Effect of Mindfulness Training on Opioid Use and Anxiety During Primary Care Buprenorphine Treatment (MINDFUL-OBOT)

NCT04278586

Informed Consent Document

Version Date: 08/05/2022

Ca INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

We try to make this form easy to understand. But it may have words or ideas that are not clear to you. Please ask a member of the study team to explain anything you do not understand. You may take this form home with you to discuss with family or friends before you decide whether to be in this research study.

Study Title: Effects of Live-Online Groups on Stress, Opioid Use and Anxiety During Buprenorphine Treatment.

Your name (Participant):	**Today's Date:**

Not including this study, are you taking part in any research now? ☐ Yes ☐ No

Name of Principal Investigator: Zev Schuman-Olivier, MD

Name of Co-Investigator(s): Richa Gawande, PhD, Alaine Fredericksen, LICSW, Randi Sokol, MD, Alexandra Oxnard MD, David Roll, MD, Ellie Grossman, MD, Benjamin Cook, PhD, Todd Griswold, MD, Nancie Rouleau, PhD, Laura Holland, MD, Annalee Wells, MD, Sarah Moore, PhD, Roger Weiss, MD, Timothy Creedon, PhD; Colleen LaBelle; Paula Gardiner, MD.

Consent form version date or number: Version 1.12 08/05/2022

Name and telephone number of study contact to call with questions:
Hannah Goodman, Study Coordinator (781-873-9814, stressreduction@challiance.org)

CHA IRB Number: CHA-IRB-1114/06/19 **Study Sponsor(s):** NIH/NCCIH

Key Information

- You are invited to take part in an online study called “Effects of Live-Online Groups on Stress, Opioid Use and Anxiety During Buprenorphine Treatment”
- Taking part in this study is voluntary. You have the choice to take part or not. You may leave the study at any time for any reason.
- You will be asked to participate in the study for 24 weeks. You will be asked to complete surveys before your first group, and then again at 8, 16, and 24 weeks. You will also be asked to complete weekly surveys throughout the 24-week study. You will also be asked to complete saliva sample collections at various timepoints.
- You will be randomly assigned to participate in a live-online group for at least 4 weeks with the option to continue up to 24 weeks. The groups aim to help you lower your stress, decrease your anxiety and depression, feel less isolated and more supported, and help you manage your opioid use.
- You may not benefit from this program. You may have moments where you feel stressed, embarrassed, or anxious due to being in a group. You may spend extra time learning stress and anxiety reduction techniques and be asked to practice skills at home between groups. You may have physical discomfort from gentle movement in groups. Despite strong efforts to maintain

confidentiality, if you participate in online programs, as with any activity on the internet, it is possible that your protected health information (PHI) may be exposed.

- You can choose at any point to discontinue participation in this study.

Introduction

Please read this form carefully. This form tells you about a study called “Effects of Live-Online Groups on Stress, Opioid Use and Anxiety During Buprenorphine Treatment.” This study is being conducted by researchers at Cambridge Health Alliance, in Cambridge, Massachusetts. We are recruiting study participants who are prescribed buprenorphine in Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Texas, Vermont, California, North Carolina, Alabama, Virginia, Illinois, Michigan, or Arizona. You will participate in this study online via Zoom videoconference and through a confidential study survey website called REDCap. If you choose to take part in this study, you will be asked to electronically sign and date this form. You will be given an electronic copy of the signed form for your records.

Taking part in this study is voluntary. You have the choice to take part or not. If you take part in this study, you may leave at any time for any reason. If you don’t want to take part, it does not change any part of the standard health care you will receive at your primary care site.

Having the support of a group can help people lower stress and anxiety, while feeling less isolated and more supported. Learning stress and anxiety reduction techniques in a group can be beneficial to people’s well-being and help decrease anxiety and depression. This program aims to bring stress reduction tools to patients with opioid use disorder who are currently receiving buprenorphine/naloxone treatment. It is not, however, guaranteed that you will experience these benefits.

The National Institutes of Health (NIH) is providing funding for this research. If you have any questions about the research or about this form, please ask us.

We will tell you about any new findings that may cause you to change your mind about being in this study.

