UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

Full Title: Men Who Have Sex with Men & Substance Use Cohort at UCLA Linking Infections, Noting Effects

Short Title: mSTUDY

Consent Type: Remote Visit – Web-based Behavioral Assessment

Text for Inclusion at the Outset of the Off-cycle Remote Visit Behavioral Survey:

Welcome to the "mSTUDY COVID-19" survey. The following information is important to you as a participant in this study. Please read carefully:

INTRODUCTION

Dr. Pamina Gorbach, Dr. Steven Shoptaw, and their mSTUDY team from the University of California, Los Angeles (UCLA), Los Angeles LGBT Center (the Center), UCLA's Vine Street Clinic (VSC), and the Veteran’s Administration (VA) are asking enrolled mSTUDY participants to consent to participate in web-based behavioral assessments (questionnaires) in addition to you regular semi-annual mSTUDY clinic visits. Participation is completely voluntary and is not part of any treatment nor will it affect any treatment you may be receiving at the sites or your relationships with clinic staff and clinicians.

Research studies are voluntary and include only people who choose to take part. Please take your time about deciding whether to participate in this study. Before deciding, you can:

- Discuss this study with family and friends
- Discuss it with a regular physician or request a second opinion

If you have any questions, you can ask the researchers for more information before deciding to participate. Contact information is provided at the end of this document.

WHY IS THIS STUDY BEING DONE?

The main purpose of mSTUDY is to find out how drug use affects the immune system and if it alters the risk of acquiring HIV and the viral load of those already HIV infected. To do this, we would like to assess your sexual behavior, social networks, health risks, and substance use through questionnaires. This study is sponsored by the U.S. National Institute on Drug Abuse (NIDA).
WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you would like to take part in the off-cycle web-based behavioral assessment, please check the box at the end of this form to indicate your consent to participate. Please review all the details described below and ask questions about anything you do not understand.

If you chose to participate, this behavioral assessment will take about 30 minutes to 1 hour. You will be asked to complete a questionnaire about things such as your sexual behavior, social networks, health risks, medical history, and substance use.

WHAT KINDS OF RISKS OR DISCOMFORT COULD I EXPECT?

General Risks of Participation:
Although every effort will be made to protect your privacy and confidentiality, it is possible that your involvement in the study could become known to others, and that social harms may result.

Risks from Web-based Behavioral Assessments/Questionnaires:
There may be discomfort or embarrassment related to questions dealing with sexual behaviors and personal habits. You will be asked questions about your sexual behavior and substance use. If some of the questions upset you or make you uncomfortable, you may choose not to answer them. You may do this at any time and continue to participate in the study.

There may also be a risk to confidentiality if someone views the computer or smart phone screen while you answer the questionnaires. To avoid this, we ask that you complete the survey when you feel you will have reasonable assurance of privacy.

Unknown Risks and Discomforts:
The procedures listed above may involve risks that are currently unforeseeable, and the researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

You or others may benefit in the future from information learned in this study. You may also get some personal satisfaction from being a part of the research as well as information about your health status that may be important to your long-term wellness.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO PARTICIPATE?

Your participation in this research is voluntary, and if you choose not to participate, that will not affect your relationship with your doctor or your access to other services at any site. If you choose
to participate and change your mind, you are free to withdraw and discontinue your participation at any time.

**HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?**

The researchers will do their best to ensure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with the use of any electronics to store data, there is a risk that data security may be compromised.

**Certificate of Confidentiality:** To help us protect your privacy, we have obtained a Certificate of Confidentiality from the U.S. National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings (for example, if there is a court subpoena). The researchers will use the certificate to resist any demands for information that would identify you, except as explained below.

The certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the certificate to withhold that information.

The certificate does not prevent the investigators from voluntarily disclosing, without your consent, if they learn of harm to yourself or others, including sexual or physical abuse of a child, elderly, or dependent adult. We will report alleged, reasonably suspected, or known cases to the proper authorities.

**Use of Personal Information That Can Identify You:** You will be given a code to use to access the questionnaires on a private computer or smart phone. This code is only known to the study staff; the online system for these questionnaires cannot link this code with your name or any other identifying information.

**People and Agencies That Will Have Access to Your Information:** The research team, authorized UCLA personnel, study sponsors, study monitors, and regulatory agencies may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA investigators will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.
How Information About You Will Be Stored:

- The data from questionnaires you complete while in the study will be stored electronically on a secure web server with encryption and password protection measures in place. This server is maintained by the designated mSTUDY data management team.

How Long Information From the Survey Will Be Kept:

- The researchers intend to keep the research data and records until the study is over and then transfer the data, which will be kept indefinitely, for future research conducted by Drs. Gorbach and Shoptaw.
- In the future, data collected for this study may be shared with other researchers for other studies that are unknown at this time. Any data shared with other researchers will not include your name or other personal identifying information.

COMPENSATION

You will be compensated $25 for the remote visit web-based behavioral assessments. Compensation (in the form of in cash or gift card equivalent) will be provided upon the completion the questionnaire.

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

The Research Team: You may contact Dr. Gorbach at (310) 794-2555 or Dr. Shoptaw at (310) 794-6206 with any questions or concerns about the research or your participation in this study. Additionally, you may contact mSTUDY staff at the UCLA Vine Street Clinic at (323) 461-3106, mSTUDY staff at the Los Angeles LGBT Center at (323) 993-8912 / (323) 993-8949, or VA at (310) 478-3711 with questions or concerns about your participation.

UCLA Office of the Human Research Protection Program (OHRPP): If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.
HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study, you should check the box “I agree” below.

You can be given a copy of this consent form for our records.