CONSENT FORM COVER SHEET

Study Title: Mindful Body Awareness with Medication Treatment for Opioid Use Disorder

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UNIVERSITY OF WASHINGTON

CONSENT FORM

Body Awareness Training in Opioid Dependency Treatment

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Researchers' statement

We are asking you to be in a University of Washington (UW) research study funded by the National Institutes for Health (NIH). The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The purpose of this research is to learn if a mindfulness approach called Mindful Awareness in Body-oriented Therapy (MABT) is helpful for individuals engaged in medication assisted treatment for opioid use disorder. MABT is a mind-body approach that includes massage, body awareness exercises, and mindfulness skills to teach body awareness skills for self-care. If you choose to be part of this study, you will be randomly assigned (like with a flip of a coin) to one of two study groups: 1) control group, involving no MABT sessions; or 2) treatment group, to receive eight MABT sessions. Additional MABT sessions may be offered at 6 months to participants initially assigned to MABT who are in need of additional treatment support.

STUDY PROCEDURES

Those who receive MABT will be given eight sessions, provided once a week over eight weeks. Each session is 75 minutes long and will be delivered over clothes. The sessions will be delivered by a practitioner who has been trained and can legally provide this approach. Sessions will begin with a seated check-in, followed by work on the massage or examination table during which time you will be lying down, and will end with time to discuss the session while seated. All MABT sessions will take place at the medical facility where you receive your medication assisted treatment. All sessions will be provided free of charge.

For all study participants, there will be five study appointments over the course of 1 year. The first appointment is approximately 1.5 hours, and the second and third appointments are approximately 55 minutes. These appointments will be scheduled at the beginning of study involvement and again in 3 months (after completion of the MABT sessions for those assigned to this study group), and at 6, 9 and 12 months. All appointments will primarily involve completing a set of questionnaires. The same set of measures will be used at each appointment. This set of measures is designed to assess the following areas: substance use (self-reported use as well as a urine drug screen), and well-being (for example: depression, anxiety, physical symptoms, opioid craving). Some of the questions are personal, for example you will be asked to respond to the following questions: *"How often in the past two weeks have you been bothered by feeling nervous anxiety or on edge?"* "*Over the past two weeks how often have you been bothered by the feeling down, depressed, or hopeless?*" You may refuse to answer any question or any item on any questionnaire.

In addition, there is an initial questionnaire given at the first appointment only that asks questions about your demographic characteristics (age, education, etc.) and about your life history. For example you will be asked: "Do you have ongoing medical health problems/concerns?" and "Have you experienced an event(s) that you consider traumatic (car accident, natural disaster, domestic violence, sexual or physical assault or abuse?)" You may refuse to answer any question or any item on any questionnaire. For those who receive the MABT treatment, there will be two additional questionnaires about satisfaction, skills learned, and impact of MABT.

At all study appointments for all participants, you will be asked to provide a urine sample for drug and alcohol screening. The results of this screening test are only for the research study.

If you agree to be in this study, we will obtain the following information from your medical chart related to your medication assisted treatment: buprenorphine treatment start date and attendance to treatment program visits through study period; co-occurring mental and physical health diagnoses; during study period only, the buprenorphine dose and urine toxicology results collected at nurse manager visits, and number of appointments attended for mental health or physical therapy.

All MABT sessions will be digitally audio-recorded. These recordings will be used to ensure that the all elements of the approaches are provided as designed.

RISKS, STRESS, OR DISCOMFORT

It is possible that you may experience anxiety related to questions asked on the questionnaires. For those that receive MABT, you may experience anxiety due to the use of touch in the MABT sessions, and/or to the development of a new therapeutic relationship. If you feel distressed or uncomfortable at any time during a MABT session, you may request that the procedures change or stop. The MABT therapist is an experienced clinician who has received training in working with physical and mental health concerns. They may also contact your healthcare providers if there is a concern about your overall comfort, safety, or well-being.

There is a risk that you may experience an invasion of your privacy or a breach of confidentiality as a result of your participation in this study. It is possible that there could be some unknown side effects. Precautions will be taken to minimize harmful side effects. The procedures for minimizing risks are described in the Confidentiality of Research Information section.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you are interested in seeking body awareness education and do not want to participate in this study, referrals are available from Dr. Cynthia Price: (206) 685-4739.

BENEFITS OF THE STUDY

If you participate in this study and are assigned to MABT, you may experience a reduction in symptoms of physical or emotional discomfort. MABT may help to reduce your overall level of stress. You may also experience enhanced self- awareness and learn tools for self-care and more effective coping in response to emotional stressors. We do not guarantee or promise, however, that you will receive any of these benefits. It is the researchers' hope that the results of this study will provide information on additional approaches that may promote the well-being of people seeking treatment for opioid use.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

Another exception that may occur involves contact with your healthcare providers if there is concern about your safety or well-being. Agreeing to participate in this study includes agreeing to exchange of information between your healthcare providers and research staff members. The purpose of any such communication would be to ensure your safety and well-being. Examples of times when such contact might be made is when a participant expresses severe depression, suicide intention, self-harm, harm to others, or extreme anxiety. It may be necessary to terminate your involvement in the study because the study is not right for you.

The data gathered at the assessments will be strictly confidential. You will be assigned a code number that will link identifying information with your responses. Your name, phone and address and other identifying information will be kept separately in a password protected electronic file at the UW. All paper study data will be kept in a locked research-only file at the clinic or UW or in a secure, password protected electronic file.

The link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law. Other data will be kept indefinitely and may be used for research and non-research activities. Names and other identifying information will not be used in the reporting of the study findings in any publication. Results may be published as group results, or in case study format.

Audio-recording the MABT sessions allow researchers to ensure the quality of the treatment and gain understanding about the processes used in MABT and how the processes work. The digital audio-recordings will be identified by your study identification number and will be retained indefinitely. Digital recordings will be securely stored in password-protected electronic file at the UW.

We have a Certificate of Confidentiality from the federal **National Institutes of Health**. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- state and local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

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.

OTHER INFORMATION

To show our appreciation for the time involved in study participation, all study participants will be given grocery store gift cards after completion of study visits: $30 for the first assessment visit, $40 for the second, $50 for the third, $60 for the fourth, and $70 for the 5th and final assessment. In addition, participants assigned to the MABT intervention will receive a $10.00 gift card for every completed MABT session as well as a $20.00 gift card for completion of the initial final (or 8th) MABT session.

Participants will receive a voucher to cover public transportation costs for study visits if needed, or parking vouchers if driving to study visits located at the Harborview Medical Center.

There are conditions for attending the intervention sessions. If you are assigned to receive MABT, a specific time for a weekly appointment will be arranged. If you 'no-show' for two appointments in a row (no-show means you do not contact the therapist to cancel and reschedule the visit), we will not continue to reserve your scheduled time. However, if this occurs, you are welcome and encouraged to contact study personnel to re-

engage and schedule MABT sessions at any time before the 3-month (2nd) assessment. Additionally, if you are using alcohol or non-prescribed drugs at the time of the MABT session, the session will be cancelled.

Participation in this study is entirely voluntary. You may choose to stop participating, or withdraw, from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

RESEARCH-RELATED INJURY

If you think you have an injury or illness related to this study, contact one of the Investigators, Cynthia Price at (206) 685-4739 or Joe Merrill at (206) 744-9917, and you will referred for treatment.

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Printed name of participant	Signature of participant	Date

Printed name of Research Staff	Signature of Research Staff	Date

Copies to: Researcher & Subject