Purpose for the Study

This study will offer a weekly live-online group with other people who are prescribed buprenorphine for opioid use disorder, which may focus on education, stress reduction, anxiety reduction, supporting each other, checking in about any stressors from the week, and/or talking about recovery. This group will take place online, and you will be asked to use the video camera on your computer or phone to participate. During groups, you will NOT be forced to talk about difficult past events and can choose to pass at any time you feel uncomfortable. You will be randomly assigned to one of the groups, and groups will be focused on helping you reduce stress or anxiety, maintain sobriety, and live well in recovery. The study will examine how the different groups affect your well-being, your substance use, and your relationships. Approximately 236 participants will be enrolled in this study between November 2020 and January 2023.

Reasons why you have been invited to be in this study

You have been invited to participate in this study because you are a patient who is receiving a prescription of buprenorphine and you live in Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York,

Rhode Island, Texas, Vermont, California, North Carolina, Virginia, Alabama, Arizona, Illinois, or Michigan. Your provider or nurse care manager may have referred you to this study or you may have referred yourself to this study.

To take part in this study, you have to meet the following criteria:

- You are between 18 and 70 years of age.
- You have a diagnosis of opioid use disorder and are prescribed buprenorphine from a qualified prescriber.
- You understand English well enough to understand procedures and questionnaires and provide informed consent.
- You are able to fill out weekly surveys on an electronic device (like a tablet smartphone, or computer) at home.
- You are NOT participating in another research study.
- Either you have used non-prescribed opioids (e.g. Oxycodone, Vicodin, Percocet, Fentanyl, Heroin, etc.), non-prescribed benzodiazepines (e.g. Xanax, Klonopin, Ativan, etc.), non-prescribed stimulants (e.g. Adderall, Crystal Meth), cocaine, OR alcohol in the past 90 days OR you have an anxiety or stress disorder.
- You are able to access the internet using an electronic device with a camera to participate in online groups and complete surveys. A tablet electronic device or smartphone may be provided during the study if needed.

Period of Participation (how long you will be in this study)

You will be screened during your first online visit to determine whether you are eligible for this study. You will be compensated for this visit even if you are not eligible to join the study.

If you are found to be eligible for the study, you will be randomly placed in one of two groups with different approaches to stress and anxiety reduction, creating community and providing support, and maintaining sobriety while helping you to live well in recovery. You will be expected to participate in your assigned group for 60-90 minutes a week for at least four weeks. After 4 weeks, you will have the option to continue with the group that you're in or to stop attending groups. You will be able to continue as part of the study for up to 24 weeks. Throughout the study, you will continue to receive your buprenorphine prescription from your prescriber at your primary care site and to follow your primary care clinic's standard treatment expectations.

You will be expected to complete an online survey session before your first group and then again at 8, 16, and 24 weeks. These sessions may last up to 60-minutes and you will be paid for time completing study tasks. You will also be asked to complete a computer survey interview before your first group, then again at 12 and 24 weeks. You will be emailed a secure link to complete these surveys online. You will also be expected to complete weekly surveys for the first 24 weeks of the study, which may last about 7 minutes each week.

We ask you NOT to participate if you expect to be hospitalized in the next 24 weeks for a health problem. We will ask you NOT to participate if you expect to go to jail in the next 24 weeks. You may participate in this study if you are pregnant. No other experimental treatments or participation in other investigational trials are allowed during the study.

Procedures (what will happen during this study)

This study has 7 components: a screening session, 4 full survey sessions, computer survey interviews, group sessions, weekly brief surveys, saliva drug and alcohol testing, and an optional interview after your 24 weeks

of participation in the study.

1) Group Sessions: You will be asked to attend an online weekly group for 60-90 minutes each week for at least 4 weeks. These groups will take place via the video conference application Zoom, and you will be asked to use a tablet, smartphone or computer with a camera to join from a private location. The groups are regular groups designed for people in early recovery. In your group you may learn skills to help you reduce stress and anxiety and prevent relapse. The group may also help you cope better with pain and cravings. The group may

also help you connect with other people in early recovery prescribed buprenorphine helping you feel less alone and isolated and more connected. You will not be asked to pay a co-pay.

2) Weekly Surveys: You will fill out weekly surveys online that ask questions about your substance use in the past week and your use during the past week of the skills you have learned about in group.

