

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

Study Title: LetSync: an mHealth approach to HIV care engagement among couples

Research Project Director:	Greg Rebchook, Ph.D. Professor and Director, UCSF Prevention Research 550 16 th Street, 3 rd Floor San Francisco CA 94143 Study Phone: 510-214-6945 E-mail: greg.rebchook@ucsf.edu
Study Coordinator:	Guillermo Obando guillermo.obando@ucsf.edu letsync@ucsf.edu Jack Johnson Jack.johnson@ucsf.edu BettyRose Green Bettyrose.green@ucsf.edu

This is a research study to understand how the use of a mobile app (*LetSync*) developed for couples can improve HIV care outcomes among couples.

Research studies include only people who choose to take part. Please take your time deciding if you want to participate, and discuss your decision with your family or friends if you wish. If you have any questions, please ask the researchers.

You are being asked to take part in this study because you:

- 1) Self-identify as a cisgender man, transgender woman, OR gender-fluid/non-binary individual
- 2) Self-identify as a racial/ethnic minority (ex., American Indian/Alaska Native, Asian/Asian American, Black/African American, Hispanic or Latinx, Middle Eastern or North African, Native Hawaiian or Pacific Islander)
- 3) Are living with HIV
- 4) Have been in a primary relationship with another cisgender man, transgender woman, or gender-fluid/non-binary individual for at least two months
- 5) OR, you are being asked to take part in this study because you are the partner of someone who fits the above criteria.

Both you and your partner must own smartphones to participate.

We will ask you and your partner to verify your age using a government-issued form of identification (e.g., license, passport) via videoconference (e.g., Zoom, Skype).

If you are living with HIV, we will ask for verification of your HIV status by showing us ONE of the following items below with your name on it, via videoconference (e.g., Zoom, Skype).

- Letter of diagnosis

- Copy of pharmacy ART prescription
- Recent ART pill bottle

Alternatively, you may also email us a photo to our study email, letsync@ucsf.edu. All photos will be kept confidential and can only be accessed by study staff. We will delete your photo after verification happens.

Why is this study being done?

The purpose of this study is to assess the feasibility and acceptability of using *LetSync* among couples in which one or both partners are living with HIV.

The National Institute of Mental Health (NIMH) is funding this study.

How many people will take part in this study?

About 300 people will take part in this study.

What will happen if I take part in this research study?

Because this is a couples' study, both you AND your partner must agree to be in the study to participate. Your partner will also be asked to read and sign this consent form. You will be enrolled if your partner also gives us informed consent to participate.

If you and your partner agree, the following will occur at enrollment:

- You and your partner will be randomized as a couple into two groups: Group A or Group B. Being randomized is like flipping a coin. As a couple, you both will have equal chance of being randomized into either group.
 - If you are in a couple assigned to Group A, you will begin using the app right away, for 8 months.
 - If you are in a couple assigned to Group B, you will not use the app.

Regardless of which group you are randomized into, you and your partner will be asked to do the following:

- Complete three online surveys throughout the study. Each survey will take 30 minutes or less.
- Provide dried blood spot (DBS) samples that you will collect yourself and mail to us 3 times throughout the study. We will teach you how to do this through a video tutorial and send the DBS kit at no cost to you.
 - For the partner living with HIV, the DBS will ONLY be used to track how much antiretroviral medications are in your body throughout the study.
 - For the partner not living with HIV, the DBS will ONLY be used to track how much pre-exposure prophylaxis (PrEP) medications are in your body throughout the study.
- Complete a urine test. The urine test is similar to a take-home COVID test. It will ONLY be used to track how much antiretroviral medications or PrEP medications are in your body throughout the study. The urine test will be sent at no cost to you.
- Towards the end of the study, we will interview you and your partner separately to learn about your experiences with this study. We will ask what you thought about using the app and sending in samples (if applicable). We will audio record interviews for accuracy and have them professionally transcribed. All identifiers, such as names and personal information, will be removed from the transcripts.

When the study is over, you have the option of continuing to use the app or deleting it from your phone.

