KEY INFORMATION FOR DEVELOPMENT OF A PAIN NEUROSCIENCE EDUCATION (PNE) PROGRAM FOR PATIENTS WHO ARE OPIOID DEPENDENT WITH CONCURRENT CHRONIC MUSCULOSKELETAL PAIN

We are asking you to choose whether or not to volunteer for a research study about the influence of an education program about how your body interprets and processes pain messages and its effectiveness in changing your pain experience, reducing fear of movement and improving self-efficacy. We are asking you because you currently experience chronic musculoskeletal pain and participate in the University of Kentucky (UK) Polk Dalton Chronic Opioid Analgesic Therapy (COAT) clinic on a monthly basis. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The primary objective of this research is to study the effects of a Pain Neuroscience Education (PNE) program with patients who are opioid dependent with concurrent chronic musculoskeletal pain. PNE is an education program about how your body interprets and processes pain messages and its effectiveness in changing your pain experience, reducing fear of movement and improving your self-efficacy. By doing this study, we hope to learn how to better treat individuals with chronic musculoskeletal pain who are concurrently taking time-based opioid medications. Your participation in this research will last two sessions for 30-minutes each, the first at your regularly scheduled COAT appointment. The second session will be at a date and time of your convenience; both held at the University of Kentucky Polk Dalton clinic.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You will understand how the brain interprets pain and how best to manage it. You may find that your pain is more manageable after the education sessions. Your willingness to take part will help healthcare professionals better understand how to treat others in similar situations. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

We do not anticipate any risks to you; your care ongoing prescriptions and participation in the COAT clinic will proceed as per usual. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact the Principal Investigator, Nicole D. Windsor, PT, DPT, FAAOMPT, CERP, at the UK Polk Dalton clinic. The Polk Dalton clinic phone number is (859) 257-8801.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the UK Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at (859) 257-9428 or toll free at (866) 400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

The participant may be excluded from this study if they are not actively participating with the UK Polk Dalton Chronic Opioid Analgesic Therapy (COAT) clinic; the participant may also be excluded if they are under 18 years of age, over 90 years of age, or if the patient scores 24 or less points on the Mini-Mental State Examination.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at the UK Polk Dalton clinic, the first session will be at your regularly scheduled COAT appointment time. You will need to come two times during the study; each visit will last 30 minutes. The total amount of time you will be asked to volunteer for this study is 1 hour over two sessions. The second session will be at a date and time that is convenient for you.

WHAT WILL YOU BE ASKED TO DO?

The following procedures will be performed. However, some procedures may not be performed due to time constraints by the decision of the investigator. At the initial visit, we will review the consent/HIPAA form and you will sign it (if agreeable to participate in the study); you will complete the Mini Mental State Examination; you will also complete four questionnaires which will ask about chronic pain and how it is affecting your daily life and activity level; we will also complete the first education session. You will be asked to participate in one additional 30-minute education session at a date and time of your convenience. You will be provided handouts to take home for review. At the second and final PNE session, you will complete the four questionnaires and be asked to complete a survey providing feedback about your experience.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The researchers do not anticipate any risks to your care, ongoing prescriptions or participation in the COAT clinic. Although we do not anticipate a breach of confidentiality, it is a possible risk. There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, you may find that your pain is more manageable. You will understand how the brain interprets pain and how best to manage it. Your willingness to take part will help healthcare professionals better understand how to treat others in similar situations.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in this study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There is no charge or fee associated with this study. Your insurance will be charged, as usual, for your COAT appointment.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the PNE intervention done strictly for this research.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. We will make every effort to prevent anyone who is not

on the research team from knowing that you gave us information, or what that information is. Your information will be combined with information from other people participating in the study. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. We will make every effort to keep all research records that identify you confidential to the extent allowed by law. Officials from the University of Kentucky may look at or copy portions of records that may identify you.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions, or
- we find that your participation in the study is more risk than benefit to you.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

We do not believe there are any physical risks in participating in this study. However, if you believe you are hurt or if you get sick because of something that is due to the study, you should call Nicole D. Windsor, PT, DPT, FAAOMPT, CERP or Judi Daniels, APRN, PhD at the UK Polk Dalton clinic (clinic phone: (859) 257-8801) immediately, who will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in this study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will not provide you with individual research results.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about thirty-five people to do so. The principal investigator, Nicole D. Windsor, PT, DPT, FAAOMPT, CERP, is a PhD Student. She is being guided in this research by Anne Harrison, PT, PhD (Advisor). There may be other people on the research team assisting at different times during the study.

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

HOW WILL YOUR PRIVACY AND CONFIDENTIALITY BE PROTECTED?

Researchers will take careful steps to keep your information confidential. Researchers will remove your name or other direct identifiers from your information. We will label your information with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code to you. The information collected during this study, as outlined previously, will not be retained in your medical record.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- History and mechanism of injury
- History of treatment for any injury or illness that has led to chronic pain
- Demographic information: gender, date of birth, smoking status, employment status, highest level of education, race, presence of previous injury, presence of previous treatment.
- Medication history and current medications

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity.
- Law enforcement agencies when required by law.
- University of Kentucky representatives.

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- Current or future healthcare at the University of Kentucky
- Current or future payments to the University of Kentucky
- Ability to enroll in any health plans (if applicable)
- Eligibility for benefits (if applicable)

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to the Principal Investigator, Nicole Windsor, to inform her of your decision. Please mail the letter to the UK Polk Dalton clinic at the following address:
  University of Kentucky Polk Dalton Clinic
  217 Elm Tree Lane
  Lexington, KY 40507
- Researchers may use and release your health information **already** collected for this research study.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

You are the subject. You have read this information, and you will receive a copy of this form after it is signed.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ **Signature of research subject**	_____ **Date**
_____ **Printed name of research subject**	
_____ **Printed name of [authorized] person obtaining informed consent and HIPPA authorization**	_____ **Date**