3) Saliva (Oral Fluid) Toxicology Testing: You may be randomly selected to participate in a saliva drug and alcohol test up to once a week during the study. This test will take place over Zoom video chat and will be supervised by a member of the study team. When you are ready to start the study, you will be sent a package with saliva drug tests by mail that you will use when your number is randomly drawn by study staff to provide a test that week. These oral fluid toxicology testing results will only be used for research purposes and will not be shared with your primary care provider.

4) Screening Session: After you sign the informed consent form, you will participate in a 30-40-minute long online screening session to determine your eligibility for the study. The online session will include a 12-minute computer survey interview, a 3-minute long survey, and may include a 10-minute cognitive test. The goal of this session is to ensure you are eligible for the study.

5) Full Survey Sessions: If you are determined to be eligible to participate in the study, you will participate in a full 60-minute online survey session 4 times: at the beginning of the study before you start group, after 8 weeks of group, at 16 weeks, and at 24 weeks. Each visit will be conducted through an electronic device and you will be allowed to take a break if needed while completing the surveys.

During these sessions, you will do the following:

- You will be asked to fill out surveys on a computer, electronic tablet, or smartphone for 60 minutes using a link that will be emailed to you by the study team.
- You will be able to take a short break if needed during the session.
- You will be paid for your time conducting study surveys.

6) Computer Survey Interviews: If you are determined to be eligible to participate in the study, you will be asked to complete a 12-minute computer survey interview 3 times. This survey will be emailed to you at the beginning of the study before you start group, at 12 weeks, and at 24 weeks. Each survey can completed through an electronic device.

7) Interviews: You may be given the opportunity to share your experience during an online, one-on-one, 30-60-minute interview with a study staff member after week 24. We will be conducting 12 to 25 interviews, so whether or not you are asked to participate in one will depend on the number of interviews that have already been completed. These interviews will be audio-video recorded and all identifying information will be removed from the recording by a study staff member. The files will be stored on a secure CHA computer server and transcribed using HIPAA compliant software.

Collection of identifiable private information or identifiable biospecimens The saliva specimens will be collected using oral fluid toxicology kits sent to you at the beginning of the study. We will take an image of the test result through the Zoom videoconference and store this in a confidential file at Cambridge Health Alliance. We will provide you with instructions to safely discard the saliva samples after use at home and the samples will not be stored by the study team. This oral fluid test is not FDA cleared and should not be used on

its own to make any decisions about your care. The results will only be used for research purposes. This information will not be shared with your primary care buprenorphine provider. You will be able to request that your attendance and oral fluid toxicology screen results be mailed to you at monthly intervals for the duration of the study.

Identifiers might be removed from the identifiable private information we collect from you during the course of this study. Only after any identifying information is removed, the de-identified data we collect may be used for future research studies, or distributed to another investigator for future research studies, without additional informed consent.

Participant Engagement Call (Every other week):

You will be called by a member of the study staff every other week during the 24-week study. This will be a short (5-minute) outreach call to provide you support as you participate in the study. During this call, the study staff can help you answer any questions, help you with any problems you may have in filling out the surveys, and hear about anything that you would like to share with the study staff. If you don't answer this phone call, the study staff will leave a message. A study team member may also reach out to you via text message or email to remind you about various study assessments you might have forgotten.

Possible Risks, Discomforts, Side Effects, and Inconveniences

The following are possible risks and side effects associated with your participation in this study:

- Some questions that you will be asked are personal. You might feel stressed or embarrassed. You may ask to see the questions before you participate in the study. If you get upset or stressed, you can call the research staff. The research coordinator can connect you with behavioral health resources if needed.
- You may spend extra time learning techniques and doing study tasks.
- You may have physical discomfort from any gentle movement that you do in your group.
- You may feel anxious being in a group or due to what you learn or do in group.
- You might not benefit from this program.
- Despite strong efforts to maintain your confidentiality, your protected health information (PHI) might be exposed. All digital information collection and transfer using the internet carries the risk of loss of confidentiality due to privacy breach.
- Group members will be asked to keep what you share confidential, but they may not. You may be invited to share your experiences, but you will not be forced to share personal information in group and can always ask to speak privately with a study clinician afterwards if there is something you feel you want to discuss but feel worried to do so in group.
- You might experience eye strain and finger/hand discomfort from completing surveys.

