IGHID 12219 - A brief alcohol intervention to reduce alcohol use and improve PrEP outcomes: A randomized controlled trial (BPrEP)

NCT number NCT06094634
Document Date 03/27/2025

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants – ENROLLMENT – PrEP Initiators or Re-initiators

---

Consent Form Version Date: Version date 27 March 2025
IRB Study # 23-0256
Title of Study: IGHID 12219 - A brief alcohol intervention to reduce alcohol use and improve PrEP outcomes: A randomized controlled trial (BPrEP)

Local Principal Investigator: Associate Professor Le Minh Giang, PhD
Department of Epidemiology, Institute for Preventive and Public Health
Hanoi Medical University
Tel: +84 2435741596
Email: leminhgiang@hmu.edu.vn

US Principal Investigator: Professor Vivian Go, PhD
Health Behavior Department, The University of North Carolina at Chapel Hill
Tel: +1-919-966-3908
Email: vgo@unc.edu

Funding Source and Study Sponsor: National Institute on Alcohol Abuse and Alcoholism

Study Contact Telephone Number: Dr. Le Minh Giang: +84 2435741596
Study Contact Email: Dr. Le Minh Giang: leminhgiang@hmu.edu.vn

CONCISE SUMMARY

The purpose of this research study is to evaluate the effectiveness of a brief alcohol intervention (BAI) vs. standard of care (SOC) to improve HIV pre-exposure prophylaxis (PrEP) use among PrEP initiators or re-initiators with unhealthy alcohol use.

If you choose to participate in this study, you will sign this form to confirm your choice. Participation in the study will include 5 study visits. Some participants may additionally have qualitative interview visits or additional study activities. Each study visit will last about 2 hours, and you may be in the study overall for 12-15 months. As part of this study, you would be randomly assigned to SOC arm or BAI arm.

While you may benefit from the BAI if you are assigned to that arm, you may not directly benefit from taking part in the study.

The possible risks of taking part in the study include embarrassment, emotional distress, and potential loss of confidentiality, which may also result in social stigma. There are also the potential risks due to alcohol withdrawal symptoms and low risk of injury and discomfort due to sample collection.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study at any time, for any reason, without penalty. You do not have to be in this study in order to receive care at this clinic.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above or study staff any questions you have about this study at any time.

What is the purpose of this study?
The purpose of the study is to find out how effectiveness a brief alcohol intervention (BAI) is compared to the regular standard of care (SOC) at the clinic to improve pre-exposure prophylaxis (PrEP) use among PrEP initiators or re-initiators who have unhealthy alcohol use.

You are being asked to take part in a research study because you expressed interest in participating and you meet the following criteria:

- You are eligible for PrEP
- You have newly initiated PrEP or re-initiated PrEP after at least 3 months from a missed PrEP appointment
- You are 16 years old or older
- You reported unhealthy alcohol use
- You intend to receive PrEP care in Hanoi for 12 months

Are there any reasons you should not be in this study?
You should not be in this study if you are suffering from psychological disturbance, you have cognitive impairment or threatening behavior, or you are identified to be at risk for alcohol withdrawal based on our assessment. If you are unwilling to provide locator information, currently participating in alcohol programs or studies, have ever participated in an HIV vaccine study, or are currently participating in other research studies (unless permitted by the researchers), you should also not participate in this study.

How many people will take part in this study?
Approximately 564 PrEP initiators or re-initiators and up to 35 stakeholders will take part in this study.

How long will your part in this study last?
If you agree to participate, then you will be in the research study for up to 15 months overall.

What will happen if you take part in the study?
<u>Enrollment and Baseline Visit Procedures</u>

If you agree to participate in this study, you will proceed with enrollment steps including confirming your study enrolment eligibility and obtaining your written informed consent to enroll in this research study. Your participation in the study will include at least 5 study visits in the span of up to 15 months. The first study visit will be your baseline visit, then you will have follow-up visits every 3 months after baseline.

You will participate in your baseline visit procedures today, including a baseline questionnaire which will take approximately 1.5 hours to complete. If you are not able to complete your baseline visit today, you will be scheduled to complete your baseline visit within 1 month from today.

After completing the baseline procedures, you will be assigned to 1 of 2 study arms: one arm is the standard of care "SOC arm" and the other arm is the Brief Alcohol Intervention "BAI arm". These two study arms are very important to this study. You cannot choose which study arms you are in. You will be randomly assigned to a study arm. This means that your study arms will be assigned to you "by lot" (like drawing straws or flipping a coin). You and other study participants will all have the same chance of being placed in any one of the 2 study arms.