Here is some more information about the app, *LetSync*:

- *LetSync* is an app that's designed to help you and your partner work together on health-related goals. Specifically, this app will let you:
 - Create an "action plan" for goals you'd like to achieve via a feature called My Action Plan.
 - Keep track of health appointments and know how to prepare for them via a feature called Appointment Minder. For example, if you a blood draw coming up, the app will remind you how to prepare for it (like fasting) and questions to ask your doctor.
 - Keep track of medications and know when you've already taken them for a given day via a feature called Digital Pill Case.
 - Track how you feel each day and see your progress over time via pop-up questions that you may answer when you use the app.
- We will ask you and your partner to "add" each other on the app (study staff will show you how) so you can communicate with each other in the app.
 - You'll have the option of sharing certain information with your partner via a feature called My Partner. For example, you may share goals that you make with your partner so they can see your progress and encourage you along the way.
- Study staff will communicate with you via text/call/email. You will be mostly interacting with your partner in the app. But if needed, study staff may send you push notifications in the app, such as reminders to complete surveys and/or send DBS samples and urine test results.

How long will I be in the study?

You and your partner will be asked to participate for 8 months regardless of which group you and your partner are randomized into.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, or if the study is stopped.

What risks can I expect from being in the study?

- *Discomfort with survey or interview questions:* Some of the questions may make you uncomfortable or upset. You are free to decline to answer any questions you do not wish to answer.
- *Loss of privacy or confidentiality:* Participation in this research may involve a loss of privacy, but your information will be handled with maximum confidentiality.
- *Discomfort or minor injury from dried blood spot (DBS) collection:* there is minimal physical risk from the finger prick. The finger prick may cause a small amount of pain and bruising, and the site may bleed slightly after the prick.
- *Discomfort from urinalysis collection:* there is a risk of experiencing discomfort with handling your urine.

Use of Electronic, Web-based, and Mobile Phone Programs: This study is using new technology, which may have some problems. For example, you might miss app notifications that are sent to you. Information that you enter into any mobile phone programs will be maintained on a secure server via a password-protected log-in. We will not be able to access any private information on your mobile

phone that you use to access these programs. Information collected through these programs will be encrypted (meaning that it will be coded in a special way so that only the researchers can view it) while on your device and during transit to our secure servers.

But, it may be possible for your information to be viewed by others who are successful at breaking this encryption. We will follow best-practice security precautions, but there is always some risk your information could be compromised. It may also be possible that someone who has access to your phone or computer may see the information you enter.

Are there benefits to taking part in the study?

There are no direct benefits if you participate in this study. You might gain knowledge and awareness, and satisfaction from contributing to research and advancing scientific knowledge for improving the health of your community. Finally, you may enjoy using the app individually and with your partner.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you.

How will my specimens and information be used?

Researchers will use your specimens and information to conduct this study. Specimens and information gathered during this research study will be de-identified and only be used for this study. They will not be shared with other researchers. Any and all samples that you provide (DBS and/or urine) will be destroyed at the conclusion of the study.

Any and all samples will only be used to measure levels of antiretroviral medication. A third-party lab at the University of North Carolina, who we have entered into agreement with, will handle DBS analysis. The urine dipstick can be carried out by yourself individually and will only tell if ARV medications are present or absent in your urine. We will NOT measure for other substances.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your records may be reviewed by representatives of groups who watch over this study to see we are protecting your rights, keeping you safe, and following the study plan. These groups include:

- Representatives of the National Institutes of Mental Health
- Representatives of the University of California

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. All reviewers will take steps to keep your information private.

Are there any costs to me for taking part in this study?

No.

Will I be paid for taking part in this study?

In return for your time and effort, you and your partner can receive up to \$430 total. A breakdown of the incentives is as follows.

Timepoint	Enrollment	Survey	DBS sample	DBS on-time bonus	Urine test	Exit Interview	Total
Baseline	\$10	\$30	\$30	\$10	\$15	-	\$95
Month 2	-	-	\$30	\$10	\$15	-	\$55
Month 4	-	\$40	\$30	\$10	\$15	-	\$95
Month 6	-	-	\$30	\$10	\$15	-	\$55
Month 8	-	\$50	\$30	\$10	\$15	\$25	\$130
Total							\$430

In addition to monetary incentives, we would also like to offer you and your partner thank-you tokens such as items like a travel hairbrush/mirror kit, manicure kit, and hot/cold eye mask.

Payment will be in the form of a reloadable debit card, known as a ClinCard.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?

You can talk to the researcher about any questions, concerns, or complaints you have about this study. Contact the researcher, Dr. Greg Rebchook, at 510-214-6945.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

CONSENT

You have been given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date

Participant's Name

Date

Participant's Signature for Consent

Date

Person's Name Obtaining Consent

Date

Person's Signature Obtaining Consent