

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

Study Title: The PRIDE Study: iOS Mobile App for Community-Based Participant-Driven Collaborative Study Design

This is a research study about the health of sexual and gender minorities, which are primarily member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ) communities. The study researchers – Mitchell R. Lunn, MD from the UCSF Department of Medicine and Juno Obedin-Maliver, MD, MPH from the UCSF Department of Obstetrics, Gynecology, and Reproductive Sciences – will explain this study to you via this informed consent module in The PRIDE Study iPhone mobile application (“app”). They are also available to answer questions via e-mail (pridestudy@ucsf.edu) or telephone at 855-421-9991 (toll-free).

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

You are being asked to take part in this study because you have self-identified as a lesbian, gay, bisexual, transgender, queer, or another sexual or gender minority adult living in the United States.

Why is this study being done?

The purpose of this community-based study is to gather research questions and health priorities that are important to the LGBTQ community and to test functionality of an iPhone app for this research. The information collected from this study will help create a long-term study that the study researchers are currently planning. That long-term study’s goal is to better understand the conditions and experiences that influence the physical and mental health of LGBTQ people and other sexual and gender minorities.

This study is funded by the University of California, San Francisco with *pro bono* development of the app by THREAD, a digital creative agency. None of the study researchers or staff have any conflict of interest with THREAD.

How many people will take part in this study?

Because the numbers of LGBTQ people in the United States is not known, it is hard for the study researchers to estimate the number of people that will eventually participate in the study. Because the study researchers are interested in hearing the research questions and health priorities that are important to all members of the LGBTQ and sexual and gender minority communities, we want to have as many people as possible participate.

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

If you agree, the following steps will occur:

- You will download an app (free) from the Apple App Store on your iPhone (or computer). You need to have the app on your iPhone in order to participate in this study.
- You will answer a series of questions to determine eligibility for participation in this study.
- If you are eligible and after signing this consent, you will create a personal account.
- You will be asked if we can contact you for research purposes in the future, especially when we launch the long-term health study of LGBTQ and other sexual and gender minority people because we believe that you may be interested in participating.
- Study Surveys: You will be asked to complete a survey that gathers personal demographic information. Periodically, you may be asked to complete study surveys that we are using to determine the best way to ask particular health- or behavior-related questions. This will be helpful for the design of the long-term health study that we are planning. We may periodically send surveys that ask more about your health including any health problems that you have, medications you are taking, etc. The more information you provide, the more we can learn about the best ways to design our long-term study (launching in late 2015-early 2016). You may choose to not answer questions that make you uncomfortable.
- Location Validation: If you agree to let us use your location (determined by your iPhone's GPS), you may occasionally receive a survey that lists locations that you may have visited in the prior days. By confirming whether or not you visited any of these locations, you will help us improve the matching of a GPS location signal to an actual place, like a hospital. This technology may be useful in the long-term health study of LGBTQ and other sexual and gender minority people that we are planning.
- Community Forum: You will be asked to participate in a community discussion forum in which you can propose research questions or health topics that are important to you. In addition to proposing research questions or health topics, you can comment on topics proposed by others and indicate how important they are to you by voting a topic "up" or "down." These questions and your comments will help inform the design of a long-term health study of LGBTQ and other sexual and gender minority people. When you participate in the forum, identifying information about you will not be shared. Instead, you will be represented by the screen name that you selected during enrollment. No one will be able to tell if you voted on a particular topic.
- Reminders: We will send notices on your iPhone asking you to complete surveys/tasks or participate in the community forum. You may choose to complete the surveys at your convenience, either then or later. You can use the notification settings on the iPhone to control the notifications you receive.

Study Location: All these procedures are performed using the app. As such, all procedures can be done at whatever location is comfortable for you.

How long will I be in the study?

This community-based app-powered study will last for approximately 6-9 months (*i.e.*, until late 2015 or early 2016). The amount of time you spend in the app and how often you access the app depends on you. We think that participation will take 10-15 minutes each week, but you are able to spend more or less time as you desire. At the end of the study, you may be invited to join the long-term study that the study researchers are planning to better understand the factors that

influence the physical and mental health of LGBTQ and other sexual and gender minority people.

Can I stop being in the study?

Yes. You can decide to stop at any time. You can withdraw from the study directly in the app or you can contact a study researcher or staff person right away at pridestudy@ucsf.edu or 855-421-9991 (toll-free) if you wish to stop being in the study.

Also, the study researchers may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study rules, or if the study is stopped.

Your data collected prior to withdrawing will still be used in the study. By choosing to withdraw, no data will be transmitted to the databases, and all notifications will stop. Data will remain stored within the app on your iPhone. In order to delete these data, you will need to delete the app from your iPhone.

What side effects or risks can I expect from being in the study?

There are risks associated with nearly all studies. This study has minimal risks.

- Answering personal questions about sensitive issues may make you uncomfortable or upset.
- Participating in anonymous community-based discussions – including reading comments written by others – may make you uncomfortable or upset, but you do not need to participate in the discussions that make you uncomfortable.
- Other people may catch a glimpse of study notifications/reminders on your iPhone and realize that you are enrolled in a study or even that you are a LGBTQ or another sexual or gender minority person. This could cause embarrassment or self-consciousness.
- Please do not interact with the app while driving or doing other things that require your full, undivided attention. Please wait until you are in a safe place to conduct your study participation.
- The risk of a breach of your data security, privacy and confidentiality is rare. All databases are encrypted, and all transmissions from the iPhone app to the databases are encrypted. Your identifying information (*e.g.*, name, e-mail address) and study data are stored securely. The encrypted databases that are used are physically and digitally separated. The digital key that links these databases to each other is also encrypted, so even if the study database is hacked, it would be exceedingly difficult for you to be identified.
- Participation in this study may involve risks that are not known at this time.
- For more information about risks and side effects, please contact the study researchers.

Are there benefits to taking part in the study?

There may be no direct benefit to you from participating in this study. Some participants may feel personal satisfaction knowing that they contributed to the planning of a large study designed to improve the health of their communities. The information that you provide in this study may help health professionals better understand the health concerns and priorities as defined by

LGBTQ and other sexual and gender minority community members. Additionally, your participation may help researchers design better mobile applications for medical research.

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. You will not lose any of your regular benefits, and you can still get your care from The University of California San Francisco, the way you usually do.

Will information about me be kept private?

We take privacy very seriously, and 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 that could identify you will not be used.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include The University of California.

Because you will select your own user name for participation in the community discussion groups, your identity will not be disclosed in that setting unless you write personally identifying information in the discussion group.

What are the costs of taking part in this study?

You will not be charged for any of the study procedures. It is important that you know that data collected in this study will count against your existing mobile data plan, but you can set up the app to only use Wi-Fi connections to limit impact on your data plan.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

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 The University of California, San Francisco the way you usually do.

Who can answer my questions about the study?

You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact the researchers: Mitchell R. Lunn, MD and Juno Obedin-Maliver, MD, MPH at 855-421-9991 (toll-free) or by e-mail at pridestudy@ucsf.edu.

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 University of California, San Francisco Office of the Committee on Human Research 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, please sign below.

Date

Participant's Signature for Consent

Date

Person Obtaining Consent