CONSENT TO BE PART OF A RESEARCH STUDY

Part 1 of 2: GENERAL INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

You are being invited to take part in a research study conducted at several different locations (multi-site research). The University of Michigan is providing IRB oversight for all sites in this study. This consent form includes two parts. Part 1 (General Information) includes information that applies to all study sites. Part 2 (Site Information) includes information specific to the study site where you are asked to enroll. Both parts of consent form must be provided to you.

Study Title: Persist Study

Agency sponsoring the study: The National Institutes of Health HEAL Initiative

1. KEY INFORMATION ABOUT THIS STUDY

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand all the details of the research study.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about health conditions and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all of these matters carefully.
The purpose of this research study is to look at the effect of new programs aimed at helping people manage chronic pain and medications. The program sessions focus on educational information and strategies for managing pain and medications. We are looking to enroll people who have chronic pain and have also recently begun buprenorphine treatment to see if they could benefit from these programs. For this research study, you will first be asked to complete a baseline interview either in person, over the phone, or over video chat. It's possible that during the baseline interview we may learn that you do not qualify and at that point you would no longer take part in the study. Otherwise, you will then be asked to complete a baseline survey after which you will be assigned to either the Group 1 program focused on pain and medication management or the Group 2 educational program. The Group 1 program includes 8 one-on-one sessions done over the phone or video chat with a study therapist. The Group 2 program includes 2 sessions done over the phone with a study therapist. These sessions will be audio-recorded (voice only) but you do not have to agree to be recorded to be in the study. You will be asked to complete brief weekly surveys for 13 weeks as well as follow up surveys and interviews at 1-, 3-, 6-, 9-, and 12-months after your enrollment. Voluntary urine samples will also be collected at baseline and follow-up visits in person with research personnel or with an at home test provided by the study. You can earn up to $500 and the study will last about 12 months.

This study involves a process called randomization. This means that the group you are assigned to is not chosen by you or the researcher. The study design divides study participants into two separate groups based on chance (like the flip of a coin), to compare the different programs.

There can be risks associated with joining any research study. The type of risk may affect whether you decide to join the study. For this study, some of these risks may include feelings of discomfort answering personal questions on sensitive topics, and loss of confidentiality. More detailed information will be provided later in this document.

It is possible that this study may not offer any benefit to you now but it may benefit others in the future by helping us to improve therapies for people with chronic pain. More information will be provided later in this document.

You can decide not to be in this study. Choosing not to participate will not affect the clinic care in any way. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this research study is to look at the effect of two different programs aimed at helping people manage chronic pain and medication treatment. The program sessions focus on educational information and strategies for pain and medication management. We are looking to enroll people who have chronic pain and have recently begun buprenorphine treatment to see if they could benefit from these programs. This research study will help us learn how we can improve current therapies for pain and medication management.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

To take part in this study, you must be at least legal adult age to consent without a guardian in your state. In all states except Alabama (requires 19 years of age), Nebraska (requires 19 years of age), and Mississippi (requires 21 years of age), the legal adult age to consent is 18 years old. You must experience chronic pain, and have started the medication buprenorphine within the last 6 months. You must also have access to a phone that you can use during the study. It's possible that during the baseline interview, we may learn other information that might disqualify you and at that point you would no longer take part in the study. Pregnant women are not eligible to enroll.

See Part 2 *Site-Specific Procedures* for any additional information about the site where you are participating.

3.2 How many people are expected to take part in this study?

This is a multi-site study, meaning that it will be conducted at multiple sites across the United States. We hope to enroll 200 people overall. Some people will be enrolled from community locations, and others will represent the Veteran population.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to be in this research study, this is what will happen:

- We will start with a baseline interview and survey. The interview will ask questions about medications and substance use and will take up to 60 minutes. If we learn that you do not qualify, your participation in the study will be over after the interview is done. Otherwise, we will then ask you to complete the baseline survey. This survey will ask questions about your background, physical and mental health, pain and substance use, criminal record and illegal activities. This will take up to 60 minutes. You will receive a $50 gift card for completing the baseline interview and survey.
- You will be asked to provide a voluntary urine sample for drug testing. If you are meeting with study staff in person, study staff will record the results of the test and immediately discard the sample. If you are providing the urine sample from home, you will obtain the sample and take a picture of the results for study staff to review. The results of your test will not be shared with anyone outside of the study, except as noted below. You will receive a $10 gift card for completing the urine test.
- You will then be randomly assigned to Group 1 or 2 of the study. This means that our study design divides participants into two groups, based on chance (like flipping a coin).
- Over the next 4 weeks:
    - Group 1: The study therapist will speak with you briefly to explain the therapy program and give you a copy of the program workbook. You will be asked to meet one-on-one with the study

therapist twice a week for 4 weeks (a total of 8 sessions). These sessions will last about 60 minutes each and will take place over the phone or video chat.

- Group 2: The study therapist will speak with you briefly to explain the educational program and give you a copy of the program handouts. You will be asked to meet one-on-one with the study therapist twice during the next 4 weeks (a total of 2 sessions). These sessions will last 5-10 minutes each and will take place over the phone or video chat.

