**Participant Information Sheet**

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| Version Date: | *5/29/2025* |
| IRB Project #: | *0525-15* |
| Title of Project: | Identification of gaps in care for patients with chronic pain through the establishment of a state-wide pain registry in Maine – PainRegistryforME2 |
| Principal Investigator (PI): | *Ling Cao* |
| PI Contact Information: | PainregistryforME@une.edu*, 207-602-2213 (office)* |

**INTRODUCTION**

* This is a project being conducted for research purposes. Your participation is completely voluntary.
* The intent of the Participant Information Sheet is to provide you with important details about this research project.
* You are encouraged to ask any questions about this research project, now, during or after the project is complete.
* The use of the word ‘we’ in the Information Sheet refers to the Principal Investigator and/or other research staff.

**WHAT IS THE PURPOSE OF THIS PROJECT?**

Chronic pain is a serious public health problem but little is known about how pain affects Mainers. We plan to establish a pain registry through this study. This registry will collect information from Maine adults who experience recurrent and frequent pain. It is estimated that one in three Mainers experience chronic pain. We would like to hear from as many Mainers as possible. The information we obtain could inform public health approaches to improve pain care across Maine in the future.

*Note that you may have been contacted about the MaineHealth-funded PainRegistryforME study previously. Due to funding termination, the previous study has been terminated and this current study (****PainRegistryforME2****) reflects our effort at rebuilding the pain registry in Maine. Because only de-identified data are available from previous study, we cannot copy previous responses into the new study, and responses from previous participants need to be re-collected.*

**WHY ARE YOU BEING ASKED TO PARTICIPATE IN THIS PROJECT?**

You are being asked to participate in this research project because you:

1. are at least 18 years old;
2. are a Maine resident, or currently living in Maine;
3. currently experiencing 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 days or every day)*;
4. can acknowledge that you understand the study information as described in this document; and
5. are willing to answer our survey on-line.

**WHAT IS INVOLVED IN THIS PROJECT?**

You will be asked to decide whether you would like to participate in a confidential survey study and then potentially complete the survey. Here is how:

1. You will arrive to this study survey site through a web link or a QR code included in a study flyer that has been presented or sent to you.
2. Once you are at the study survey site, you will review this “Participant Information Sheet.” 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*?”
3. 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.
4. 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. Once you have clicked on “Yes”, “Next”, and “Submit”, this means you provided your consent to participate the study. 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 by selecting “Prefer not to answer” to any question or simply skipping it. You can submit an incomplete survey.
5. 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.
6. If you decide to continue with the survey (see above option (2)), here is the information about the survey.

The survey asks about you, your pain, and other specific aspects of your life. You will be asked about the following:

1. 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).
2. Your pain and its impact on your life (including questions about depression and anxiety; most questions are taken from an established survey).
3. 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; many of these questions were developed in-house with the help of physicians who work with individuals who experience chronic pain).
4. 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; most of the questions were taken from an established questionnaire).
5. The study will also ask your permission to contact you to complete these surveys again in the future.

There are multiple 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. You do not have to complete the survey in one sitting. You can save the response and reenter the survey later to complete it. You can do this by clicking on “Save & Return Later” at the bottom of the survey. You then can follow the instructions given on the screen to return to the survey later. Please note that once you click on “Save & Return Later”, any responses you have entered will be recorded. All recorded information may be used in data analysis.

The researchers plan to conduct the same survey every year. We would like to receive answers from you every year. After you submit your survey, we will ask you whether you want to complete the survey again next year. If you choose “Yes”, you can provide contact information. You will receive three reminder emails about this around the same time the following year. If you later choose not to participate, you can simply ignore the three reminder emails. We will not contact you again. However, any survey answers you have submitted previously can still be included in the study.

We will also ask you if you want to be contacted about other research studies in the future. If you answer yes, we will ask you to provide your contact information.

Your response to survey questions will be kept separately from your contact information. For more detail, please see the section “WHAT ABOUT PRIVACY AND CONFIDENTIALITY?”

If you did not provide your contact information for any reasons, your survey response will remain anonymous. If you did provide contact information, your survey response will remain confidential.

**WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS INVOLVED FROM BEING IN THIS PROJECT?**

When participating in this study, the risks are minimal. Some questions may trigger unpleasant emotional responses. Some questions may be sensitive to you. These questions may include those asking about prescription opioid usage, economic status, and exposure to violence. You can choose “Prefer not to answer” or skip these questions. You can stop participation at any time. Research team members will not connect your contact information with your survey responses. The research team will not provide clinical follow-up either. If answering the survey questions upsets you, please contact your health care providers. You can also use the resources listed below.

