Adaptation and Implementation of an Evidence-based Approach to Advance HIV Prevention and Care

CONSENT FORM

University of California, Los Angeles, Los Angeles, USA
Friends Research Institute, Los Angeles, USA
University of Medicine and Pharmacy, Ho Chi Minh City, Vietnam

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Purpose of the Study
The goal of this study is to address critical gaps in HIV prevention, care, and outcomes and increase vulnerable population's access to HIV prevention services and social services in Ho Chi Minh City (HCMC). Your participation will be valuable in devising culturally appropriate strategies that will reduce HIV risks and provide social support for local sexual minority groups. This research is being conducted by the University of Medicine and Pharmacy in HCMC, the Friends Research Institute, and the University of California, Los Angeles in the U.S. Dr. Chunqing Lin and Sherry Larkins are the Principal Investigators and Dr. Do Van Dung is the In-Country Principal Investigator of this study.

Why am I being invited to take part in this research study?
You were selected as a possible participant in this study based on your sexual identity and your current residence in HCMC. Your participation in this research study is entirely voluntary.

What will happen if I take part in this research study?
If you agree to participate in this study, you will be randomly assigned to either an intervention condition or a control condition, with a 50-50 chance. If you are in the **intervention** condition, you will be invited to three individual counseling sessions led by trained transgender women (TW) peer facilitators. The three individual sessions will be approximately a week apart. These sessions will cover topics such as HIV risk behaviors, regular HIV/CD4/viral load testing, starting and sticking to ART/PrEP, substance use, sexual health, mental health, family relationships, and disclosure. You will also be invited to attend skills-building groups and open discussion support groups focused on overall health, name/gender changes, job opportunities, continuing education, gender transition options, safe sex and dating, self-esteem, violence against TW, family and social relationships, financial literacy, and community involvement. The group sessions will rotate, and you can join them in any order. You can attend as many group sessions as you like, with at least three sessions recommended. You can also invite a family member to the individual or group sessions if you feel comfortable and believe it will help improve your family relationships. You can choose to participate in the individual and group sessions either online via Zoom or in person, depending on what works best for you. If you are in the **control condition**, you will not attend these sessions. However, regardless of which group you are in, you will be invited to two social events that will happen about three months apart, around major holidays. At these events, there will be food, light refreshments, entertainment activities, and health-related information and resources.

You will also be asked to complete three surveys: one at the start of the study before any sessions or events, and the other two at three months and six months afterward. Each survey will take about 30-40 minutes to complete. You can choose to complete the surveys on your own device, or if you need help or do not have the right device, a study interviewer can assist you in person at our project office or over the phone/video call. The surveys will ask about your overall health, HIV status, the services you are using, any stigma you have experienced, and how confident you feel about seeking services. You can choose not to answer any specific question if you don't want to, as participation is entirely voluntary. If you report that you are HIV-negative in one of the surveys, our interviewer will arrange a time for you to either take a rapid saliva HIV test at our project office or send you a rapid saliva testing kit and verify your HIV status via video call. We will also ask for your permission to check your medical records to verify your HIV prevention/treatment medication prescription dates and/or viral load testing dates and results in order to make sure the data is accurate.

How long will I be in the research study?
Each individual or group session will be approximately 60 minutes. Each social event will be approximately 120 minutes. Participation in each of the surveys will take approximately 30-40 minutes.

Are there any potential risks or discomforts that I can expect from this study?
Participation in this study is unlikely to bring any physical risk to you. However, participating in the research activities may require you to use your free time. Some of the survey questions might be sensitive in nature and may make you feel uneasy or uncomfortable. However, providing responses to any of the survey questions is completely voluntary, and you can skip any question if you feel awkward or uncomfortable answering. In addition, some group activities are personal in nature and may also cause you to feel awkward or stressed at times. You may tell the study investigators how you feel and we can help to reassign you to a different group. The peer facilitators will enforce group rules such as being respectful and keeping the confidentiality of other group members. Participants who are disrespectful to other members or do not obey the confidentiality rules will be removed from the group.

Are there any potential benefits if I participate?
You may benefit from the study by getting the opportunity to talk amongst peers who share similar life experiences and gain social support for one another. Participation in the study may increase your awareness and knowledge of the health and social services available to you. You may feel better having a chance to express your challenges accessing health and social services. In addition, the results of the study will help in designing and implementing future programs that will reduce HIV risks, increase access to care, and enhance social support for you and other people like you.

