UNIVERSITY OF WASHINGTON
INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**University of Washington / "Collaborating to Heal Addiction and Mental Health in Primary care (CHAMP)"**
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Key Information

Participation in this study is voluntary. The purpose of this study is to evaluate different approaches to helping primary care patients stop their unhealthy use of opioids. Your participation in the study would last for six months, during which time we would offer you medications and counseling programs that are known to be effective. Participation also involves completing three surveys. You may find answering these survey questions to be inconvenient and some of the survey questions may make you feel uncomfortable. All of your answers to the survey questions will remain strictly confidential, but we cannot guarantee your privacy. The clinical care offered to you is designed to help stop the unhealthy use of opioids, but there is no guarantee that your health will improve if you take part in this study. If you do not take part in this study, you can stick with the treatment you are currently receiving or look for other treatments opportunities. The rest of this form describes these things in more detail.

Introduction

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to volunteer to participate in the study. 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 study 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 signed and dated form for your records.

PURPOSE OF THE STUDY

Many people having problems with opioids also have other common behavioral health conditions like depression and/or anxiety that can make it harder to get their unhealthy use of opioids under control. However, many primary care providers are not comfortable managing behavioral health conditions and unhealthy opioid use. To address this problem, we created a collaborative care program that involves primary care providers and behavioral health specialists working together to help patients stop their unhealthy use of opioids and to treat other common behavioral health conditions. The purpose of this study is to determine whether collaborative care programs can help primary care patients stop their unhealthy use of opioids.

STUDY PROCEDURES

You are being invited to participate in the study because you reported that opioids are causing problems for you. Your participation in this study will last for approximately 6 months. We are recruiting 1,200 people experiencing similar problems from primary care clinics. Half of the clinics have been randomly selected to have a collaborative care program that treats unhealthy opioid use and other common behavioral health conditions, and half of the clinics were randomly selected to have a collaborative care program that treats behavioral health conditions, but not unhealthy opioid use directly. By "randomly", we mean like the flip of a coin. You will not be told which program your clinic has been selected to use.

If you decide to participate in the study, you can expect the following:

1. The behavioral health specialists will work with your primary care provider to find the best treatment for you. You and your primary care provider will be in charge of your treatment. You will not have to go to another clinic to get care.
2. A care manager with training in behavioral health will be part of your primary care team. The care manager will give you information about opioids and behavioral health conditions, describe your treatment options, and answer your questions. For up to six months, the care manager will meet with you every couple of weeks in person or by

phone to find out how your treatment is going, and to provide counseling. The care manager will share important information with your primary care provider.

3. The care manager will also share important information with a psychiatric consultant who is a clinician with specialized training in behavioral health medications. If the treatment is not working, the psychiatric consultant will recommend that your primary care provider try a different treatment.
4. The treatments that you will be offered are medications and counseling. You will be able to choose just medications or just counseling, or both. You can also choose to receive no treatment at all. All medications and counseling programs have been proven to be effective and/or are used routinely to treat patients. This study is NOT testing experimental drugs, devices or therapies.
5. The care manager will enter information about your treatment into a study computer and your clinic's electronic medical record system.
6. To evaluate whether collaborative care is helpful to you, you will be asked to complete a survey in the next few days and follow-up surveys 3 and 6 months later. You can choose to complete the surveys by phone or on the internet if you have a computer or smartphone. The surveys will ask questions about your health, your opinions about treatment, and your use of health services. You may refuse to answer any question. The surveys will take less than an hour to complete.
7. We will also review the medical notes written by the care manager and psychiatric consultant in the study computer. You will NOT need to go to a clinic to conduct any medical tests or provide any biospecimens (for example, urine analysis) for the evaluation.
8. We will collect information about your opioid prescriptions from your clinic's medical records. We may also collect information about your opioid prescriptions from your state's Prescription Drug Monitoring Program. This database is maintained by your state and includes information about all dispensed opioid medications.

