

Participant Information Sheet

1. Title of the study

Identification of gaps in care for patients with chronic pain through the establishment of a state-wide pain registry in Maine, Pain Registry for ME:

2. Purpose of the study

Chronic pain is a serious public health problem but little is known about how pain affects Mainers. We are starting a registry to collect information from Maine adults who suffer from pain and will use this information to guide public health approaches to improving pain care across Maine.

In order for us to conduct this study, we will protect your personal information and keep any data that identifies you separate from any survey responses that you provide. We have identified an "Honest Broker" to keep your data protected. The Honest Broker is a neutral third party (not a part of the research team). When using an Honest Broker, the Principal Investigators will NOT be able to link your survey response to your personally identifiable information.

3. This is a research study. You may participate in this study if you:

- 1) are at least 18 years old;
- 2) are a Maine resident, or currently living in Maine;
- 3) suffer from persistent or recurrent pain, with or without an official diagnosis of chronic pain from a healthcare provider; (*Persistent and recurrent pain is pain experienced most of the days or everyday*)
- 4) can acknowledge that you understand the study information as described in this document; and
- 5) are willing to answer our survey on line.

4. Participation of this study is voluntary.

This is a research study and your participation is voluntary.

After you review this "Participant Information" section, you can then decide whether you would like to continue by answering the question at the bottom of this page: "Would you like to continue with the survey?".

- 1) If you do not wish to participate, you can select "**No**" followed by "Next" at the end of the page to exit the survey. Or, you can simply close the browser (web-page) and nothing will be recorded.
- 2) If you would like to participate, you can select "**Yes**", and "**Next**" to start the survey. When you reach to the end of the survey, you will click on the "**Submit**" button. After clicking "Submit" all of your responses will be recorded. We hope that you will answer all of the questions. However, you can choose not to answer any questions that makes you uncomfortable (you may select "Prefer not to answer" to any question). Or, you can submit an incomplete survey.

- 3) If you select **“Yes” initially but decide to quit the study later**, you can close the browser at any time. Without clicking on the “Submit” button at the end of the survey, researchers will not receive any of your answers.

5. Study procedures

This study uses a survey to ask about you, your pain, and other specific aspects of your life. You will be asked about the following:

- Basic information about yourself (such as age, biological sex, gender, race/ethnicity, time spent living in Maine each year, the Maine county where you live, and whether you are a Veteran).
- Your pain and its impact on your life (including questions about depression and anxiety).
- How your pain is managed (including whether you use opioids, and your visits with healthcare providers; we will **not** ask you to list your medications).
- Your economic status, education, food security, physical environment (including questions about whether or not you feel safe in your home or if you have experienced any sexual or physical abuse).
- The study will also ask your permission to contact you to complete these surveys again in the future.

There are 75 questions in this survey. We estimate that it will take you about 10-30 minutes to complete the survey. You can use the voice-to-speech feature of the online survey. However, this may not work on every device. If you like, you can ask a family member or a friend for help when filling out the survey. You do not have to complete the survey in one sitting. You can save the response and reenter the survey later to complete it by clicking on “Save & Return Later” at the bottom of the survey and then follow the instructions given on the screen to return to the survey later. Please note any responses to the point where you chose to click on “Save & Return Later” will be recorded and may be used in data analysis.

The researcher plan to conduct the same survey every year. We would like to receive answers from you every year. At the end of each survey, you will be asked whether you would like to complete the survey again next year. If you agree, you will receive reminder emails regarding this at around the same time the following year. If you initially agree to continue to participate but change your mind later, you can simply ignore the reminder emails and do not enter the survey. We will not contact you in the following year. However, any survey answers you have submitted up to that point will still be included in the study.

You will also be asked if you would be willing to be contacted for possible participation in other research studies in the future.

6. Incentives for participating in this study

- 1) If you are one of the first 500 new participants of this Pain Registry
The first new 500 participants are eligible to receive a \$25 electronic gift card after completing the survey for the first time. You can choose to receive a \$25 electronic gift card via email after completing the survey for the first time.
- 2) If you are NOT one of the first 500 new participants of this Pain Registry or you are a returning participant in subsequent years

If you are not one of the first 500 new participants of this Pain Registry or you are a returning participant in subsequent years, after completing the survey, if you choose to have an opportunity to receive a \$25 electronic gift card, then you will automatically enter a random drawing to receive a \$25 gift card. We estimated that initially, the rate of winning a gift card would be 1%. However, this rate may decrease as more participants are recruited overtime. In any given year, each participant will only receive one gift card. No more than 4 gift cards will be sent to the same address.

3) Please note that if the study team has evidence to indicate a response was from a scammer, the study team reserves the right to not provide the gift card.