- We will audio-record (voice only) all program sessions to be sure that that the research therapists are conducting the sessions the same way for everyone. These recordings will be used only for this research study. You will be asked for your permission to be audio-recorded later in the form. You may still take part in the study if you don't want to be audio-recorded.
- You will be asked to complete weekly surveys for the 13 weeks. For the next 13 weeks, we will send you an email or text with a link to complete the weekly survey. You also have the option to complete the surveys by phone. The survey will ask questions about your treatment involvement and medication use. It will take about 5 minutes to complete each survey. You will receive $10 for each weekly survey you complete and a $10 bonus if you complete all thirteen surveys.
- Follow up interviews will take place 1-, 3-, 6-, 9-, and 12-months after the day you enrolled These interviews will also include a survey and a voluntary urine drug test. These follow up activities will take about 90 minutes each. You will receive a $40 gift card for completing each of the 1-9-month follow-ups, $50 for the 12-month follow-up and $10 for each urine test.
- We will ask your permission to keep your contact information on file after you have completed the study so that we can contact you about opportunities to participate in future studies associated with the Persist Study. If you are contacted and are willing to take part in a new study, you will be asked to sign a separate consent form for that study. You do not need to agree to future contact to participate in this study.

4.2 How much of my time will be needed to take part in this study?
The first session (baseline interview, survey, and information about the program) will take about 2 hours to complete. For those in Group 1, each session (1-8) will last about 60 minutes. For Group 2, each session (1-2) will last 5-10 minutes. Each of the 13 weekly surveys will take about 5 minutes and each follow up visit will last about 90 minutes. Please see chart in section 8 for more details about timing of study activities.

4.3 When will my participation in the study be over?
You will be done with the study after you complete the 12-month follow-up.

4.4 What will happen with my information used in this study?
Your collected information and biospecimen (urine) test results may be shared with the National Institutes of Health and the NIH HEAL Initiative who is sponsoring this study.

Biospecimens (urine) will not be stored, or shared outside of the study. Urine test results will be immediately recorded and the sample promptly discarded by a member of our study staff or by you personally.

With appropriate permissions, your collected information and urine test results may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers (meaning any information that would identify you, like name, address or phone number, would be removed) and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Some of the questions that will be asked and program topics are about sensitive or personal information such as your substance use. These questions or topics may make you feel uncomfortable or anxious. You may skip any question you don't want to answer and you are free to end any session or leave the study at any time. Study staff will conduct sessions and interviews in private spaces to ensure privacy or over the phone. You will be asked during sessions to try not to say your name or any information that would allow someone to determine who you are from the audio recording.

Additionally, there may be a risk of loss to confidentiality or privacy. See Part 2 *Site Information* section 9 for information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems, even when the researchers are careful to avoid them. Please tell the researchers listed in the Part 2 *Site Information* section about any problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, possible benefits may include learning new strategies to better cope with pain and medication management. Others may benefit from the knowledge gained from this study. We hope to learn how to improve current therapies for people with chronic pain who are taking buprenorphine.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Participation in this study is voluntary. Choosing not to take part in this study will not affect the medical care you receive.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in the Part 2 *Site Information* section.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
We do not expect that you would experience any harm if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.

- You do not follow instructions from the researchers.
- The study is suspended or canceled.
- Other administrative reasons or unanticipated circumstances arise.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study?

There are no costs or billing for this study. Because the sessions will be done by phone, we will give you $40 to help cover your phone costs. See Part 2 *Site Information* for additional information on this topic.

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

8.2 Will I be paid or given anything for taking part in this study?

Total potential compensation for participating in the entire study is $500. You will receive a gift card after completing each study activity listed below.

Time Period	Approximate length	Amount	Main Interaction Type
Enrollment (Baseline) Interview	Two hours	$50 (+ $10 for urine sample)	In-person/Phone/Video Chat
*Group 1 (8 sessions)	One hour each	$40 for phone use	Phone/Video Chat
*Group 2 (2 sessions)	10 minutes each	$40 for phone use	Phone/Video Chat
Weekly Surveys (13 total)	5 minutes each	$10 each (+ $10 for completing all)	Online/Phone
1-month follow up interview	90 minutes	$40 (+ $10 for urine sample)	In-person/Online/Phone/ Video Chat
3-month follow up interview	90 minutes	$40 (+ $10 for urine sample)	In-person/Online/Phone/ Video Chat
6-month follow up interview	90 minutes	$40 (+ $10 for urine sample)	In-person/Online/Phone/ Video Chat
9-month follow up interview	90 minutes	$40 (+ $10 for urine sample)	In-person/Online/Phone/ Video Chat
12-month follow up interview	90 minutes	$50 (+ $10 for urine sample)	In-person/Online/Phone/ Video Chat
		Total: Up to $500	

*You would only be included in one group

8.3 Who could profit or financially benefit from the study results?

Research can lead to new discoveries. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them. Part 2 *Site Information* may have additional information on this topic.

