

## **ClinicalTrials.gov Consent Form Coversheet**

Study Title: Non-Steroidal Anti-Inflammatory Drug (NSAID) Response and Central Sensitization of Pain in Women With Dysmenorrhea

NCT Number: NCT05900336

Document Date: 6/7/2024



**Research Consent Form**

General Template - Drug Clinical Trial

Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: Pain and medication responsivity in women with menstrual pain

Principal Investigator: Laura A. Payne, PhD

Site Principal Investigator:

Description of Subject Population: Women ages 18-50 with menstrual pain

## 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.

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

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are a woman between ages 18 and 50 and you experience moderate to severe menstrual pain. We are doing the research to learn more about how different women respond to pain and pain medication. If you agree, we will ask you to make 1 study visit to McLean Hospital in Belmont, MA; during this visit you will answer questionnaires and complete pain tasks. You will then take one dose of either Naproxen or placebo during each of the next two menstrual cycles. You will provide a few pain ratings each time you take a dose of the medication, and you will collect a urine sample during each cycle. You will be in the study for approximately 3 months if you decide to stay for the whole study.

The main risks of being in the study are possible side effects from the medication and possible discomforts from the pain tasks.

**Research Consent Form****General Template - Drug Clinical Trial****Version Date: November 2022**

Subject Name:

MRN or DOB:

Subject Identification

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?”.

This study is not being done to improve your health. However, you might benefit from being in the study by experiencing decreased menstrual pain after taking the medication or placebo.

You will be paid up to \$225 for taking part in this research study. You will find more information about the payment amount for each part of the study later in this form.

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

Dr. Laura Payne, PhD, is the person in charge of this research study. You can call her at (617) 855-3478 or email her at [LPayne@mclean.harvard.edu](mailto:LPayne@mclean.harvard.edu). If you have questions about the scheduling of appointments or study visits, call Laura Seidman at (339) 368-4364 or email her at [menstrualpainstudy@partners.org](mailto:menstrualpainstudy@partners.org).

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. 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

Subject Name:

MRN or DOB:

Subject Identification

## Detailed Information

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.

### Why is this research study being done?

We are doing this research study to help us understand what contributes to some women responding differently to medication than others. We hope that this information can eventually lead to better treatment options for pain in women.

This research study will compare Naproxen to placebo. Naproxen is a non-steroidal anti-inflammatory drug (NSAID) that is approved by the U.S. Food and Drug Administration (FDA) to treat pain, including menstrual pain. The placebo looks exactly like Naproxen but contains no Naproxen. Placebos are used in research studies to see if the results are due to the study drug or due to other reasons.

For one menstrual cycle, we will give you Naproxen. For another menstrual cycle, we will give you placebo. The order will be random (assigned by chance, like a coin toss). You and the research team cannot choose and will not know the order that you've been assigned to, but the research team can find out if necessary.

### Who will take part in this research?

We are asking you to take part in this research study because you are a woman between the ages of 18 and 50 years and you have moderate to severe menstrual pain.

About 70 subjects will take part in this research study; all subjects will take part at McLean Hospital. The United States Department of Defense (DoD) is paying for this research to be done.

### What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

#### Phone Screening

The phone screening will take about 15 minutes. During this phone call, we will describe the study and ask you some questions to see if you qualify to participate. These questions will be

**Research Consent Form**

General Template - Drug Clinical Trial

Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

about your menstrual period, medications that you take, and medical problems you may have experienced.

**Study Visit**

If you are eligible to participate, you will then complete the Study Visit. This visit will take around 2½ hours. At this visit you will:

- Answer some questions about your menstrual cycle, pain, and emotions.
- Complete a urine pregnancy and drug test. You cannot take part in this study if you are pregnant.
- Participate in a laboratory pain session during which you will complete four safe lab stress tasks involving pressure applied to your thumbnail, arms, shoulders, and abdomen; and putting a hand in cold water. You will also complete a bladder filling task. These tasks are quick and you may stop at any time.
- Receive either Naproxen or placebo for your upcoming menstrual cycle. Researchers will tell you when to take the medication during your upcoming menstrual cycle.