We will be happy to answer any questions you have about these risks and/or side effects. Please talk with a study team member if you have any study-related questions or concerns.

Alternatives to Participation

Participation is **voluntary.** Whether or not you enroll in this study will not affect your health care at your primary care site. Participation in this study does not replace standard of care at your primary care site. You may choose not to participate in the study and return to solely participating in standard care options that are approved by your primary care clinical treatment team.

Benefits (good that may come from being in this research)

Potential benefits to you from being in this study are:

- You may learn about others who have similar problems as you do, helping you feel less alone
- You may feel increased accountability in your recovery by being in group
- You may have less of a need for symptom-relieving medication like benzodiazepines and opioids
- You may find that you smoke fewer cigarettes and drink less alcohol
- You can learn skills for controlling behavior and improved well-being
- You may feel less craving
- You may feel less anxiety, panic, and stress
- You may feel less depression and pain
- You may feel more joy and gratitude

Some of these benefits may not help you directly. However, what we learn from this research may help others in the future. There is no guarantee you will benefit from being in the study.

Costs

You will not have any additional costs from being in this study. The time related to research group sessions will be given to you at no cost. You will be asked to continue with your Buprenorphine treatment as usual, for which you may be responsible for co-pays or other costs related to your standard care situation.

To access online groups, you will need an internet enabled electronic device with a video camera. If you do not have access to this device, you will have the option to receive a smartphone or electronic tablet device with unlimited data for the duration of the study. If you have a smartphone and would like to upgrade to unlimited data for the duration of the study, you will have the option to do so and the study team will pay the difference if you provide receipts showing your upgrade costs.

Payment

You will be paid up to $478 during the study:

- o Payment 1: $20 for screening/consent visit
- o Payment 2: $40 for baseline surveys/computer task + $5 for completing the survey in 48 hours
- o Payment 3: $40 at 8-week study visit + $5 for completing the survey in 48 hours
- o Payment 4: $40 at 16-week study visit + $5 for completing the survey in 48 hours
- o Payment 5:
  - ▪ $40 at 24-week study visit + $5 for completing the survey in 48 hours
  - ▪ Up to $48 for a completion bonus at the 24-week visit. You will get this bonus only if you have completed your baseline, 8-week, 16-week, and 24-week study visits, and at least 90% of your randomly assigned saliva drug testing visits and at least 75% of your weekly surveys. If you are given a study phone, you must return it to the team to receive this bonus. This bonus could range from $36 to $48 depending on your weekly survey completion (at a rate of $2/week for 24 surveys completed).
  - ▪ $50 at 24-week study visit if you are selected for and choose to participate in an hour-long one-on-one interview about your experience with a study staff member
- o Weekly payments:
  - ▪ $5 for every group you attend
  - ▪ $5 for every two-week period in which you complete both of your weekly surveys and any saliva toxicology screens you are assigned to complete.
  - ▪ Over the course of the study, this amounts to a total of $180 for participants who complete all of their weekly surveys and saliva toxicology screens and attend each group session.

You will receive an email link to an individual gift card at each payment time point. Study staff will assign an amount to each card with the appropriate amount of your study payment after your screening/consent, baseline, week 8, week 16, and week 24 visits. You can choose whether to receive weekly payments each week, or at the next payment time point. The study staff will ask you to disclose your personal information (e.g., name, email) to the gift card service in order to use these cards. You will then be able to choose a retail vendor to spend your gift card amount on (e.g. Amazon, Best Buy, etc.).

Study-Related Injury

If you think that you have been injured by being in this study, please let the investigator know right away. Use the phone number on the first page of this form. You can get treatment for the injury where you get primary care or at any healthcare facility you choose. There is no program to provide compensation for the cost of care for research related injury or for other expenses. Other expenses might be lost wages, disability, pain, or discomfort. You or your insurance will be billed for the medical care you receive for a research injury. You are not giving up any of your legal rights by signing this form.

Voluntary Participation

Taking part in this study is voluntary. If you do not take part, you will not be punished or lose benefits that you have the right to receive. The quality of your medical care will be the same at your primary care site whether you take part in the study, refuse to take part, or decide to leave the study.

If you choose to take part and then decide to stop, tell a member of the research team. It may not be safe for you to suddenly stop being in this study. The study team will help you stop safely.