People in all 2 study arms will have generally the same study visits, but people in the BAI arm will have more visits, some of a different kind, than the SOC arm. Details about the study arms and visits are described below:

If you are placed in the "SOC arm", this means that you will receive the usual clinical and counseling services available for you at your PrEP clinic.

If you are placed in the "BAI arm", you will additionally be asked to come in for 2 in-person counseling sessions and receive 2 booster telephone sessions with a trained counselor. These sessions will be in addition to the 4 follow-up study visits. The BAI counseling sessions are as follows.

- Within about 7 weeks of your enrollment date, the appointment will be made for the initial BAI counseling session to occur at the PrEP clinic. This is an approximately 45-minute face-to-face session administered by clinic staff to assist you with skills and strategies to cut down or quit alcohol use. The second appointment will occur within about 7 weeks and may be conducted virtually as needed.
- You will also receive 2 booster telephone sessions. These are 10-15-minute telephone sessions occurring 2 to 3 weeks after each face-to-face session.

Participants in the BAI arm will also be asked an additional brief survey about their experiences with their BAI counselor.

For all participants: During this study visit, the study will be explained to you. You will have time to ask questions and discuss any concerns you may have with the study staff. During this visit:

- If your screening occurred prior to today, we will give you a questionnaire to reassess your possibility of experiencing severe alcohol use disorder if needed.
- We will ask you to confirm your contact information.
- Our trained study staff will conduct a baseline assessment questionnaire, including questions about demographics, alcohol use, drug use, sexual behavior, HIV testing and sexually transmitted infection (STI) history, PrEP use history, experiences seeking PrEP care, and health care costs associated with PrEP care and/or alcohol use,
- Our trained study staff will also administer the baseline Timeline Follow Back (TLFB) interview for alcohol use with you, which uses a daily behavior calendar to prompt memory to recall quantities of alcohol consumed each day of the 30-day period prior to the assessment.
- We will review your medical records to confirm and document HIV and STI testing results.
- You will be randomized to either the BAI arm or SOC arm.
- Your blood will be drawn for rapid testing HIV and Syphilis, an STI.
- We will collect dried blood spot (DBS) specimen from you, which is a small amount of blood placed on a DBS card for laboratory testing. Your DBS specimens will be stored through the end of this study for alcohol use and PrEP metabolites testing.

- Urine, Rectal and Pharyngeal swabs will be collected for testing Gonorrhea and chlamydial infection (GC/CT) which are STIs.
- We will tell you the results of any tests we do during the study at the study site and will refer you to your HIV/STI care for treatment, if needed.
- We will offer you condoms and lubricant.

Follow-up visits

After your enrollment visit, we will ask you to come back for 4 follow-up visits at 3 months, 6 months, 9 months, and 12 months after your enrollment visit. During these visits, participants will go through all following activities:

- We will ask you to confirm or update your contact information again.
- We will give you a questionnaire to reassess your possibility of experiencing severe alcohol use disorder if needed.
- We will give you a follow-up assessment questionnaire, including questions about demographics, alcohol use, drug use, and sexual behavior.
- We will review your pharmacy records for PrEP use
- We will review your medical records to confirm and document the most recent HIV and STI testing results.
- We will collect your blood specimen for HIV/STI rapid testing and store for other testing related to this study or other future research as baseline visit if you did not have testing performed at your clinic.
- We will tell you the results of any tests we do during the study at the study site and will refer you to your HIV/STI care for treatment, if needed.
- We will offer you condoms and lubricant.

However, each follow-up visit will have other activities in addition to the common procedures above. More specifically,

At the 3-month visit:

- Our trained study staff will also administer a follow-up Timeline Follow Back (TLFB) interview for alcohol use.
- Urine, Rectal and Pharyngeal swabs will be collected for Gonorrhea and chlamydial infection (GC/CT) testing.
- You will be asked to have dried blood spot (DBS) specimen collected and stored through the end of this study for PrEP metabolites and alcohol use testing.
- Approximately up to 25 people each arm will be asked to take part in a qualitative cohort subgroup at month 3 and month 12. A qualitative in-depth interview will be administered by study staff to ask about your knowledge about the overall study, perceptions of drinking alcohol, sexual behaviors, PrEP use, and the BAI for those in the BAI arm.

You will be asked to sign your initials at the bottom of this form to take part in these activities.

At the 6-month visits:

- We will give you another questionnaire asking about health care costs associated with your PrEP care and/or alcohol use.
- Urine, Rectal and Pharyngeal swabs will be collected for Gonorrhea and chlamydial infection (GC/CT) testing.

At the 9-month visit: The procedure at this visit is the same as common procedure of follow up visit.