**Menstrual Cycle #1**

During your next menstrual cycle, you will:

- Take the medication (either Naproxen or placebo).
- Provide a pain rating immediately before taking the medication and again 4 hours later.
- Collect a urine sample and store it in your freezer at home until it can be collected.

**Menstrual Cycle #2**

During the following menstrual cycle, you will complete the same procedures as during Cycle #1:

- Take the medication (either Naproxen or placebo).
  - Research staff will send you the medication to take during Cycle #2 after Cycle #1 is completed.
- Provide a pain rating immediately before taking the medication and again 4 hours later.
- Collect a urine sample and store it in your freezer. At the end of the study, you will return both frozen samples to us at McLean Hospital. We will provide instructions for how to transport the samples.

**Urine Drug Test**

The results of the urine drug test will only be used for data analysis purposes; they will not become part of your medical record. These test results will, however, remain part of your confidential study record.

**Laboratory Pain Tasks**

**Research Consent Form**

General Template - Drug Clinical Trial

Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

These tasks are used internationally in pain research so that pain perception can be assessed the same way across all study participants. A few different devices are used to put pressure on your thumbnails, shoulders, arms, and abdomen. For most of the tasks, the area of the pressure is about the size of a dime; for one of the tasks the pressure device is similar to a pencil. Each pressure lasts for between one to ten seconds. During the tasks we will have you give different types of ratings, such as when you first start feeling pain and number ratings for how much pain you feel. During the cold water task, your hand will be in a tub of cold water up to 1-2 inches above your wrist. For the bladder filling task, we will have you drink bottled water for a few minutes and we will ask you to tell us when you feel certain urges to use the restroom. All of the tasks are safe and have been used in pain research for many years. Any discomfort or pain you might experience will stop quickly when the task is completed. You may stop any task at any time by telling the researcher that you would like to stop.

**Interview**

After the second menstrual cycle is completed, we will ask you to complete an interview with us over a video conferencing platform. This interview will last around 15-30 minutes. During the interview, we will ask you about your experiences with menstrual pain, your experiences with different types of menstrual symptom relief, and your experiences during the study. Both the audio and video of these visits will be recorded; however, only the audio portion will be sent to an outside company for transcription. All files will be stored digitally on MGB-owned, password-protected computers. Video files will be kept until the transcription process is completed and confirmed for accuracy, after which point they will be deleted. Audio files will be kept indefinitely for future research, but will only be labeled with your study ID code. No audio or video files will ever be labeled with your name or other identifying information.

Study staff will provide you information on how to access the video conferencing platform. We will launch the video conferencing in a private and secure area. To protect your privacy we ask that you do not take screenshots, photographs, or recordings of any kind with any electronic equipment. We would like to remind you that a video meeting is similar to us visiting you at home. We may learn more about your home and the people living with you than we would during a visit at the hospital. For example, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child or elder abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies. Please ask the research staff if you have any questions about this prior to your video visit.

**Stopping the Study Early**

Subject Name:

MRN or DOB:

Subject Identification

If you decide to stop taking part in the study for any reason, we will ask you to return any unused study medication.

Also, the study doctor may take you out of the study without your permission. This may happen because:

- The study doctor thinks it is best for you to stop participating
- We stop doing the study for other reasons

If this happens, the study doctor will explain why you need to stop taking part in the study.

### **Study Information Included in Your Electronic Medical Record**

A notation that you are taking part in this research study may be made in your electronic medical record.

### **Sending Study Information to Research Collaborators Outside Mass General Brigham**

We will send your study information and/or samples to researchers working with us at the University of Illinois. We will label all your study materials with a code instead of your name. The key to the code connects your name to your study information and samples. We will keep the key to the code here at Mass General Brigham and will not share it with our research collaborators. No one outside of Mass General Brigham will know which study information or samples are yours.