If you no longer want to participate in your assigned study group ("Group Discontinuation"), you may do so at any time by notifying a study staff member in writing or via email. You can leave a study group, but still remain in the study and complete study activities and be paid for your time, including for completing saliva drug screens, weekly surveys, computer tasks and survey sessions.

If you choose to withdraw from the study completely ("Study Withdrawal"), you will no longer be expected to complete study activities listed above and you most likely will not be able to continue in a study group. Any information collected from you before the date you leave the study will be used in the research study. If you wish to withdraw from the study, please notify the study staff either in writing or via email that you wish to do so.

The research team may decide that you can no longer be in the study group ("Group Discontinuation"). This could be for several reasons, including:

1. You have had a bad reaction to the study.
2. Your substance use worsens substantially requiring referral to a higher level of care.
3. You did not follow all the group rules.
    a. You breached the confidentiality of other people in the group by sharing their information outside of the group.
    b. You threatened others in the group or provided serious disruption to group.
    c. You were found to be sharing or selling your buprenorphine medication.

The research team may decide that you can no longer be in the study ("Study Withdrawal"). This could be for several reasons, including:

1. You threaten study staff.
2. You tamper with your saliva toxicology screens.
3. You are unable to complete baseline survey sessions.
4. You are repeatedly too intoxicated to complete study assessments.
5. You meet study exclusion criteria.
    a. You are experiencing acute psychosis, mania, or suicidality with plan.
    b. You are unable to complete study surveys or cognitive screening.
    c. You are currently participating in another experimental research study.
    d. You have previously participated in a related study.
    e. You expect to be medically hospitalized in the next 24 weeks.
    f. You expect to go to jail or prison in the next 24 weeks.
    g. You are experiencing substance use severity likely requiring inpatient hospitalization.
    h. You are unable to participate in the study group without disrupting the group.

Video Recording of Group Sessions

Some group sessions during the course may be video recorded through Zoom. This is so that we can monitor the way the group leader leads each session. Video will NOT be linked to any personal or identifying information collected in other aspects of the study, including your name. Please indicate your agreement to be video-recorded during group sessions.

I agree to be video recorded during group sessions.

☐ I agree ☐ I do not agree

Future Contact

Sometimes the study team has information about other studies or opportunities that might interest you. Please indicate below whether you give permission for us to contact you about future studies or opportunities via email or phone. We will retain your phone number and e-mail address in a separate database from the study database.

□ I agree □ I do not agree

Social Media, Text, and Email Contact

The study team will ask you to provide your Facebook and Instagram handles, as well as the text, email, and home addresses for 3 close contacts who you are likely to stay in touch with. This is so that we can reach you regarding study surveys if you choose to discontinue the intervention. Only private, direct messages will be sent to you through social media from the “Stress Reduction Study” Facebook account and “Stress Reduction Study” Instagram account. When reaching out to your 3 close contacts we will not mention this research study or the nature of the study. All of these conversations will be limited to scheduling study visits by a healthcare provider. We will also use email and text to contact you about scheduling study visits and about logistical issues related to the study group.

□ I agree □ I do not agree

Contact with Referring Provider about Enrollment Status

You may have been referred to this study by a member of your existing care team (e.g., nurse care manager, buprenorphine prescriber, etc.). By checking I agree below, I give the study team permission to contact my referring provider with communication limited specifically to informing them about my study enrollment status.

□ I agree □ I do not agree

Privacy / Confidentiality

There are laws (state and national) that protect your health information to keep it private. We follow those laws. Your identity, medical records, and study data will be kept confidential, except as required by law. We will protect all of your health information, including your Protected Health Information or "PHI." Your PHI is any health information that identifies you. This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local proceeding. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal

or state government agency sponsoring the project that is needed for auditing or program evaluation by the agency which is funding this project.

If you take part in this study, you acknowledge that we may be in contact with your clinical team if there is significant concern about your wellbeing.

We will follow these guides:

- The research team will view your health information from the year before you enrolled in the study. during the life of this study, and for one year after you finish the study.
- We will not include any information that could identify you in any publication.
- Anonymous data from this study may be made available on a public database – it will never be made available in a way that can identify you.
- We will remove all of your identifiable information (name, address, telephone number, *etc*.) from the study database 7 years after the study has been completed.

