INDIANA UNIVERSITY

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

R33 Clinical Trial
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NCT04295135

IRB #1911922583
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Organizations:

Indiana University
Regenstrief, Inc.
Eskenazi Health

Funding Sources:

National Institute on Drug Abuse
National Institutes of Health

A-Level of Review

q720

Does any research activity in this study present more than minimal risk to human subjects?
No.The research may qualify for Expedited review if all research procedures fall into one of the categories below.

q721

Check all category(ies) which apply to this research. Category 5 - Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes
Category 7 - Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

q724

Will the researchers be using a data collection form?
No

q725

List all data points that will be recorded or collected.
The data points that will be collected will all be participating provider behavior within Epic during qualifying patient visits. These data points will be the following: • Daily MMEs (Morphine Milligram Equivalents) of opioid medications being prescribed • Retrieval of Prescription Drug Monitoring Program (PDMP/INspect) reports (not the results of the reports) • Urine toxicology screens being ordered (not the results of the screens) • Goal- setting - using the goal-setting feature already in Epic • Pain and function measurement using PEG

scale instrument already in Epic

q23340

Would identification of subjects and/or their responses reasonably place them at risk for any of the following (check any that apply):
None

B-Lay Summary Research Design

q22122

Describe the purpose of this study in lay terms, including research question(s) and hypothesis.
The Chronic Pain OneSheet (OneSheet) is a dashboard that was developed at Eskenazi, and built in Epic at Eskenazi Health and at Wake Forest Baptist Health, in close collaboration with the Primary Care leadership and clinics at both institutions. The Dashboard does not provide new information to providers, but rather works by aggregating and structuring information that is already being collected, and that is available in other places in the medical record. By aggregating and structuring this information in a more convenient manner, the goal of the OneSheet is to make the information that is important in clinical decision-making more readily available, and to reduce the amount of time that providers need to spend locating this information.
The purpose of the study is to determine whether and how having access to the Chronic Pain OneSheet activity in Epic affects the ordering, prescribing, goal-setting, risk monitoring, and outcome measuring behavior of participating providers in visits with patients with chronic pain. We will also assess whether access to the Chronic Pain OneSheet results in primary care providers making chronic pain treatment decisions that are more concordant with the CDC Guideline for Prescribing Opioids for Chronic Pain.

q22123

List and describe all research interactions and/or interventions, including the frequency and duration of procedures, and length of participation for individual subjects.
The Chronic Pain OneSheet (OneSheet) is a dashboard that was developed and built in Epic at Eskenazi Health, in close collaboration with the Eskenazi Health Clinical Information Technology Governance committee, and Eskenazi Health Primary Care leadership and clinics. It was subsequently built into Epic at Wake Forest Baptist Health primary care clinics, in close collaboration with WFBH Primary Care leadership. The Dashboard does not provide new information to providers, but rather works by aggregating and structuring information that is already being collected, and that is available in other places in the medical record. By aggregating and structuring this information in a more convenient manner, the goal of the OneSheet is to make the information that is important in clinical decision making more readily available, and to reduce the amount of time that providers need to spend locating this

information. Qualifying providers will be recruited for the study and will be formally consented. The enrolled providers will be randomized to treatment and control groups (using the OneSheet vs. NOT using the OneSheet). The participating providers that have been randomized to the treatment group will be given instructions on how to access and use the OneSheet when treating patients' chronic pain. These providers will also be given ongoing technical support and assistance with integrating the OneSheet into their clinical workflows. Those participating providers who have been randomized to the control group will not be given any information or instructions on accessing and using the OneSheet. At Eskenazi, when a qualifying patient, identified by Regenstrief through an algorithm developed in collaboration with the researchers, comes to a visit with a participating provider in the treatment group, a BPA will appear in the patient's record, alerting the provider to consider utilizing the OneSheet for that patient's chronic pain management during the visit. Eskenazi will share the MRNs of qualifying patients, and dates of qualifying visits with Regenstrief Data Core, who will collect outcome measure data, remove patient identifiers (with the exception of dates), and share this limited data set with the research team for analysis. At Wake Forest, when a qualifying patient, identified through the same process, comes to a visit with a participating provider in the treatment group, a BPA will appear in the patient's record, alerting the provider to consider utilizing the OneSheet for the patient's chronic pain management during the visit. Wake Forest Baptist Health will share the MRNs of qualifying patients, and dates of qualifying visits with an honest broker, who will collect outcome measure data, remove patient identifiers (with the exception of dates), and share this limited data set with the research team for analysis. At both sites, formal informed consent and HIPAA authorization will not be obtained from qualifying patients being treated by participating providers.