At the 12-month visit:

- Our trained study staff will also administer a follow-up Timeline Follow Back (TLFB) interview for alcohol use.
- We will give you another questionnaire asking about health care costs associated with your PrEP care and/or alcohol use.
- Urine, Rectal and Pharyngeal swabs will be collected for Gonorrhea and chlamydial infection (GC/CT) testing.
- A qualitative in-depth interview will be administered by study staff for a subgroup at the month 3 visit.
- You will be asked to have dried blood spot (DBS) specimen collected and stored through the end of this study for PrEP metabolites and alcohol use testing.

Qualitative Cohort Subgroup

A subset of all study participants (up to 25 participants from each study arm) will be selected to additionally participate in qualitative interviews. If you are selected for the qualitative cohort, you will be administered in-depth interviews at 3 months and 12 months after enrollment in the study. Each in-depth interview will last approximately 1 hour.

We will ask you about your experiences with your overall study participation and your perceptions of drinking alcohol, sexual behaviors, PrEP use, and BAI if you are in the BAI arm. Up to 50 people will take part in the qualitative cohort in-depth interviews. These interviews will be recorded. **Please indicate at the end of this consent form if you agree or not to take part in the qualitative cohort interviews, if selected.**

BAI Completion Interviews Subgroup

A subset of BAI arm participants will be selected to additionally participate in a one-time individual BAI completion interview that will last approximately 1 hour. These interviews will be conducted after the last BAI session learn about the participant's experiences with participating in the BAI. Up to 48 BAI arm participants will take part in the BAI completion interviews. These interviews will be recorded. **Please indicate at the end of this consent form if you agree or not to take part in the BAI completion interview, if selected.**

Other

Follow-up interviews including the qualitative cohort and BAI completion interviews will occur in person at a study site, but may be conducted over the phone or virtually, as needed.

We would like to audio-record the BAI counseling sessions, qualitative cohort interviews, and BAI completion interviews. The audio-recordings will allow us to assure the quality of the counseling sessions and to analyze the results of the qualitative cohort and BAI completion interviews. Your name will not be included on the audio-recordings. The recording will be destroyed after all analysis is completed. You can refuse to allow these recordings at any time with no penalty. This will not affect your participation in the study or your quality of care at the clinic. **Please indicate at the end of this consent if you agree or not to the counseling sessions, qualitative interviews, and BAI completion interviews being recorded.** If you agree now but change your mind during the study, you can ask the counselor or interviewers to stop recording. They will then stop recording before continuing with the session/ interviews.

While you are in this study, you may be asked to carry a clinic timesheet with you during your PrEP clinic visit to document the time spent with each clinic staff member. The clinic timesheet will not have any information linking to your name or identity.

Any participant who leaves the study prior to 12 months will be asked to participate in a brief study termination interview. **Please indicate at the end of this consent form if you agree or not to take part in the study termination interview if applicable.**

We also want to keep your contacts so that we can contact you in the future if needed. You will be asked to give consent to be contacted for future studies.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You may benefit from the SOC and/or BAI and learning about your HIV and STIs status on a quarterly basis, getting referrals for treatment if needed, and learning ways to prevent HIV and STI acquisition or transmission. Participants in the intervention arm may benefit from intervention sessions that aim to help participants reduce their alcohol use. You may also benefit from being able to share your experiences and opinions about the SOC and/or BAI intervention. You may benefit from potentially more effective implementation of SOC.

You will not receive any direct benefit from sharing your data. However, sharing your data may contribute to research that could help others in the future.

What are the possible risks or discomforts involved from being in this study?

- You may become embarrassed, worried, or anxious when discussing your sexual practices, alcohol use, or HIV.
- We will make every effort to protect your privacy and confidentiality. However, there is potential for the loss of confidentiality. If people learn that you are here for this study, people may think that you are at risk of HIV, learn that you are initiating or re-initiating PrEP, or assume that you are a person with unhealthy alcohol use, and they may treat you unfairly.
- There may be uncommon or previously unknown risks. You should report any problems to the researcher listed on this form or to our study staff.

<u>Social Impact Reporting</u>

We will make every effort to protect your privacy and confidentiality while you are in this study. However, it is possible that you could have problems if people learn that you are here for this study. People may think that you are at risk of HIV because of sexual behavior. It is also possible that others may find out that you have been screened for this study and assume that you are a person with unhealthy alcohol use. If people think you are at risk of HIV or a person with unhealthy alcohol use, this could cause you problems with some people who may treat you unfairly, including your family, community members, or employer.

We will do our best to protect your data during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data. In either case, we cannot reduce the risk to zero.

