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Vía Libre | Epicentro | Fred Hutchinson Cancer Center

## INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**TITLE OF STUDY:** Development and Evaluation of a Multi-Component Intervention to Support HIV Testing and Linkage to Services among Men Who Have Sex with Men in Perú

*Phase 3 – Randomized Pilot Trial of the “Mercury” Intervention*

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### IMPORTANT THINGS TO KNOW ABOUT THIS STUDY:

You are invited to participate in a research study. The purpose of this study is to test an intervention for supporting HIV testing and linkage to treatment and prevention services.

People who agree to join the study will receive HIV testing and be signed up for a text messaging application. Participants will receive the text messages for 3 months. There is an questionnaire to complete after 3 months. There are no follow-up visits.

We do not know if the intervention will help participants or provide any other benefit. Participating in the study involves receiving HIV testing. In some people, doing an HIV test can make them feel anxious. Collection of the blood sample for the test may cause brief physical discomfort.

You do not have to join this study. You are free to say “yes” or “no”. We will give you details about the purpose, procedures, risks, and possible benefits related to the study, as well as any other information you need to make an informed decision about whether to participate.

Below is a more complete description of the study. Please read this carefully and ask us any questions that you want to help you decide whether to participate. If you join the study, we will give you a signed copy of this form to keep for your future reference.

### We invite you to join this research study.

We are inviting you to participate in this study because you identify as a man who has sex with men, you are at least 18 years old, and you do not have a known diagnosis of HIV infection.

### WHY IS THIS STUDY BEING DONE?

We are doing this study to evaluate an intervention, called “Mercury”, to increase access to HIV testing and linkage with treatment and prevention services. The intervention includes two components: 1) offering HIV testing at sex-on-premises venues (e.g., saunas, sex clubs, hourly hotels) in Lima, and 2) a mobile application (adapted from the ‘WeITel’ platform) to facilitate the linkage to HIV services. The purpose of the study is to evaluate the acceptance and feasibility of

this strategy among men who have sex with men in Lima, and to determine the best form of offering HIV testing in this setting.

**There are 4 groups of participants in this study, based on the form of HIV testing received.**

By comparing the results between the different groups, we hope to find out which is the best form of HIV testing to offer as part of the Mercury intervention. On each given date, only one of the four forms of HIV testing will be offered. Everyone who joins the study on that date will be assigned to the same group and will receive the same form of HIV testing. The form of HIV testing offered on each date is assigned randomly ahead of time. If you decide to join this study, you cannot choose a different form of HIV testing than the one offered today.

**WHAT TESTS AND PROCEDURES ARE DONE IN THIS STUDY?**

If you agree to be in this study, you will receive one of the following forms of HIV testing:

- **Group 1.** We will do a rapid HIV test today. We will collect a drop of blood for the test by pricking your fingertip. The result is given in approximately 15 minutes, and we will give you post-test counseling according to the Perú Ministry of Health (MINSA) guidelines. If you are *HIV positive*, we will refer you to a health center to confirm the diagnosis of HIV infection and start treatment. If you are *HIV negative*, we will refer you to a center where you can get HIV prevention services.
- **Group 2.** We will give you a HIV self-test kit to take with you. It is your decision where and when to use it. This test uses a blood sample similar to the rapid test that's done in a health center. We will give you instructions for how to do the test and what to do after. If you prefer, you can also ask us to help you do the test here today.
- **Group 3.** We will give you a coupon for a future HIV test at Vía Libre or Epicentro. You can redeem it for a free HIV screening test at either of these sites. Testing will be done based on standard clinical practice at the clinic where you choose to redeem the coupon. The coupon is valid for 3 months.
- **Group 4.** You will have the option to choose any one of the three forms of HIV test (rapid test, self-test, or coupon for future testing).

**The following is a description of the general procedures for all participants:**

Event	What will happen?
<i>Enrollment (Today)</i>	<p>You will receive the HIV testing form assigned to today's date, as well as HIV pre-test counseling according to MINSA guidelines.</p> <p>We will register you in the WeITel application using your primary cellphone number, and you will choose a private password that you'll use to access your personal portal online.</p> <p>We will ask you to complete a brief questionnaire about your past experience with HIV testing, sexual behaviors, and mobile technology use.</p>
<i>Use of the WeITel application (3 months)</i>	<p>For 3 months, you will receive text messages (SMS) from WeITel at least once weekly. Depending on your response, we may send you other messages or call you.</p> <p>Some of the messages will contain a brief greeting (e.g. "How are you?"). Others will include links to infographics, videos, and online maps related to HIV and other health topics.</p> <p>If you have a question, you can send a text message by responding to the WeITel number at anytime. Your message will be reviewed and replied to by a member of our 'Provider Team' as soon as possible within 24 hours of getting your message.</p>