q23358

Will any non-English study documents be uploaded?

No

q24919

Is this research funded by, or has a funding application been submitted to, a federal agency? This includes federal pass- through funding.

Yes

q23234

List inclusion criteria - eligibility criteria for subjects.

Inclusion criteria for provider participants: 1. Primary care provider (including Family Medicine, Internal Medicine, Med-Peds, and General Medicine) 2. Is able to prescribe medication (i.e., MD, NP, PA) 3. Sees patients at an Eskenazi or Wake Forest Baptist Health primary care clinic. Data will only be collected from visits that participating providers have with patients who meet the following criteria: 1. 18+ years old 2. No cancer diagnosis in the prior 3 years. 3. Meet the following indications of chronic pain over the most recent 24 months: a. 3+ unique* instances of a qualifying pain diagnosis (either billed diagnosis or

problem list) OR b. 3+ unique* prescriptions for one or more of the following drugs: an opioid (“opioid agonist,” “opioid partial agonist,” “opioid combinations”), Tramadol, Nortriptyline, Amitriptyline, Gabapentin, Pregabalin, Duloxetine, desipramine, milnacipran, tapentadol OR c. 2 unique* instances of a qualifying pain diagnosis AND 2+ unique* pain medication prescriptions containing one or more of the drugs listed in b. * To count as unique, diagnoses or prescriptions should be separated by at least 30 days from any previous qualifying diagnosis or prescription. **Qualifying pain diagnoses and prescriptions listed separately. - Because chronic pain treatment is often discussed during visits not identified as chronic pain visits, any visit that a qualifying patient has with a participating primary care provider will be a qualifying visit for the purposes of the trial.

q23235

List exclusion criteria (any criteria which would exclude otherwise acceptable subjects).
The following are exclusion criteria for providers: 1. Does not practice primary care 2. Does not regularly see patients at an Eskenazi or Wake Forest Baptist Health Primary Care clinic 3. Is not able to prescribe medication

q23346

Will subjects be paid for their participation in the study? Payment includes reimbursement of expenses (other than compensation for injury).
Yes

q23347b

Describe the payment arrangement, including amount and timing of disbursement.
No payments

q23348

Justify the proposed payment arrangement described above, specifically why payment does not provide undue influence for subject participation.
No payments

q23349

Will partial payment be provided if the subject withdraws prior to completion of the study?
No

q23350

Explain why failure to offer partial payment will not unduly influence subjects to complete the study.

Primary care providers are highly paid individuals, so we do not think $25 gift card will be a high enough amount to unduly incentivize completion.

q23352

Does this research involve (choose all that apply):

- the STUDY of any of the following products (regardless of FDA approval status). “The study of” means at least one objective of the study is related to obtaining data about the product
- USE of any of the following products which have not been cleared or approved by the FDA for use in the US
- USE of any of the following products for open label extension, treatment, or compassionate use

None apply

q25049a

Is this research considered a prospective clinical study?

Yes - This study may require entry in OnCore.

q30000a

Is this community-engaged research?

No

C-Sites and Collaborations

q700

Are there additional locations of research, not already listed?

Yes

q701c

Provide the name of the site, including city and state.

