Nudging Primary Care Providers Toward Guideline-Recommended Opioid Prescribing Through Easier and More Convenient EHR Information Design

NCT04295135

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

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ABOUT THIS RESEARCH

You are invited to participate in a study to test a pain dashboard tool in the Epic EHR system to assist primary care clinicians in providing guideline-concordant care for patients with chronic pain conditions. You were selected as a possible subject because you are a primary care provider who treats patients with chronic pain conditions. Please read this form and ask any questions you may have before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Indiana University or Eskenazi Health.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test the Chronic Pain OneSheet, a pain dashboard tool in the Epic EHR system intended to assist primary care clinicians in providing guideline-concordant care for patients with chronic pain conditions. The study is being conducted by Christopher Harle, PhD from University of Florida and Olena Mazurenko, MD, PhD, from Indiana University's Fairbanks School of Public Health. It is funded by the National Institutes on Drug Abuse.

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of up to 250 primary care providers who will be participating in this research.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, the researchers, in collaboration with Regenstrief Institute and Eskenazi Health, will collect data from your interaction with the Epic EHR during visits with patients who have chronic pain. This data will be extracted from Epic by the Regenstrief Institute, and patient identifiers will be removed before being received by the researchers for analysis. The data being collected will include the dates of services provided, the daily MMEs (Morphine Milligram Equivalents) of any opioid medications being prescribed, the retrieval of Prescription Drug Monitoring Program (PDMP/Inspect) reports (but not the results of the reports), urine toxicology screens being ordered (but not the results of the screens), the use of the goal-setting feature in Epic, pain and function measurement using the PEG scale instrument in Epic.

Additionally, if you agree to be in the study, you may be given access to the Chronic Pain OneSheet in the Epic EHR system and given instructions and assistance in using it and incorporating its use into your clinic workflow. If you randomized to the OneSheet group, your Epic EHR will be updated with access

to the Chronic Pain OneSheet, including a favorite tab to easily access the OneSheet. Then data regarding your interaction with, and use of, the OneSheet will also be collected from the Epic EHR.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

While in the study, there is a small risk of breach of confidentiality. However, because this data is already routinely collected in the Epic Electronic Health Record (EHR) system, you are already subject to this risk, and it is not increased by your participation in this research. To mitigate this risk, the researchers will only receive de-identified data, and all information collected will be stored in a password protected database or locked filing cabinets.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

By participating in this study, you will help to assess the effectiveness and usefulness of a decision support tool in the Epic EHR system that is designed to assist clinicians in providing guideline-concordant care for patients with chronic pain conditions.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. Only authorized investigators affiliated with the project will have access to the data collected, for the purpose of analyzing the data.

A description of this clinical trial is available on **ClinicalTrials.gov**, as required by U.S. law, number NCT04295135. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigators and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor, the National Institutes on Drug Abuse, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), etc., who may need to access the research records.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?
Information collected for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?
You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There is no cost to you for taking part in this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study contact the principal investigator Olena Mazurenko, MD, PhD Health Policy and Management Fairbanks School of Public Health, 317-274-3341, omazuren@iu.edu, or the study's project manager, Lindsey Sanner, MPH, 317-278-0140, lmsanner@iu.edu.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 800-696-2949 or irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?
If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, contact the study's principal investigator or project manager.

PARTICIPANT'S CONSENT
In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____ **Date**:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____