Randomization:
   After you finish the online assessment you will be randomly (by chance) assigned to one of two conditions: 1) Immediate App Access; or, 2) Delayed App Access. Both conditions gain access to the exact same app and participants in both conditions will be given 30-days to complete the 24 sessions. You cannot change to a different condition. You will be asked to keep your phone charged. A research assistant will instruct you how to lock your phone, establish and use a pin code to password protect your phone (if necessary), and how to log in to the *Getting Off* app. We ask that you contact us immediately if you lose your phone and need to download the app again on to a new mobile device.

- Condition 1: Immediate App Access: You will be given a unique user passcode to access the *Getting Off* app immediately after enrollment.

- Condition 2: Delayed App Access: You will be given a unique user passcode to access the *Getting Off* app 30-days after enrollment.

7. Schedule a follow-up visit approximately one month from today.

Follow-up Visits:
You will be contacted for follow-up data collections approximately 1-, 3-, 6-, and 9-months after your enrollment. If randomized to Condition 2 (Delayed App Access) you will be asked to complete one additional follow-up data collection approximately 2-months after enrollment. During these data collections you will be asked to complete an ACASI assessment that will include questions about your alcohol and drug use, sexual risk behaviors, HIV prevention or care, family and social support, general health, emotions, and psychiatric status. In addition, you will be asked to update your Confidential Locator Information Form.

After you complete your follow-up assessment, we will mail you a specimen collection kit and ask you to give a urine sample that will be tested for methamphetamine and other drugs. You will also be tested for gonorrhea, Chlamydia, syphilis and, if you are HIV-negative, you will be asked to take another HIV-antibody test (at the 3-, 6-, and 9-month follow-up visits). If, following enrollment, you test positive for syphilis and can verify a positive syphilis test, the syphilis test will not be included in your at-home HIV/STI test kit. If you are HIV-negative and on PrEP, you will be tested for PrEP medication adherence; and, if you are HIV-positive your viral load will be tested (at the 3-, 6-, and 9-month follow-up visits) unless you are able to provide recent (within 3 months) lab results with your viral load. If you are unable to provide recent viral load results, you will be asked to return to the study site for further testing.

Study staff will check in with you before a kit is mailed to make sure we have the correct address and that you are comfortable receiving the test kit. We will provide you with instructions on how to collect the samples and will ask you to mail the kit back to the lab within 45 days of receiving it. If you are not in a space where you feel comfortable to receive the test kit and collect the samples, we will not mail you a kit. However, we will then ask you to identify a location where we can mail you a kit and you can collect and return the samples within 45 days.

POTENTIAL RISKS AND DISCOMFORTS

There are few anticipated risks in participating in this study. Your methamphetamine use and high-risk sexual behaviors could continue if the study is not effective in reducing your methamphetamine use and high-risk behaviors. You may also feel discomfort or embarrassment related to the collection of blood and urine samples, throat and rectal swabs, and the HIV-antibody test. There may also be discomfort or embarrassment answering questions about your sexual behaviors, HIV-status, personal habits, lifestyle or drug and alcohol use. Additionally, there may be possible unauthorized disclosure of your personal information. There may be anxiety while awaiting test results for HIV, Chlamydia, gonorrhea and syphilis. You could learn that you are HIV infected or have a STI during the course of this study. If you learn you have

HIV or a STI, study staff will help you find medical care. If you experience discomfort during any of the study procedures, a staff member will be available for you to discuss these issues. Despite the significant measures we have taken to protect your information, confidentiality breaches are a potential risk of this study.

Risks Related to STI Testing

Some persons experience a sensation of gagging during the throat swab. Some persons experience discomfort or a small amount of fecal leakage/soiling during swabbing of the rectum. The fingerstick and/or intravenous blood sample may cause discomfort, bleeding, and bruising where the skin is punctured. Occasionally, there is swelling in the area where the skin is punctured and there is a small risk of infection. There is also a risk of lightheadedness and/or fainting.