	The text messages you send, as well as information related to your use of the app, will be kept confidentially as part of your study record.
<i>Collection of data</i> (6 months)	<p>At the end of 3 months, we will ask you to complete an online survey about your experience with the WelTel app. A virtual appointment will be set up to deactivate your WelTel account and ask you about the HIV services you may have received.</p> <p>We will collect information about the HIV services you may receive for 6 months. We might contact you to ask you about this.</p> <p>We might also use your DNI number to look for this information in the medical records at Via Libre, Epicentro, or other health centers in Lima, or in the Ministry of Health (MINSA) databases related to HIV. If we did this, we would only obtain the information needed for this study, which might include details about the healthcare services you've received and laboratory results related to HIV.</p>

**HOW LONG WILL I BE IN THIS STUDY?**

If you agree to join this study, your participation will last for a maximum of 6 months. There are no in person follow-up visits.

**HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?**

Up to 180 people will participate in this pilot study of the Mercury intervention.

**WHAT ARE THE RISKS OF PARTICIPATING IN THIS STUDY?**

- Loss of privacy. Others could find out you are participating in this study if they see you talking to study staff or using the WelTel app on your phone.
- Loss of confidentiality. We will collect your personal information, including the result of your HIV test, and we will ask you to use your mobile phone to exchange text messages. We will do everything we can to keep your information confidential, but there is still a small risk that information about you could be accidentally disclosed.
- Emotional distress. We will ask you some personal questions about HIV and sexuality, which may make you feel uncomfortable. You may also have anxiety or worry about your HIV test.
- Physical discomfort. Finger-prick blood collection for HIV testing may cause brief discomfort.

**WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

People who join this study will receive HIV testing plus a mobile health application designed to link them with HIV services. The benefits of HIV testing are personal. For someone who is worried about HIV, they may feel better knowing their status. If the result is negative, they might feel less worried. If the result is positive, they could start treatment earlier than they otherwise would have. We do not know if the WelTel app will help people access HIV services or provide any other benefit, but we hope the information we learn in this study will lead to more effective strategies for increasing access to HIV treatment and prevention services in the future.

**WHAT ARE THE ALTERNATIVES TO PARTICIPATING IN THIS STUDY?**

You do not have to join this study. You are free to say “yes” or “no”, or to leave the study after joining, without it affecting the regular medical care or benefits you may receive.

**WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?**

There is no cost to you for participating in this study. You might go to Via Libre, Epicentro, or another health center in the future as a result of information we give you during the study. Any treatments, tests, or services you receive as a client there would not be part of the study. In some

cases, you could be asked to pay for this care. This would be your responsibility. The study would not help you pay.

**WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?**

You will not receive any payment for participating in this study.

**HOW WILL MY INFORMATION BE USED?**

Your information will be used for the purposes of this study. The information we collect about your use of the app and the HIV services you may receive will be used to help us know how useful the Mercury intervention is in supporting HIV testing and linkage to the right services.

We will give you the result of the HIV test you receive as part of study. We do not expect to learn about any other information or results that would affect your medical care.

**WILL MY INFORMATION EVER BE USED FOR FUTURE RESEARCH?**

In addition to the planned uses of your information described above, we might use or share it with other researchers for future research. In that case, we would remove all identifiers and codes in order to make it anonymous. If you do not want your anonymous information used for other projects, you should not participate in this study. If we do share your information with others, we would not be able to stop the future research, even if you asked later, since there is no way to link the information back to you. We would not inform you before sharing your anonymous information in this way.

**HOW IS MY PRIVACY AND THE CONFIDENTIALITY OF MY INFORMATION PROTECTED?**

We will do everything possible to protect your privacy. The text messages we send you will use neutral wording. They won't directly mention HIV or any other sensitive topic, unless you first ask us about these things. Only the health professionals who are part of our study team will have access to the text messages you send us through the WeTel application.

Your information will be stored using a code that does not include your name or other identifiers. Your name, DNI number, and any information that could identify you will be kept confidential. Only the researchers of this study will be able to access this information, and to the extent that the laws permit, it will not be revealed to anyone else. When we publish or present the study results at scientific meetings, we will not include anything that could reveal your identity. The electronic tools and databases used to store your information include strong security features to make sure it stays confidential. All study data will be stored on a secure server, accessible only to study staff using a password. All the devices (computers, laptops, and tablets) used in this study are password protected. Any physical document with your personal information will be stored in a locked office in a locked file cabinet.