If you have questions or want to talk to a professional resource about your situation, you can contact any of the following. You can save a copy of the survey. You can find to these resources later.

* **Your primary care physician (or any of your trusted health care providers).**
* **211** **Maine (**[**https://211maine.org/about/**](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**](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](http://www.mcedv.org). For a list of resources in Tribal communities, visit: [www.mcedv.org/get-help](http://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>.

If you are a UNE student, your decision to engage/not engage in this research project will have no effect on your academic status, class grade(s), or relationship with any instructor(s) at UNE.

If you are UNE employee, your decision to engage/not engage in this research project will have no effect on your employability or performance review at UNE.

**WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS PROJECT?**

There are no likely benefits to you by being in this research project. However, you can choose to save a copy of your response. You can share it with your care provider. Your response may help your provider understand your pain condition better.

Further, the information we collect may help researchers understand the status and needs of Mainers who suffer from pain. This may aid in the creation of more effective programs. These programs can help people with persistent or recurrent pain in the future.

This is a confidential registry. Therefore, the research team will not provide any clinical recommendations.

**WILL YOU BE COMPENSATED FOR BEING IN THIS PROJECT?**

You will not be compensated for being in this research project.

**WHAT ABOUT PRIVACY AND CONFIDENTIALITY?**

We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Additionally, your information in this research project could be reviewed by representatives of the University. This may include individuals in the Office of Research Integrity and/or the Institutional Review Board.

This survey is administered through REDCap. REDCap is a secure web-based application. Once you respond to the survey, your response will be assigned a unique code. This unique code is also called the Participant ID. Only your participant ID will be used when data are analyzed. This helps to protect your privacy and data confidentiality. Your name and your contact information you provide will be kept separately from your survey responses. The PI is the only researcher who has access to this information. This information will be securely stored within REDCap. If any information is downloaded from REDCap, it will be stored in password-protected drives.

The contact information will be used for three purposes:

1. It will be used to link your responses in the first year to responses you provide in later years
2. It will be used to remind you when it is time to respond to the survey again. This happens if you have indicated that you would like to respond to the survey again.
3. It will be used to contact you about potential new studies you may want to participate in. This happens if you have indicated that you would like to be contacted about future studies.

All messages related to this project will contain “PainRegistryforME2” in the subject line. Please note your email provider may direct it to your Junk or Spam folder.

Survey results exported from REDCap will not contain your name or contact information. This is the only information we will share among research team members. Data will be stored in institutional, password-protected computer drives. Paper copies of data may be created during data analysis. These will be stored in a locked office. We will shred them immediately after usage. The results of this research project may be shown at meetings or published in journals. These will allow other professionals to learn about the results. Your identifiable information will not be shown in talks or publications. Only accumulated data will be presented or published.

We may use data from this research project in future research. In this case, the data will not contain any personal identifiers. We will not ask for your consent for this usage. When appropriate, additional approval may be obtained from the Institutional Review Board before any data can be used in future research.

Since this is a registry, we do not plan to delete the database. If the study ends, all other data will be kept for at least 3 years after that before being destroyed.

**WHAT IF YOU WANT TO WITHDRAW FROM THIS PROJECT?**

You have the right to choose not to participate. You can withdraw your participation at any time without penalty or loss of benefits. You will not be treated differently if you decide to stop taking part in this project.

Please refer to the section “WHAT IS INVOLVED IN THIS PROJECT?” option (2) for more details. Any information you provided up to the point when you click on “Submit” will be collected. These may be used in our study. This applies to the first time and any subsequent times when you fill out the survey.

**WHAT IF YOU HAVE QUESTIONS ABOUT THIS PROJECT?**

You have the right to ask and obtain answers to any questions you may have about this project. If you have questions about this project, complaints or concerns, you should contact the Principal Investigator (PI). The name and contact information of the PI are listed on the first page of this document.

When contacting the investigator, please be sure not to provide any information that could potentially link you to your survey responses.

**WHAT IF YOU HAVE QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH PARTICIPANT?**

If you have questions or concerns about your rights as a research participant, or if you would like to obtain information or offer input, you may contact the Office of Research Integrity at (207) 602-2244 or via e-mail at irb@une.edu.