<u>Blood draw, urine samples, rectal and pharyngeal swabs</u>

- There are minimal risks to giving blood, such as slight pain when the needle is inserted and possible bruising.

- There may be some minor, temporary discomfort when collecting the rectal and pharyngeal swabs.

In-Depth Interview

- There may be a small risk of psychological distress by study questions. You can terminate the interview at any time.

Alcohol withdrawal symptoms:

There are a set of symptoms that can occur following a reduction in alcohol use after a period of excessive use. People with alcohol withdrawal may experience symptoms such as tremors, anxiety, nervousness, depression, fatigue and irritability or more severe symptoms including agitation, severe confusion, hallucinations, fevers, and seizures.

To reduce your risk of alcohol withdrawal, the following measures will be implemented:

- We will have a physician or trained study staff to monitor if you have potential alcohol withdrawal symptoms. If we determine you have or at high risk for alcohol withdrawal, we will suspend your study activities, refer you to appropriate medical care, and provide you with guidance for tapering your alcohol use. You will be permitted to continue the study activities when you are no longer at high risk for alcohol withdrawal.

- If you have the above symptoms, please inform the study team and we will refer you to the Hanoi Medical University Hospital where you will undergo appropriate available treatment and care prior to continuing any study activities.

- A study physician will be on call 24 hours a day. Please call the study team if you experience any side effects of alcohol withdrawal.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
You will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent.

All study interviews and procedures will be administered by trained study staff in a private room. If names and identifying information are collected, a logbook will be used to link a participant's identifying information with his/her study identification number (PID); personal identifiers will not be stored in the data set. The logbook will be kept in a locked cabinet, separate from all other study file cabinets, in a locked project office room; an electronic copy will be saved on a password-protected, encrypted computer. All data, notes, and audio- recordings will also be kept on a password-protected, encrypted computer. Access to the locked files and security passwords will be given only to the PIs, UNC-Vietnam In-Country Director, Research Manager and selected well-trained project staff. The logbook will be destroyed and the electronic copy deleted 12 months after the end of data collection. Tapes of qualitative interviews will be destroyed within one year of being transcribed electronically. Raw data files will be destroyed one year after electronic coding.

The study team will protect the privacy of your study records and test results to the extent permitted by law, but cannot guarantee that your study records will never be released to others. Unless required by law or unless you give written permission, study records that identify you will not be released to other parties or entities. However, your study records may be reviewed by various government agencies that have a legal right to do so, such as the sponsor of the study (National Institute on Alcohol Abuse and Alcoholism), the University of North Carolina at Chapel Hill Institutional Review Boards and the Institutional Review Board for Ethics in Biomedical Research – Hanoi Medical University, selected well-trained study staff and study monitors. It is also possible that a court or other government agency could order that study records identifying you be released to others. Any publication or presentation of the results of findings of this study will not use your name and will not include any information that will identify you.

The Sponsor will not share individual participant data with you in order to maintain the scientific integrity of the study.

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 is a Certificate of Confidentiality?
Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

Will you receive results from research involving your specimens?
We will tell you the results of any tests (HIV/STI rapid testing) we do during the study at the study site and will refer you to your HIV/STI care for treatment, if needed. However, your DBS specimens will be stored through the end of this study for alcohol use and PrEP metabolites testing. There are no plans to re-contact you or other subjects with information about these research results involving your specimens. Your biospecimens (even if identifiers are removed) may be used for commercial profit and you will not share in this commercial profit.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time for any reason, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study, all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal. If you do not want your data used for other projects, you should not participate in this study.

Reasons why you may be withdrawn from the study without your consent.
You may be removed from the study without your consent for the following reasons:

- The study is stopped or canceled.
- Staying in the study would be harmful to you.
- You are not able to attend study visits or complete the study procedures.

Will you receive anything for being in this study?
You will be compensated for your time and travel expenses as follows:

- An amount of VND 300,000 (USD $12.90) for completion of the survey at enrollment;
- An amount of VND 200,000 (USD $8.60) for completion of the surveys at 3, 6, 9, and 12 months;
- An amount of VND 200,000 (USD $8.60) for dried blood spot collection at enrollment, 3, and 12 months;
- An amount of VND 200,000 (USD $8.60) for completion of the BAI completion interview if selected;
- An amount of VND 300,000 (USD $12.90) for completion of any in-depth interview if selected.

You will receive travel support in an amount of VND 100,000 (USD $4.30) for attending the BAI in-person counseling sessions if selected.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the US. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

NIAAA Data Archive (NIAAADA)
Data from this study will be submitted to the National Institute on Alcohol Abuse and Alcoholism Data Archive (NIAAADA) at the United States National Institutes of Health (NIH). NIAAADA is a large database where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate, and phone number) is removed and replaced with a code number. During and after the study, the study researchers will send deidentified study data about your health and behavior to the NIAAADA. Other researchers across the world can then request your deidentified study data for other research. You will not be contacted directly about the study data you contributed to NIAAADA.

Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every

attempt to protect your identity. You may not benefit directly from allowing your study data to be shared with NIAAADA. The study data provided to NIAAADA may help researchers around the world do more powerful research.

You may decide now or later that you do not want your study data to be added to the NIAAADA. **You can still participate in this research study even if you decide that you do not want your data to be added to the NIAAADA.** If you decide any time after today that you do not want your data to be added to the NIAAADA, inform the study staff, and they will not share your data collected on or after that date. The study researchers cannot remove the study data that was shared before they were notified that you changed your mind. If you would like more information about NIAAADA, this is available on-line at https://nda.nih.gov/niaaa.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant, or if you would like to obtain information or offer input, please contact:

- Dr. Le Minh Giang, Head of Department of Epidemiology, Institute for Preventive and Public Health, Hanoi Medical University at +84 2435741596 or at leminhgiang@hmu.edu.vn
- Hanoi Medical University Institutional Ethical Review Board in Biomedical Research at +84 2438527622 or by email to irb@hmu.edu.vn

Or you may contact the University of North Carolina at Chapel Hill Institutional Review Board (IRB) at +1-919-966-3113 or by email to IRB_subjects@unc.edu.

SIGNATURES - ENROLLMENT CONSENT FOR PrEP INITIATOR or RE-INITIATOR ADULTS

Please indicate below by writing your initials or make your mark if you agree or not to have your study data, including information collected during the study screening assessment, submitted to the NIAAA Data Archive.

I agree _____

I do not agree_____

Please indicate below by writing your initials or make your mark if you agree or not to take part in the two **Qualitative Cohort interviews** (at 3 months and 12 months), if selected.

I agree _____

I do not agree_____

Please indicate below by writing your initials or make your mark if you agree or not to take part in the one-time **BAI completion interview**, if selected.

I agree _____

I do not agree_____

Please indicate below by writing your initials or make your mark if you agree or not to take part in a brief **study termination interview** if you leave the study prior to 12 months.

I agree _____

I do not agree_____

Please indicate below by writing your initials or make your mark if you agree or not to having your BAI counseling sessions, BAI completion interview, and qualitative cohort interviews **audio-recorded**, if you participate in any of those sessions or interviews.

I agree _____

I do not agree_____

Please indicate below by writing your initials if you agree or not to be contacted by the study team for future studies or to follow-up or clarify information you provided, when appropriate:

I agree _____

I do not agree _____

Can the study team send you unencrypted (unprotected) messages to you about your study participation?

The study team would like to message you by text messages, Zalo, or email. However, you may say “no” to receiving these messages and still participate in this study. If you say “yes”, messages may contain personal information about you and may be sent or received by the study team’s personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of the consent. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing:

My Cell phone number _____

My Zalo user name _____

My Email address _____

If my phone number or email address changes, and I want to continue receiving unencrypted messages, I will notify the study team and provide them with my new information but will not be required to sign this document again.

_____ No, I do not consent to receive un-protected communication from the study team.

Participant’s Agreement:
I have read and understand the information provided in this consent form. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

If you agree with the above Participant’s Agreement, then please sign your name, make your mark or place your thumbprint below.

PART A: LITERATE PARTICIPANT

Participant is literate ☐

_____	_____
Your signature if you agree to be in the study	Date
_____	
Print your name if you agree to be in the study	

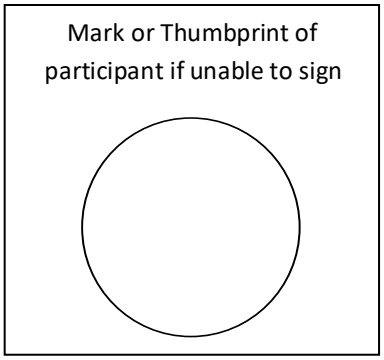
_____	_____
Signature of Research Team Member Obtaining Consent	Date
_____	
Printed Name of Research Team Member Obtaining Consent	

PART B : ILLITERATE PARTICIPANT

Participant is illiterate ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The **study staff must write participant's name and date of consent** below**.**



Participant Mark or Thumbprint

_____ _____

Participant Name (print) Date

Participant name and date written by _____ on _____

_____ _____ _____

Study Staff Conducting Consent Discussion (print) | Study Staff Signature | Date

_____ _____ _____

Witness Name (print) | Witness Signature | Date