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how the confidentiality of your research records will be protected in this study. See Part 2 *Site Information* for information pertaining to Protected Health Information (PHI) and the Health Insurance Portability and Accountability Act (HIPAA) if relevant.

9.1 How will the researchers protect my information?

To keep your information confidential, we'll create a unique study ID number to use for your research information, rather than your name or any other details that someone could use to identify you. Although we'll keep a list of all the people who take part, no one outside our study team will be able to figure out who

participated or which people gave which answers. Your name and other identifying information will be kept securely and separately from your research data. Audio recordings will be collected using a digital recorder and sessions will be immediately uploaded to a password protected server and deleted from the recorder.

The computerized surveys are designed and administered using the REDCap database (https://www.project-redcap.org/). REDCap is dedicated to protect all customer data using industry best standards. For more information, REDCap security and privacy statements can be found at https://www.iths.org/wp-content/uploads/About-REDCap-Vanderbilt.pdf

We will use the telephone or a video chat platform of your choice (e.g., Zoom, BlueJeans, FaceTime or Skype for Business) for your assessments or sessions with the health coach. We encourage using a University of Michigan HIPAA compliant platform such as Zoom. Your confidentiality will be kept to the degree permitted by the technology being used. If a platform is used which is not affiliated with the University of Michigan (i.e., FaceTime), it is possible that you could be automatically recorded by the platform – similar to when you use these platforms in everyday life. Although every reasonable effort will be taken, confidentiality during actual web-based, phone or video chat communication procedures cannot be guaranteed. See Part 2 *Site Information* for additional information on this topic.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, and threats to harm yourself or others (see more information below). The Certificate CANNOT BE USED to stop a sponsoring United States 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 say it is okay. 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.

Exclusion to confidentiality noted above include child or elder abuse, threats of harm to others or harm to yourself. Harm to yourself can include thoughts of suicide or using opioids in a harmful way. If any of these situations were to come up, we would talk to you more about it and may help you get in touch with others, including your provider or other authorities, to make sure that you are safe.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.

- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

END OF PART 1 *GENERAL INFORMATION*

SEE PART 2 *SITE INFORMATION* FOR ADDITIONAL INFORMATION ABOUT THE SITE WHERE YOU ARE ENROLLING

CONSENT TO BE PART OF A RESEARCH STUDY

Part 2 of 2: SITE INFORMATION

INFORMATION ABOUT THIS DOCUMENT:

This part of the consent form includes additional information about being a research participant at your enrolling site. Before making your decision to join the study, review both the General study information and this Site information.

Study title: Persist Study

Site Name: University of Michigan

8(A) FINANCIAL INFORMATION (CONTINUED)

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
See the Part 1 *General Information* section 8.1 for additional information on this topic. There is no site-specific information on this topic.

8.2 Will I be paid or given anything for taking part in this study?
See the Part 1 *General Information* section 8.2 for additional information on payment.

Total potential compensation for participating in the entire study is $500. You will receive a gift card after completing each study activity listed in the table in Part 1 section 8.2.

8.3 Who could profit or financially benefit from the study results?
See the Part 1 *General Information* section 8.3 for additional information on this topic.

9(A) CONFIDENTIALITY OF SUBJECT RECORDS

9.1 How will the researchers protect my information?
See the Part 1 *General Information* section 9.1 for additional information on this topic.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
See the Part 1 *General Information* section 9.2 for additional information on this topic.

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even if you leave before the study is finished.
Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

10 CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report a problem
- Leave the study before it is finished
- Express a concern about the study

Site Principal Investigators:	Mark Ilgen, PhD and Lewei (Allison) Lin, MD
Site Principal Investigator Contact:	2800 Plymouth Road Ann Arbor, MI 48109 Telephone: (734) 845-3646 (Ilgen) (734) 845-3637 (Lin)
Site Study Coordinator:	Mandy Lewis, MS
Site Study Coordinator Contact:	2800 Plymouth Road Ann Arbor, MI 48109 Telephone: (734) 936-1386

You may also express a question or concern about a study by contacting the Institutional Review Board responsible for the review of the study:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*
- Other (specify): session handouts

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____.

My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent to audio recording solely for purposes of this research

This study involves audio recording. If you do not agree to be recorded, you can still take part in the study.

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent for Future Contact:

We may contact you again in the future in order to offer you opportunities to participate in a new study related to the Persist Study. If you are contacted and are willing to participate in a new study, you will be asked to sign a separate consent form for that study. Your contact information will be maintained by the Persist Study research investigators and stored in a password protected computer data file or locked file cabinet. It will only be available to the Investigators and research staff of the Persist Study and their future studies. If you do not want to be contacted in the future, you may still participate in this study. If you have questions, feel free to ask them.

_____I give *Persist Study* **permission to keep my contact information on file in order to contact me for opportunities to participate in future studies associated with** *Persist Study***.**

_____I DO NOT give *Persist Study* **permission to keep my contact information on file in order to contact me for opportunities to participate in future studies associated with** *Persist Study***.**

Signature: _____Date_____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____