Wake Forest University and Wake Forest Baptist Health; Winston-Salem, NC.

q702

Is any research taking place outside the United States?

No

q704

Are you requesting that IU provide IRB approval for any researchers who are NOT IU

affiliates?
Yes

q25332

Please choose the option which best describes the role of the non-affiliated investigators in the research.
Non-affiliated investigators are conducting only some of the procedures specified in the protocol.

q25334

Please choose the research activities being conducted by the non-affiliated investigators.
Collection or analysis of identifiable data or identifiable biospecimens

q25335

Please list the non-affiliated investigator(s) and the name(s) of the institution(s) with which they are affiliated (e.g. name of academic institution, academic medical center, corporation or other entity).
Wake Forest University and Wake Forest Baptist Health; Winston-Salem, NC.

q25336

Please choose the best description of the non-affiliated investigator's role at their own institution.
Faculty or staff

q25338

Please describe the plan for management and communication of IRB-related information to sites and/or non-affiliated investigators, including ensuring that non-affiliated investigators are familiar with and will follow IU HRPP policies and procedures, that required reporting and requests for amendments by non-affiliated investigators are submitted to the IU IRB, and that IRB decisions and approved documents are communicated. Alternatively, attach a document describing this plan.

The lead investigator and the site-specific PI for the study at Indiana University will be responsible for ensuring that all non-affiliated investigators complete all training and tasks required by IU HRPP policies, and follow the protocol that is approved by the IU IRB. All study personnel will meet regularly to communicate any decisions by the IRB, and to ensure that all policies and procedures are being followed at all sites. All IRB approved, and stamped documents will be circulated to study personnel.

q710a

Is this a multi-center study or multi-site clinical trial?

Yes

q711a

State the number of subjects to be enrolled in the study at all sites.

250

q712a

Is the Lead investigator at IU?

Yes

q714

Describe the plan for the management and communication of multi-site information that may be relevant to the protection of participants.

The study teams at all sites have a standing biweekly meeting to manage the study and communicate information between sites. Data Use Agreements between the sites will protect the sharing of participant information among the study team. Files with participant information will be shared between the sites only when necessary and then only via secure electronic shared drives.

D-Recruitment Methods

q23236

Describe how potential subjects will be initially identified. Potential subjects will be initially identified through the listing of primary care providers at each of Eskenazi's or Wake Forest's primary care clinics on their
website. Other providers will by identified by having previously collaborated on prior projects with the research team. Additionally, at both sites, researchers will identify potential subjects at presentations at clinic meetings, after receiving approval from the clinic's management. Eligible clinic visits at Eskenazi Health clinics will be identified by Regenstrief Institute Data Core and Eskenazi Health. The researchers will provide criteria for eligibility, and Regenstrief and Eskenazi will work together to identify them. Eligible clinic visits at Wake Forest Baptist Health clinics will be identified by Wake Forest Baptist Health working with an honest broker similar to the Regenstrief Institute Data Core. The researchers will provide criteria for eligibility, and the health system (WFBH) and the honest broker will work together to identify them. The researchers will not be privy to the list of eligible patients or clinic visits at either trial site.

q30002

Check any of the following sources of information which will be used to identify potential subjects.
Subject self-referral in response to recruitment materials

q30003

Describe how potential subjects will be initially contacted. Researchers will visit primary care clinics and present the research project to all primary care providers there through a powerpoint presentation and handouts/flyers. Interested eligible providers identified at the clinic presentations will be followed up with by e-mail by research staff. Providers who have previously collaborated with the research team will also be contacted by e-mail, and asked to refer other providers in their clinic who may be interested in participating. Because of operations changes related to covid-19, if visiting the clinic in person is not acceptable, researchers may also work with the primary care clinics to present the powerpoint presentation through a teleconference or a virtual meeting with a software like Zoom. The powerpoint and handouts will be shared through email.