If you test positive for a reportable STI (e.g., HIV, Chlamydia, gonorrhea, syphilis), we will report your name to the Los Angeles County Department of Public Health Services, Division of HIV and STD Programs. The reporting is done in order to ensure that you are offered treatment. The reporting only happens if the test result is positive and is always done confidentially. Notification to the County may result in attempts to identify and contact your sexual partners.

There may be risks to you from participation in this study that are currently unforeseeable.

ANTICIPATED BENEFITS TO PARTICIPANTS

Your participation in this study may provide you with insight regarding methamphetamine use, high-risk sexual behaviors, and HIV among men who have sex with men. Using the app may also help you to reduce or eliminate your methamphetamine use and high-risk sexual behaviors and, if appropriate, increase your PrEP uptake and adherence or HIV care and medication adherence. Of course, because individuals respond differently, no one can know in advance if the study will be helpful in your particular case. It is also possible that you may receive no benefit from being part of this study.

ANTICIPATED BENEFITS TO SOCIETY

This research study may help us learn how men who have sex with men can reduce or eliminate their methamphetamine use and high-risk sexual behaviors and, if appropriate, increase their PrEP uptake and adherence or HIV care and medication adherence through use of a mobile app.

ALTERNATIVES TO PARTICIPATION

There are several different organizations and counseling approaches for the treatment of methamphetamine use including self-help (12 Step), counseling, and residential approaches. Examples of 12-step groups include Alcoholics Anonymous (323-936-4343), Narcotics Anonymous (310-390-0279), or Crystal Meth Anonymous (855-638-4373). Our staff can help you locate a 12-step program in your area. In addition, the McIntyre House has a residential facility providing culturally specific, 12-step oriented residential services for substance users (323-662-0855). Another residential option is Tarzana Treatment Centers (818-996-1051). Relapse prevention treatment is available in the community for a fee, for example, at Clare/ Matrix (866-452-5273). The Los Angeles LGBT Center provides culturally specific, 12-step

oriented treatments for low cost (323-993-7440). AIDS Project Los Angeles has open, drop-in substance use support groups (213-201-1621). La Fuente Hollywood Treatment Center offers culturally specific detoxification, inpatient rehab, and outpatient programs for a fee (323-464-2947). If you are interested in finding other forms of treatment, our staff is able to assist you with referrals.

PAYMENT FOR PARTICIPATION

You may earn a $40 gift card for completing all of the admission procedures. You may earn a $50 gift card for completing the 1-month follow-up assessment, and if randomized to condition 2 (Delayed App Access), you may earn a $50 gift card for completing the 2-month follow-up assessment. You may earn a $50 gift card for completing the 3-month follow-up assessment, a $50 gift card for completing the 6-month follow-up assessment, and a $50 gift card for completing the 9-month follow-up assessment. You may also earn an additional $50 gift card for completing and returning all your HIV/STI at-home test kits, including urine sample to be tested for methamphetamine and other drugs, within 45 days of receiving the test kit in the mail at the 3-, 6-, and 9-month follow-ups. If the lab receives an incomplete test kit or if the samples provided are insufficient for processing, you may earn a $20 gift card, with the option to return to the study site to have the incomplete tests performed on site to earn the remaining $30 test kit incentive (a total of $50 in gift cards).

Additionally, you may refer a maximum of three participants and will earn a $2 gift card when a potential participant you refer contacts the research assistance and an $18 gift card if an eligible participant enrolls. The total amount you may earn for participating in the study is:

Condition 1: $40 + $50 + $50 + $50 + $50 + $50 + $50 + $50 + $20 + $20 + $20 = $450 in gift cards.

Condition 2: $40 + $50 + $50 + $50 + $50 + $50 + $50 + $50 + $50 + $20 + $20 + $20 = $500 in gift cards.

FINANCIAL OBLIGATION

There is no cost to you to be in this study.

EMERGENCY CARE AND COMPENSATION FOR INJURY

Your participation in this study is at your own risk. You will be responsible for the cost of treatment for any study-related injury. Friends Research Institute has not set aside funds to provide financial compensation for any injury suffered during this study. You are not waiving any legal claims, rights, or remedies because of your participation in this study.