7. Potential or perceived risks/discomforts

Completing the survey involves minimal risk to you. Some questions may trigger unpleasant emotional responses or may be sensitive to you (such as prescription opioid usage, economic status and exposure to violence). You can choose to skip these questions. You can stop participation at any time. Please note that research team members cannot see your identity or contact information when reviewing your responses. Therefore, there will be no clinical follow-up based on survey responses. If answering the survey questions cause you distress, please contact your primary care physician or other trusted health providers for follow-up care (or see the Resource List below).

This research study is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). 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 unless you have consented for this use. Information and documents protected by this Certificate cannot be disclosed to anyone who is not connected with the research unless: 1) a federal, state, or local law requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); 2) you have consented to the disclosure; or 3) it is used for other scientific research, as allowed by federal regulations protecting research subjects.

8. Data security

This survey is administered through a secure web-based application called REDCap. Once you respond to the survey request, your response will be assigned a unique code (Participant ID) to protect your privacy and data confidentiality. Any contact information that you choose to provide will be kept separately from your survey responses. There will be a third party (an Honest Broker) who is a neutral third party (not a part of the research team); they are the only party who can link your participation ID with your contact information. No one on the research team (including the Principal Investigator) will be able to link your contact information to your participation ID and your survey responses. The Honest Broker will use your contact information to help the research team distribute the gift card to you, and contact you when it is time to respond to the survey again (if you have indicated that you would like to respond to the survey again). The Honest Broker will also use your contact information to link your responses in the first year to any later responses you provide. You may also agree to be contacted about future studies. All correspondence related to this project will contain "PainRegistryforME" in the subject line. Please note your email carrier may direct it to your Junk or Spam folder.

Only the survey results that do not contain your name or contact information will be exported and shared among research team members during data review and analysis. Data will be stored in institutional, password-protected computer drives. Paper copies that may be created during data analysis will be stored in a locked file cabinet until entered into the data base. Then, paper documents will be shredded immediately after usage. Only aggregated data will be presented or published for sharing the results in the future.

Since this will be a registry, we do not have an established target date for deleting the database; however, if program ends due to unforeseen reasons, any information that may link you to the survey response (such as your contact information) will be destroyed up to 5 years after the end of the program.

9. Benefits of participation

Since this is a registry, the research team will not provide any clinical recommendations based on your responses. Therefore, there is no benefit to you personally. However, your responses may help researchers to understand the status and needs of Mainers who suffer from pain, particularly chronic pain. This may aid to create effective programs to help people who suffer from persistent or recurrent pain in the future.

10. Contacts

- If you would like to learn more about this study or have questions related to the study, please contact the Study Investigator:
 - **Ling Cao, MD PhD**
 - University of New England College of Osteopathic Medicine
 - Email: PainregistryforME@une.edu

Please be sure not to provide any information that could potentially link you to the survey responses you may have provided when contacting the investigator.

- **During/After Participation:** For questions about your rights as a research participant, please contact MaineHealth's Institutional Review Board (the group of people who review the research to protect your rights) at MMC_IRB@mainehealth.org or (207) 661-4474.
- If you have questions or want to talk to a professional resource about your situation, you can contact any of the following:
 - **Your primary care physician (or any of your trusted health care providers).**
 - **211 Maine (<https://211maine.org/about/>)**
 - 211 is a free, confidential information and referral service that connects people of all ages across Maine to local services. 211 Maine is based in Maine and available 24 hours a day, 7 days a week. You can reach 211 via phone, text, or email (<https://211maine.org/contact/>) to talk to someone or by searching the online database (<https://211maine.org/>) to find local services.
 - **988 Suicide and Crisis Lifeline (<https://988lifeline.org>)**

- The Lifeline provides 24/7, free and confidential support for people in distress, prevention and crisis resources for you or your loved ones, and best practices for professionals in the United States.
- **Domestic Abuse Violence Helpline 1-866-834-HELP (4357)**
 - The Maine Coalition to End Domestic Violence (MCEDV) works to end domestic abuse, dating abuse, stalking, elder abuse, and commercial sex trafficking. The statewide Domestic Violence Helpline connects callers with advocates at Domestic Violence Resource Centers and provides information, crisis counseling, emotional support and advocacy.
 - For more information visit: www.mcedv.org. For a list of resources in Tribal communities visit: www.mcedv.org/get-help.
- **Maine Coalition Against Sexual Assault (MECASA) 1-800-871-7741**
 - Call the helpline to talk to someone who can help. Free, private support is available 24/7. MECASA represents and supports Maine's sexual assault support centers. For more information visit: <https://www.mecasa.org/maine-sexual-assault-support-centers.html>.

Thank you for your consideration!