RISKS, STRESS, OR DISCOMFORT

All medications and counseling programs have been proven to be effective and/or are used in routine care. However, many patients experience side effects from medications. In addition, counseling can be uncomfortable. During the course of the study, your symptoms may get worse and you could have thoughts about ending your life. If you experience any of these problems, tell your providers and they will help you.

Answering survey questions takes time and you may find this inconvenient. We will do our best to schedule the survey at a time that fits your schedule. Some of the survey questions may also make you feel uncomfortable. An example of such a question is "*Overall, in the past two weeks how much were you distressed by thoughts of ending your life*" You do not need to answer any questions that you are not comfortable with.

Another risk of participating in this study is possible loss of privacy. This is very unlikely, but we cannot guarantee that it will not happen. All your answers to the survey questions will remain strictly confidential. Survey data will be stored on a secure computer at the University of Washington. The data will be stored and eventually destroyed in compliance with the University of Washington's data policies. When the results of this study are reported, your data will be combined with other participant's. You will not be identified in any way. For example, we will report the percent of participants saying "very satisfied" to a survey question about satisfaction with treatment.

There may be risks that are unknown.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

ALTERNATIVES TO TAKING PART IN THIS STUDY

This study is for research purposes only. You do not have to be in this study to receive treatment for your use of opioids. If you do not take part in this study, you can stick with the treatment you are currently receiving at our clinic. Or you can go to another clinic that is not part of the study.

BENEFITS OF THE STUDY

Many people do not have good access to specialty behavioral health services. This study will determine if your primary care provider (with support from a psychiatric consultant and care manager) can help you stop unhealthy use of opioids. But there is no guarantee that your health will improve if you take part in this study.

COSTS OF PARTICIPATING IN THE STUDY

You will not have to pay to participate in this study. However, if you normally have to make copayments when you receive care, you will have to make the same payments for behavioral health treatment. Likewise, if you normally have to make co-payments for your medications, you will have to make the same co-payments for any medications prescribed to you for behavioral health conditions.

COMPENSATION FOR PARTICIPATION

To show our appreciation, you will be compensated $50 after completion of the first survey, $50 after completion of the second survey and $50 after completion of the last survey (for a total of $150). You will be paid quarterly.

SOURCE OF FUNDING

The National Institutes of Health provided funding for this study.

CONFIDENTIALITY OF RESEARCH INFORMATION

We will store your responses to the survey questions and the review of your medical records in a data file. This data file will not contain any identifying information about you (for example, name, address), but will contain your study number. This data file may be shared with other researchers. We will maintain a separate file that contains your study number and your identifying information. This separate file containing your identifying information will only be available to the study team, and organizations that make sure studies like this are done safely. Specifically, the Institutional Review Board and the federal Office for Human Research Protections will be able to inspect and copy confidential study-related records which identify you by name. This is to make sure they are being done safely and legally. If a review of this study takes place, the reviewers examining your records will protect your privacy.

Identifiers might be removed from your identifiable private information collected during this study and **could then be used for future research studies or distributed to another investigator for future research studies** without additional informed consent.

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, or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, or documents 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 (see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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 or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of, for instance, child abuse or neglect, harm to self or others, and communicable diseases. If we learn that you intend to harm others, we must report that to the authorities. Also, if you report that you intend to harm yourself, we will connect you with professionals trained in suicide prevention and notify your primary care team.

Please note: if you are having suicidal thoughts call the study doctor at the telephone number listed on the first page of this form. If you feel in crisis, you can call 911 and/or a Nationwide Suicide Hotline that is answered 24 hours a day with a skilled, trained counselor. One example is the National Suicide Prevention Lifeline at 1-800-273-TALK (8255).

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

If you complete this consent form electronically,you will be emailed a PDF copy of this signed and dated consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device, especially if that PED is shared with other users or is lost, or hacked. Also the PDF copy of the consent may not be able to be permanently removed from a PED.

