Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

Protocol Title: Pain, Inflammation and Opioid Craving

Principal Investigator: R. Kathryn McHugh, PhD

Site Principal Investigator: N/A

Description of Subject Population: Adults who have chronic pain and have misused opioids

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about how response to pain affects craving in people who have misused opioids. We are asking you to take part in this research study because

you experience chronic pain and have misused opioids. About 120 people will take part in this research study at McLean Hospital. The National Institute on Drug Abuse is paying for this research to be done.

How long will you take part in this research study?

If you decide to join this research study, it will take you about 2 hours to complete the study. During this time, we will ask you to make 1 study visit to McLean Hospital.

What will happen if you take part in this research study?

If you decide to join this research study, the following things will happen. During this visit, we will ask you to complete questionnaires asking about your substance use, pain, emotions and health. We will also ask you questions about your craving and show you pictures of opioids and measure your craving after looking at those pictures.

We will randomly assign you (like flipping a coin) to one of two conditions. In each of these conditions you will receive information about pain from a member of the research team. Then, you will go through a cold water test to measure your sensory responses. The cold water test is a type of pain test that involves placing your hand in cold water. We will ask you to leave your hand in the water for a certain amount of time. You will tell the tester when you feel pain or other sensations from the test, and you will rate the pain or other things you feel on a 0-100 rating scale. This test may be painful, and you can stop at any time. During this task your verbal responses may be recorded using audio recorder to help us measure your reaction to the task.

We will also ask you to provide blood samples before and after the pain test, which will be used to measure inflammation levels, a saliva (spit) test to measure hormone levels, and a urine sample to measure recent substance use. Samples will also be used to extract DNA from the cells in your blood. DNA includes your genes, which carry information about things you inherited from your parents and what you might pass on to your offspring. Trained personnel will take the samples. Two blood samples (1 tube for each sample) will be taken.

Your blood and saliva samples and information about you will be labeled with a code that does not contain your name, initials, social security number, date of birth, or other information that identifies who you are. Only authorized study staff will have the link between these codes and information that can identify you. These samples will be sent to Boston Children's Hospital or another local laboratory, where researchers will measure these levels. Your name and other information that could identify you will not be shared with the researchers at Children's

Hospital or any other external laboratories. Only research staff at McLean Hospital will have access to that information.

We may also perform a whole genome analysis on your DNA sample. Usually, researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome analyses, all or most of your genes are looked at and used by researchers to study links to many diseases or conditions.

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. Others with substance use disorders may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include the potential for experiencing distress or strong emotions from the study tasks or from answering questions about topics like your emotions, drug use and pain.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called "What are the risks and possible discomforts from being in this research study?"

Other things to consider are that this study will take approximately 2 hours of your time. All study procedures will take place on McLean Hospital's campus.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. R. Kathryn McHugh, PhD is the person in charge of this research study. You can call her at 617-855-3169 Monday through Friday 9AM-5PM. You can also call Sarah Lavery at 617-855-2567 Monday through Friday 9AM-5PM with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Sarah Lavery at 617-855-2567 Monday through Friday 9AM-5PM.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

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Who will take part in this research?

We are asking you to take part in this research study because you have chronic pain and have misused opioids. About 120 people will take part in this research study at McLean Hospital. The National Institute on Drug Abuse is paying for this research to be done.

What will happen in this research study?

If you decide to join this research study, the following things will happen. During this visit, we will ask you to complete questionnaires asking about your substance use, pain, emotions and health. We will also ask you questions about your craving and show you pictures of opioids and measure your craving after looking at those pictures.

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your hand in the water for a certain amount of time. You will tell the tester when you feel pain or other sensations from the test, and you will rate the pain or other things you feel on a 0-100 rating scale. This test may be painful, and you can stop at any time. During this task your verbal responses may be recorded using audio recorder to help us measure your reaction to the task.

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Your blood and saliva samples and information about you will be labeled with a code that does not contain your name, initials, social security number, date of birth, or other information that identifies who you are. Only authorized study staff will have the link between these codes and information that can identify you. These samples will be sent to Boston Children's Hospital or another local laboratory, where researchers will measure these levels. Your name and other information that could identify you will not be shared with the researchers at Children's Hospital or any other external laboratories. Only research staff at McLean Hospital will have access to that information.

We may also perform a whole genome analysis on your DNA sample. Usually, researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome analyses, all or most of your genes are looked at and used by researchers to study links to many diseases or conditions.

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding opioid misuse. Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

What are the risks and possible discomforts from being in this research study?

The pain measure may cause mild to moderate pain. Looking at pictures of opioids may cause you to experience craving. You may discontinue these tasks at any time. When you complete questionnaires or interviews on sensitive issues such as psychiatric illnesses, substance use, and life history, you may have emotional reactions. Some of the questions in the research assessments may make you uncomfortable. You always have the ability to refuse to answer any questions at any time if you so choose.

You may have a bruise (a black and blue mark) or pain where we take the blood samples. There is also a small risk of infection, lightheadedness, and/or fainting.

Another potential risk is the loss of confidentiality. Although all efforts will be made to protect your privacy, there are some circumstances under which information that may identify you may be released by study staff. This may occur if you indicate or the research staff has reason to believe that you express a clear and credible threat or intention to do serious harm to yourself or to some other identifiable person. In this case, the research staff would take all reasonable steps to protect both you and the intended victim. This usually involves notifying the other person but may involve notifying the police or others who could intervene to prevent harm from being done. In this study, we will be asking questions about suicidal thoughts or behaviors. If you indicate to the research staff that you have serious plans or intention to harm yourself, we also may inform your current treaters at McLean Hospital.

In all cases, only the minimal necessary information would be released. Similar situations would exist if, during the research, you indicate that a child, elder, or disabled person in your care is being abused and/or neglected. In these cases, research staff would report admitted or suspected abuse and/or neglect of a child, elder, or disabled person to the appropriate authorities.

If you wish to discuss the information above or any other risks you may experience, you may ask questions now or call the Principal Investigator.

What are the possible benefits from being in this research study?

We cannot promise any benefits to you from taking part in this research study. Others with substance use disorders may benefit in the future from what we learn in this study.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be paid for the study assessment visit you complete to compensate the cost of your time and effort in participating in this study. If you complete the study session, you will be compensated in the form of a $50 gift card.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-

payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

If you are injured as a direct result of taking part in this research study, we will assist you in obtaining the medical care needed to treat the injury. This means arranging for (but not paying for) transportation to an acute care center for treatment of the injury. McLean Hospital is a psychiatric care facility and does not provide general health care services.

The care provider may bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.”

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.

- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version Date: November 20th, 2024