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)"**
Principal Investigator: (Study Doctor)	**John Fortney, PhD**
Telephone:	**(206) 685-6955 (24 Hours)**
Address:	**University of Washington** **1959 NE Pacific St** **Seattle, WA 98195**

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 co-payments 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).

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.

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

Printed name of Adult Participant Signature Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

A. Purpose of this form

The purpose of this form is to give your permission to the research team to obtain and use your patient information. Your patient information will be used to do the research named above.

State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form.

You do not have to sign this permission form. If you do not, you will not be allowed to join the research study. Your decision to not sign this permission will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

B. The patient information that will be obtained and used

"Patient information" means the health information in your medical or other healthcare records. It also includes information in your records that can identify you. For example, it can include your name, address, phone number, birthdate, medical record number, and relevant information from your clinic visits, including test results.

1. Location of patient information

By signing this form you are giving permission to the following organization(s) to disclose your patient information for this research.

- University of Washington School of Medicine
- Name of health care organization (*write in name of Health Care Organization*)

_____

2. Patient information that will be released for research use

This permission is for the health care provided to you during the following time period: three months before today until seven months from today.

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.

C. How your patient information will be used

1. Who may receive your patient information

    - Research team at the University of Washington
    - National Institutes of Mental Health, Data and Safety Monitoring Board
    - University of Washington's Institutional Review Board
    - Advarra's Institutional Review Board (responsible for oversight of this study)
    - Department of Health and Human Services (DHHS), Office for Human Research Protections
    - Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported

2. Why your patient information will be used and/or given to others

    - To do the research for the study
    - To see if the research was done right, and
    - To do future research that is not part of the current study

The researchers will use your patient information only in the ways that are described in the research consent form that you signed and as described in this HIPAA Authorization. If the results of this study are made public (to other researchers), information that identifies you will not be used. The privacy laws do not always require the receiver of your information to keep your information confidential. After your information has been given to others, there is a risk that it could be shared without your permission. You can ask questions about what the research team will do with your information and how they will protect it.

You have the right to obtain your patient information in your healthcare record. When the study is over, you can request access to your study data.

D. Expiration

This permission for the researchers to obtain your patient information ends when the research ends and any required monitoring of the study is finished.

E. Canceling your permission

You may change your mind at any time. To take back your permission, you must send your **written** request to:

John Fortney
Department of Psychiatry and Behavioral Sciences
School of Medicine
University of Washington

1959 Pacific Street, Box 356560
Seattle, WA 98195-6560

If you take back your permission, the research team may still keep and use any patient information about you that they already have. But they can't obtain more health information about you for this research unless it is required by a federal agency that is monitoring the research.

If you take back your permission, you will need to leave the research study. This means that you would not have any more research treatments or tests. Changing your mind will not affect any other treatment, payment, health care, enrollment in health plans or eligibility for benefits.

F. 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

_____ _____
Printed Name of Research Subject Birthdate

_____ _____
Signature of Research Subject Date of signature

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