HIPAA Research Authorization

To do this study, we need to collect health information that identifies you. We will collect the following information about you: Name, address, phone numbers, diagnoses, symptoms, drug or alcohol abuse, diagnosis, or treatment, medications, side effects, appointment information, treatment history, and survey responses. This is described in more detail in the attached "AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION" form.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Participation in this study is voluntary. You may refuse to participate in this study or withdraw at any time without penalty or loss of benefits to which you are entitled. If you withdraw your permission, you will no longer be a study participant and no new data will be collected. Data collected before the withdrawal of permission may still be used for research purposes.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If it is discovered that you do not meet the study requirements; or
- If the study is canceled.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110 Columbia,
  MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00037200.

You may contact the Beth Israel Deaconess Medical Center (BIDMC) Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

STATEMENT OF CONSENT

I have read this form and had a chance to ask questions. I volunteer to take part in this research. If I have questions later about the research I can contact the study doctor or study staff listed on the first page of this consent form. I give permission to the researchers to use my survey responses and medical records as described in this consent form. I will receive a copy of this signed and dated consent form.

Please indicate and initial below if after the study is over, you request a summary of the results.

☐ _____ (initials) Yes, I would like a summary of the results after the study has ended.

☐ _____ (initials) No, I do not want a summary of the results after the study has ended.

Please indicate and initial below, if we may want to contact you again to see if you want to participate in another research study.

☐ _____ (initials) Yes, I am willing to be contacted to participate in another research study.

☐ _____ (initials) No, I do not want be contacted to participate in another research study

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Printed name of Adult Participant Signature Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

AUTHORIZATION FOR USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION

As part of this study, we will be collecting, using and sharing with others information about you. Please review this section carefully as it contains information about the federal privacy rules and the use and disclosure of your information.

DESCRIPTION OF PROTECTED HEALTH INFORMATION [PHI]

By signing this informed consent document, you are allowing the investigators and other authorized personnel to use and disclose health information about you. This may include information about you that already exists (for example: your medical records and other sources of health information, demographic information, the results of any laboratory tests, and mental health records, if applicable, as well as any new information generated as part of this study. This is your Protected Health Information.

The specific information that will be released and used for this research is described below

- Information entered into the Care Management Tracking System by your care manager. The Care Management Tracking System is referred to as the "study computer" in the consent form. This information will include mental health diagnoses, severity of mental health symptoms, use of drugs or alcohol, medications, medication adherence, counseling notes and dates of treatment.
- Information stored in your state's Prescription Drug Monitoring Program. This information will include the names, dosages, and dates of your opioid prescriptions.

PEOPLE/GROUPS AT BIDMC WHO WILL SHARE AND USE YOUR PROTECTED HEALTH INFORMATION

Your Protected Health Information may be shared with and used by investigators working on this study, including the supporting research team (such as research assistants and coordinators, statisticians, data managers, laboratory personnel, pharmacy personnel, and administrative assistants), and may also be shared with and used by other health care providers at BIDMC who have treated you in the past and have information relevant to the research, or who provide services to you in connection with the research. Your Protected Health Information may also be shared with the members and staff of the Committee on Clinical Investigations of Beth Israel Deaconess Medical Center, which is responsible for reviewing studies for the protection of the research subjects, so that it can carry out its oversight responsibilities with respect to the study.

PEOPLE/GROUPS OUTSIDE OF BIDMC TO WHOM YOUR PROTECTED HEALTH INFORMATION WILL BE DISCLOSED (SHARED) AND WHO MAY USE YOUR PROTECTED HEALTH INFORMATION

We will take care to maintain confidentiality and privacy about you and your Protected Health Information. We may share your Protected Health Information with the following groups so that they may carry out their duties related to this research study:

