Emory University

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)	**Brandon Kitay, MD, PhD**
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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.

Your study doctor may recommend medications as part of your treatment that require following guidelines for use as outlined by the Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) Risk Evaluation and Mitigation Strategy (REMS)® program. This program requires education and counseling on the risks of buprenorphine containing medications as well as regularly scheduled visits that may include intermittent urine drug screening (UDS). Before you consent to participating in this study, your study doctor will discuss with you the any requirements of the BTOD REMS® Program should buprenorphine containing medications be recommend at any point during your participation in this study.

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.

IN CASE OF INJURY

If you believe you have become ill or injured from this research, you should contact the study doctor at the telephone number listed on the first page of this form. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured in the study, Emory will help you get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and the sponsor have not set aside any money to pay you if you are injured as a result of being in this study. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence. “Negligence” is the failure to follow a standard duty of care.

COSTS OF PARTICIPATING IN THE STUDY

The study sponsor does not plan to pay for any items or services that you may receive if you take part in this study.

You will have to pay for the items or services that are part of this study. The sponsor will not pay for your regular medical care. If you have insurance Emory will submit claims to your insurance for items and services that are part of this study. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

COMPENSATION FOR PARTICIPATION

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

After completion of the survey on the web or with an interviewer (over the phone) you will receive a gift card from the University of Washington directly to your chosen email or chosen address.

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.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA)**.** We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- 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.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI 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. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status, or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

Authorizing to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- Emory may use and disclose your PHI for normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Institute of Mental Health is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration; Veterans Administration.
    - The IRB of Record.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team in writing at the address listed on the first page of this form.

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

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 also contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experiences as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

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