If you join this study, some people and organizations may need to look at your research records for quality assurance or data analysis. They include:

- Researchers involved with this study
- Ethics committees, including the IRB of Fred Hutchinson Cancer Center and the Comité Institucional de Bioética (CIB) of Vía Libre (an IRB is a group that reviews the study to protect your rights as a research participant)
- Fred Hutchinson Cancer Center, Vía Libre, and Epicentro
- U.S. National Institutes of Health and Office for Human Research Protections
- Peruvian National Institute of Health

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.

### **WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?**

- You do not have to join this study. You are free to say “yes” or “no”. If you decide not to join, it will not affect your regular medical care or any other benefit or service you may receive.
- If you get sick or hurt during this study, you do not lose any of your legal rights to seek payment by signing this form.
- If any part of the study makes you feel uncomfortable for any reason, you can skip it. You can also leave the study at any time (even before you start) without any penalty.
- It is your right to have any questions about the study answered completely before deciding if you want to participate.

### **WHAT HAPPENS IF I DECIDE TO WITHDRAW FROM THE STUDY?**

If you start the study and later decide you no longer wish to continue, you can withdraw at any time without penalty by contacting us to let us know of your decision. Withdrawing would mean that your WelTel account would be deactivated and you would no longer receive text messages. Even if you withdraw, we may still get information from your medical records for up to 6 months, but we would not try to contact you.

### **WHAT IF I GET SICK OR INJURED AFTER JOINING THIS STUDY?**

For any life-threatening problem, you should immediately seek emergency medical care. The WelTel app is not able to provide emergency medical advice.

We do not expect any injuries or illness related to your participation in this study. However, if you were to have a problem, you should contact us to let us know. We would refer you to a healthcare provider who can give you the care you need. The study would not be able to help you pay for this. Any costs related to this would be your responsibility to pay.

### **WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?**

If you have any questions or concerns about the study, you may talk to a member of the study team anytime. You can also send us a text message using the WelTel app. We encourage you to raise any questions that you have about the study before you decide whether to participate.

For any questions about this study, or if you have a research-related problem, you can contact **Lic. Hugo Sanchez** at Epicentro, Jirón Jaen 251 Barranco, telephone **(+51) 997 912 324**.

If you have any questions about your rights as a participant or about the ethics of this study, you can contact Dr. María Luisa Cairampoma Gago, President of the Institutional Bioethics Committee (CIB) at Via Libre, by phone at 203-9900 Monday through Friday from 9am to 6pm, or come to Jr. Paraguay 478-486, Cercado de Lima, institutional email: [comitebioetica@vialibre.org.pe](mailto:comitebioetica@vialibre.org.pe). An Ethics Committee is made up of a group of people from both scientific and non-scientific fields who conduct an initial and permanent review of the research study in order to protect and safeguard the rights of the participants.<sup>1</sup>

For questions about your rights as a research participant, you can also contact the Director of Institutional Review Office, Fred Hutchinson Cancer Center, by calling (+1) 206 667 5900 or by email at [irodirector@fredhutch.org](mailto:irodirector@fredhutch.org).

<sup>1</sup> This paragraph is required by the Via Libre IRB to be included verbatim in the consent form of any approved study.

**Emergency number (24 hours): (+51) 997 912 324**

Please read each question below and think about your choice, then mark either YES or NO:

**Consent for future collection of medical records information**

Do you give us permission to use your personal information, including your Document of National Identification (DNI) number, to access your medical records at Vía Libre, Epicentro, and MINSA health centers and obtain information related to HIV services you may have received in the future (including the date, location, and type of services, and the results of HIV-related laboratory testing)?

(mark one) ☐ YES ☐ NO

**Consent for communication via text message, email, and phone call**

Do you give us permission to contact you and discuss your personal information by text message, email, and voice call?

(mark one) ☐ YES ☐ NO

**Authorization and Permission**

I have read this form (or someone has read it to me) in its entirety, I understand what is expected of my participation, and I have agreed to participate in this study. The benefits and possible risks have been explained to me and I have had the opportunity to ask questions. My signature below also indicates that I have received a copy of this consent form.

\_\_\_\_\_  
Participant's Name

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date and Time

**Researcher's Statement**

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

*Person obtaining consent signature:*

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date and Time