- The funding source and/or sponsor of this study, University of Washington and, where applicable, the people and companies that the funding source and/or sponsor use to oversee, administer, or conduct the research (for example, clinical research organizations are companies that are sometimes hired by research sponsors to help manage and run a clinical research study)
- The other hospitals and medical centers taking part in this study and research collaborators at those institutions.
- Other research collaborators and supporting research team members taking part in this study
- Any external health care providers who provide services to you in connection with this research
- Laboratories not affiliated with BIDMC that are involved in conducting tests related to the research
- Statisticians and other data monitors not affiliated with BIDMC
- The members and staff of Advarra and any other IRBs (beyond the BIDMC Committee on Clinical Investigations) that oversee the research.
- Centralized data collectors
- Your health insurance company
- The Food and Drug Administration [FDA], the Department of Health and Human Services [DHHS], the National Institute of Health [NIH], the Office for Human Research Protections [OHRP], and other federal and state agencies that may have jurisdiction over the research
- Hospital and Clinical Research Accrediting Agencies
- Data and Safety Monitoring boards that oversee this study (if applicable)

Those who receive your Protected Health Information during the course of the research may not be required by the federal privacy regulations to protect it, and they may make further disclosures to others and use your information without being subject to penalties under those laws.

PURPOSE: WHY WE ARE USING AND SHARING YOUR PROTECTED HEALTH INFORMATION

The reason for using and sharing your Protected Health Information is to conduct and oversee the current, secondary, and future research described in this Informed Consent Document. There are many other reasons beyond the research for which BIDMC may use or disclose your Protected Health Information. Not all of these reasons require your express written authorization. For example, we will use and share your Protected Health Information to ensure that the research meets legal, institutional and accreditation requirements and to conduct public health activities. The various ways in which BIDMC may use and disclose your protected health information without your authorization are explained in a document called the Notice of Privacy Practices. If you have not received a copy of BIDMC's Notice of Privacy Practices, please

ask us for one and review it before signing this form. In addition to signing this document, you may also be asked to sign a BIDMC General Agreement form acknowledging that you have received the BIDMC Notice of Privacy Practices.

NO EXPIRATION DATE – RIGHT TO WITHDRAW AUTHORIZATION

Your authorization for the use and disclosure of your Protected Health Information in this Study shall never expire. However, you may withdraw your authorization for the use and disclosure of your Protected Health Information at any time provided you notify the Principal Investigator in writing. If you would like to take back your authorization so that your Protected Health Information can no longer be used in this study, please send a letter notifying the Principal Investigator of your withdrawal of your authorization to Carolina Feris at 1000 Broadway, Chelsea, MA 02150. Please be aware that the investigators in this study will not be required to destroy or retrieve any of your Protected Health Information that has already been used or disclosed before the Principal Investigator receives your letter, and they are permitted to continue to use and disclose your previously collected information as necessary to complete the research.

REFUSAL TO SIGN

Your clinical treatment may not be conditioned upon whether you sign the Authorization for Research. However, if you choose not to sign this informed consent document and authorization for the use and disclosure of your Protected Health Information, you will not be allowed to take part in the research study.

RIGHT TO ACCESS AND COPY YOUR PHI

If you wish to review or copy your Protected Health Information as it is made part of your medical record, you may do so after the completion or termination of the study by sending a letter to the Principal Investigator requesting a copy of your Protected Health Information. You may not be allowed to inspect or copy your Protected Health Information until this study is completed or terminated.

Giving permission

I have read this HIPAA Authorization form describing how my patient information will be used. I have had a chance to ask questions about the use of my patient information and I have received answers to my questions. I agree to the use of my patient information for this research.

To release the specific information listed below, you need to also write your initials next to the type of information. This is your specific permission for release of this information, which is required by Federal and state laws. The federal rules bar any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

_____ Behavioral or mental health/illness, including counseling notes
_____ Drug or alcohol abuse, diagnosis, or treatment

XXXXXXXXXX NOT FOR OFFICIAL USE – REVIEW ONLY XXXXXXXXXX

Printed Name of Research Subject Birthdate

XXXXXXXXXX NOT FOR OFFICIAL USE – REVIEW ONLY XXXXXXXXXX

Signature of Research Subject Date of signature

You will receive a copy of this signed form. Please keep it with your personal records.