### **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?**

**Research Consent Form**

General Template - Drug Clinical Trial

Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

No. The research study we are doing is only a stepping stone in understanding menstrual pain. 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?**

- It is possible for there to be a breach in confidentiality.
- Questionnaires about sensitive topics (such as depression, anxiety, and pain) may make you uncomfortable. You do not have to answer any question you do not wish to answer and you may stop at any time.
- You may experience brief physical stress/pain during the pain tasks. However, these experiences are under your control since you may stop the task at any time. The discomfort caused by the tasks stops quickly when the task is stopped.

**Risks of Taking Naproxen**

Taking naproxen may cause you to have one or more of the side effects listed below.

- Upset stomach
- Nausea
- Heartburn
- Headache
- Drowsiness
- Dizziness
- Increased blood pressure

There may be other risks of Naproxen that are currently unknown.

As with any drug, an allergic reaction can occur. Allergic reactions can be mild or more serious, and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think you are having an allergic reaction, call the study doctor right away. If you are having trouble breathing, call 911 immediately.

**Research Consent Form**

General Template - Drug Clinical Trial

Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

**Risks of Taking Naproxen with Other Medications**

There are also specific precautions for which other medications you should take within the same time frame as you take the study medication dose. Research staff will give you this information at the Study Visit and will teach you specifically what you should/should not take and when.

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

You will not directly benefit from taking part in this research study. Others with menstrual pain may benefit in the future from what we learn in this study.

**Can you still get medical care within Mass General Brigham 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 Mass General Brigham 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?**

We will pay you \$75 for completion of the laboratory pain session (Study Visit), \$50 for completing Cycle #1, and \$100 for completing Cycle #2.

We may be using an approved, outside vendor (Advarra) to make these payments to you via a reloadable credit card-based system, called Advarra Participant Payments. This secure system is similar to a gift card or credit card. If you are paid by this system, you will be given a Participant Payments Visa card when you enroll in the study. Once the card is activated, the

**Research Consent Form**

General Template - Drug Clinical Trial

Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

study team will add a payment after each paid study event you complete. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted.

We will need to collect your Social Security number in order to make these payments, and it will be shared securely with the company that runs the card-based system. Payments like this are considered taxable income. If you receive more than \$600 in a calendar year, the payment will be reported to the IRS as income by the hospital.

The other option for payment is a check that will be mailed to your home, which you can choose if you prefer. Both methods of payment (Advarra Participant Payments and check) require your Social Security number in order to be processed.

If you do not have reliable transportation or access to public transit, we will reimburse you up to \$50 for rideshare expenses for your in-person study visit. Reimbursement of travel expenses will be made by check.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

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

Study funds will pay for the medication and placebo, study-related procedures, and study visits that are done only for research.

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

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to 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.

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.

**Research Consent Form**

General Template - Drug Clinical Trial

Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

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 Mass General Brigham 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 they may need to do so:**

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of this 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 Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees this research
- A group that oversees the data (study information) and safety of the study
- Non-research staff within Mass General Brigham 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

**Research Consent Form**

General Template - Drug Clinical Trial

Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

- 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: N/A

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain 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 health information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying 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 health 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 health 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.

Subject Name:

MRN or DOB:

Subject Identification

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 health 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 health information to be used and shared as described above.

I agree to be contacted for future research studies

I do NOT agree to be contacted for future research studies

---

Print Name

---

Subject Signature

---

Date

---

Time

Subject Name:

MRN or DOB:

Subject Identification

**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.

---

Print Name

---

Signature of Study Doctor  
or Person Obtaining Consent

---

Date

---

Time**Consent for Text Messaging**

Text messages by mobile/cell phones are a common form of communication. The Responses to Medication for Menstrual Pain research study plans to send you text messages that are relevant to the research study, including links to online surveys. Because these surveys must be completed at specific times, receiving text messages is a requirement for participating in the study.

Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Mass General Brigham are not responsible for any interception of messages sent through unencrypted text message communications.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts
- Text messages will be read based on the availability of the research staff. It is possible that

Page 13 of 14



**Research Consent Form**

General Template - Drug Clinical Trial

Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

texts sent on nights, weekends, holidays, or during vacation periods may not be read for several days.

- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."
- Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham is a separate process as well.
- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

Signature of Subject:

\_\_\_\_\_  
Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

Consent Form Version: 7/25/2023