We will make every effort to keep your information private, but we cannot guarantee it. The Cambridge Health Alliance Institutional Review Board (IRB) is responsible for protecting the safety and welfare of people who take part in research studies at our hospital. IRB staff may ask to look at any research records to make sure the study team is following the laws and rules to protect you. Certain government agencies, including the Office for Human Research Protections and the U.S. Food and Drug Administration (regulates drug and device studies), may also look at records that identify you. Additionally, the study staff may be required to disclose confidential information if it becomes clear that you risk harming yourself or others.

Sometimes, we are required to share your study records with others, too, including:

- Other researchers conducting this study
- Research collaborators
- The study sponsor and any companies that the sponsor uses to oversee, manage, or conduct the study

- Clinical staff not involved in the study, but involved in your regular treatment
- Insurance companies

If any of these groups ask to look at your information, then we cannot prevent it from being shared. Once information is shared, we cannot guarantee any further confidentiality and privacy.

We will also request that you provide us with the name and contact information for your buprenorphine (suboxone) prescriber. This person would only be contacted in case of emergency or if there is concern for your safety/wellbeing or the safety/wellbeing of others.

Some people may choose to share or interact with a study advertisement from their Facebook or Instagram profile to spread the word about the study to their social media networks. If you decide to share the study advertisement on Facebook or Instagram, it is important that you are aware that your profile may show up in other users' newsfeeds showing that you interacted with this advertisement. You may choose to edit your Facebook or Instagram advertisement/social interaction settings to prevent unintended disclosure of your interaction with the study advertisement to be viewable by others on Facebook. You can find more information about Facebook privacy settings at this link: https://www.facebook.com/help/610457675797481/your-info-and-facebook-ads. You can find more information about Instagram privacy settings at this link: https://help.instagram.com/519522125107875. Your decision to share/interact or not to share/interact with this advertisement is completely voluntary, not required by the study, and will not affect your participation in this study in any way.

- **Despite our best efforts to protect privacy and ensure confidentiality, data breaches can happen when you are using internet-based technology.**

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

Period of Authorization

Your authorization on this research project will expire 10 years after completion of data gathering for the study. If you change your mind and want to withdraw your authorization please tell a member of the study team or write to the HIPAA Privacy Officer for Research, Cambridge Health Alliance, 1493 Cambridge Street, Cambridge, MA 02139. If you withdraw your authorization, you may no longer be allowed to participate in the study described in this form.

Getting Help (Contacts)

If you have questions about this study, please ask a member of the study team. Some questions people have:

- What are the risks and benefits of being in this study?
- What other choices are available?
- What are my rights as a research participant?
- What should I do if I feel pressured to take part in this study?
- How is my health information used in this study?
- How will my health information be protected?

Call or email the study investigators for answers to any study-related questions or if you get hurt or sick as a result of being in this study. This is how to contact us Monday to Friday during regular business hours:

The easiest way to reach the study team with questions is by email at stressreductionstudy@challiance.org.

You can also call study investigators if you have an urgent question or concern.

Zev Schuman-Olivier, MD (Principal Investigator) 617-591-6056 **Hannah Goodman (Research Coordinator)** 781-873-9814

On nights and weekends, you may contact your healthcare provider if any urgent issues arise.

If you have questions about your rights as a study participant, please contact either the IRB office or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30am-5:00pm:

IRB Chair: Dr. Lior Givon
Telephone: 617-806-8702

Patient Relations: 617-591-4498

Confirmation from Person Obtaining and Documenting Consent

I, the study participant, have read this form or it has been read to me. I understand my part in this study and have had my questions answered to my satisfaction. I agree to take part in this research study.

_____ _____
Participant's Signature Date

I have informed the study participant, _____ of:
Participant's Printed Name

- The procedures, purpose, and risks related to participation in the above-described study;
- How his/her health information may be used, shared, and reported, and;
- His/her privacy rights.

The study participant has been provided with a signed copy of this form.

_____ _____ Signature of
Researcher Obtaining Consent Date

_____
Printed Name of Researcher Obtaining Consent

_____ _____ Signature of
Participant's Legally Date
Authorized Representative

_____ _____ Printed
name of Participant's Legally Date
Authorized Representative

_____ Interpreter Role ❒ CHA employee Printed
Interpreter Printed Name (if used) ❒ Other_____