What other choices do I have if I choose not to participate?
Your participation in this study is completely voluntary. You may decide to stop participating in this study at any point and your decision will have no effect on your ability to receive service health and social services. You also have the right to choose not to participate in any of the study activities, or not answer any of the survey questions but still remain in the study. The investigators may withdraw you from this research if circumstances arise that warrant doing so. If this happens, an explanation will be given to you at that time.

Will I be paid for participating?
To compensate you for your time, you will receive 200K VND for baseline, 250K VND for 3-month, and 300K VND for 6-month assessment (750,000 VND for all three surveys).

Will information about me and my participation be kept confidential?
Any information obtained in connection with this study that can be identified with you will remain confidential. All responses that you provide during the surveys will not be revealed to other participants or anyone outside the research team. Special efforts will be made to protect confidentiality when attending in-person and online group activities. You can choose to use an alias when participating in group activities. For online attendance of individual/group sessions, only participants in this project will receive an invitation, and people who are not part of the research team or not a participant will not be admitted to either the Zoom meeting room. All participants will be requested not to disclose any of the discussion contents and to keep everything said in the group activities (including in-person sessions and online discussions) confidential. Even though we will try our best to adhere to the confidentiality requirement, we cannot guarantee complete confidentiality. The information you provide will be used only for the purpose of research. Data will be stored on secure computerized files at a centralized location.

Data will be password-protected with limited access given to research staff. Your data, including de-identified data, may be kept for use in future research.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any data that may identify you unless you say it is okay. This protection includes civil, criminal, administrative, legislative, or other proceedings. The Certificate cannot be used to stop a sponsoring U.S. federal or state government agency from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you give permission. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information. Please note that the Certificate of Confidentiality provides protections only for data held within the United States and is not effective if data are maintained only in a foreign country; therefore, it is possible that this Certificate may not protect your information from disclosure under the laws of Vietnam.

Reporting Requirement

There are important limits to confidentiality related to participant safety. If, during the study, you report thoughts of harming yourself, child or elder abuse, experience of abuse, and threats to others, the research team has an ethical responsibility to help protect your safety and the safety of others. In these cases, a trained member of the research team will speak with you to better understand your safety needs. The study team may contact the study's clinical supervisors or principal investigators to review the situation. With your involvement whenever possible, the study team may help connect you to appropriate medical, mental health, or social support services. If there is a serious or immediate risk to your safety or the safety of others, the study team may contact emergency medical services, hospital emergency departments, or other local emergency response services. In rare situations involving credible threats of violence or serious harm, the study team may be required to contact local authorities. These actions would be taken only when necessary to protect your safety or the safety of others. Whenever possible, the study team will explain what steps are being taken and involve you in decisions about support and referrals.

Public Information about this Study

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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 or participate in any study activities and still remain in the study.

Who can I contact if I have questions about this study?

- **The research team:**
  If you have any questions, comments, or concerns about the research, you can talk to one of the researchers. Please contact:

  Local Research Team:
  Do Van Dung, MD, PhD
  Dean of Faculty of Public Health
  University of Medicine and Pharmacy, Ho Chi Minh City
  dovandzung@gmail.com

  UCLA Research Team
  Chunqing Lin, PhD
  UCLA Center for Community Health
  760 Westwood Plaza, 17-369E, Los Angeles, CA, 90024, U.S.A.; Telephone (001) 310-794-0361. lincq@ucla.edu

  Sherry Larkins, PhD
  UCLA Integrated Substance Abuse Program, 10911 Weyburn Ave, Ste. 200. Los Angeles, CA 90024, U.S.A.; Telephone (001) 310-267-5376; larkins@ucla.edu

- **University of Medicine and Pharmacy Institutional Review Board**
  University of Medicine and Pharmacy
  217 Hong Bang Street, Ward 11, District 5, Ho Chi Minh City, Vietnam

- **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.

Have all of your questions been answered?

ASSENT/CONSENT TO PARTICIPATE IN RESEARCH

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

_____
Name of the guardian (if participant is under age 18)

_____ _____
Signature of guardian Date

USE OF DATA FOR FUTURE RESEARCH

Please sign below if you agree that de-identified survey data from this study (including surveys collected at baseline, 3 months, and 6 months) may be retained for use in future research. All direct identifiers, including your study ID, will be removed, and age will be grouped into broader categories to further protect your identity

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

_____
Name of the guardian (if participant is under age 18)

_____ _____
Signature of guardian Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date