PRIVACY AND CONFIDENTIALITY

The only people who will know that you are participating in this study are members of the study team. No information about you, or provided by you during the study, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare. These situations include the following: 1) if you are injured and need emergency care; 2) if you disclose your intention to harm yourself or others; or, 3) if you disclose information that a child or elder has been abused or neglected.

All records will be kept confidential. No data will directly identify you. Data will be coded with a study identification number. Your name or other identifying personal information will not be directly connected with the answers you give. If the results of the study are published or discussed in conferences, no information will be included that would reveal your identity. Your contact information will be saved within the study's secure, password protected, HIPAA-compliant database and stored for at least five years, or longer, as determined by the Principal Investigator.

Authorized representatives of Western Institute Institutional Review Board (WIRB; a committee that watches over the safety and rights of research subjects), study staff, authorized representatives from the National Institute of Drug Abuse (NIDA) or FDA, and their designees may need to review records of individual participants. As a result, they may see your name, but they are bound by the rules of confidentiality not to reveal your identity to others.

PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary, so you may withdraw your consent and stop participating at any time during the study. You can refuse to answer any questions or refuse to complete any of the sessions on the mobile application. If you choose not to participate, that will not affect your relationship with Friends Research Institute, or your right to other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to future care at Friends Research Institute. Your decision to not participate or to stop participating will not result in any penalty or loss of benefits to which you are otherwise entitled.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

The investigators may withdraw you from participating in this study if circumstances arise which warrant doing so. For example, if you fail to follow instructions, have undermined the right or privacy of another participant, or because the entire study has been stopped. The Principal Investigator, Dr. Reback, will make the decision and let you know if it is not possible for you to continue. If the study is cancelled by the National Institute on Drug Abuse, or the Western Institutional Review Board (WIRB), you may be withdrawn from the study.

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NEW FINDINGS

During the course of the study, you will be informed of any significant new findings, good or bad, such as changes in the risks or benefits resulting from participation in the study or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

IDENTIFICATION OF INVESTIGATORS

If you have any questions, concerns, or complaints about the research study or a research related problem, you may contact Dr. Cathy Reback (Principal Investigator) at 323-463-1601, Friends Community Center, 6910 Santa Monica Blvd., Los Angeles, CA, 90038.

CLINICAL TRIAL INFORMATION

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

RIGHTS OF RESEARCH PARTICIPANTS

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this study. If you have questions, concerns, complaints or regarding your rights while participating in this study, you may contact the Western Institutional Review Board® (WIRB®) 1019 39th Avenue SE, Suite 120, Puyallup, Washington 98374-2115, Telephone: 1-800-562-4789.

PARTICIPANT'S AGREEMENT

If you select "Yes" below, you are voluntarily agreeing to take part in this research study:

Do you agree to participate in the study?

- o Yes, I agree to participate in the study.
- o No, I do not agree to participate in the study.

I have read and understand the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study. You may download and print a copy of this signed form to keep.

Future Contact

We would like to invite you to take part in future studies or programs. If you agree to let us contact you in the future, the researchers will keep a record of your name, phone number and address in a HIPAA-compliant cloud-based folder. By agreeing to be contacted, you are not committing to participate in any future program and you may request to remove your name from the list at any time without losing any of your rights as a participant in the current study. If we contact you, we will not reveal the name or nature of the study we conduct to anyone other than yourself. If we leave a message, we will only state that we conduct "health studies."

Remember: If you select "Yes" below, it means you are willing to provide locator information to be contacted about other studies which may interest you. **It does not mean that you are willing to take part in future studies**. It means that you are giving permission to be contacted about them.

Would you like us to contact you about future research studies?

- **YES** – I am willing to be contacted about future research studies, however this does not mean that I will take part in future studies.
- **NO** – Please do not contact me about future research studies.

BY ELECTRONICALLY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Name of Participant (please type)

_____ _____
Electronic Signature of Participant Today's Date