q23237

Check any of the following recruitment materials which will be used to contact potential subjects.
Direct
Mail/Email
Flyers/Brochures Verbal Scripts

q25426b

Select any of the following circumstances which apply to this research.
None of the above.

q23245

Would participation in this study preclude subjects from participating in other research studies?
No

E-Risks Benefits Protections

q23296

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research.
Because we will be collecting data on provider behavior, there is a risk that if a breach of confidentiality were to occur, and the provider's clinical behavior was criminal or otherwise

objectionable, they would be at risk for criminal liability, loss of ability to be employed, and damage to reputation. However, because this data is already routinely collected in the Epic Electronic Health Record (EHR) system, they are already subject to these risks, and participation in this research does not increase these risks. Patients encounter the same level of risk that their identifiable data may be breached by simply being a patient in the hospital records systems. We will work with an honest broker who can act as a firewall between personally identifiable health data and the researchers, ensuring that the risk of loss of confidentiality is not greater than minimal. Eskenazi will share the MRNs of qualifying patients, and dates of qualifying visits with Regenstrief Data Core, who will collect outcome measure data, remove patient identifiers (with the exception of dates), and share this limited data set with the research team for analysis. Wake Forest Baptist Health will share the MRNs of qualifying patients, and dates of qualifying visits with an honest broker at Wake Forest University, who will collect outcome measure data, remove patient identifiers (with the exception of dates), and share this limited data set with the research team for analysis. Use of the OneSheet does not increase the risk of viewing incorrect or incomplete data because the OneSheet functions by gathering relevant information directly from other parts of the electronic medical record (EMR) in one place. Therefore, the data in the OneSheet are as accurate, valid, and complete as any other information in the electronic medical record.

q23297

Describe procedures for protecting against, or minimizing, the potential risks listed above. Include any procedures that are already being performed on subjects for diagnostic, treatment, or standard purposes.

Participants' names will not be attached to their data. We will work with Regenstrief and another honest broker at Wake Forest who can act as a firewall between personally identifiable health data and the researchers, ensuring that the risk of loss of confidentiality is not greater than minimal. The researchers will obtain a limited dataset containing dates of qualifying visits, but patient identifiers (with the exception of dates) will be removed by the honest brokers. Furthermore, all information collected will be stored in locked filing cabinets or password protected secure network drives on encrypted devices. Data will continue to be protected on secure network drives throughout the analysis and accessed only by members of the research team. All study dissemination activities, such as presentations and journal articles, will report data in the aggregate and not identify individuals. Use of the OneSheet does not increase the risk of viewing incorrect or incomplete data because the OneSheet functions by gathering relevant information directly from other parts of the electronic medical record (EMR) in one place. Therefore, the data in the OneSheet are as accurate, valid, and complete as any other information in the electronic medical record.

q23299

Explain how research data will be protected so that only approved persons have access to subjects' identifiable data (i.e. confidentiality of data).

Participants' names will not be attached to their data. We will work with Regenstrief and another honest broker at Wake Forest who can act as a firewall between personally

identifiable health data and the researchers, ensuring that the risk of loss of confidentiality is not greater than minimal. The researchers will obtain a limited dataset containing dates of qualifying visits, but patient identifiers (with the exception of dates) will be removed by the honest brokers. Furthermore, all information collected will be stored in locked filing cabinets or password protected secure network drives. Data will continue to be protected on secure network drives throughout the analysis and accessed only by members of the research team. All study dissemination activities, such as presentations and journal articles, will report data in the aggregate and not identify individuals. All study dissemination activities, such as presentations and journal articles, will report data in the aggregate and not identify individuals.

q23300

Explain how subjects' physical privacy will be protected, both during recruitment/screening and during participation in the research.

For each participants' privacy, the consent process will be conducted privately.

q23301

Is there a potential for subjects to benefit directly from participation in the study?

Yes

q23302

Describe the potential benefits to be gained by the individual SUBJECT. Please note that payment for participation is not considered a benefit.

The participants who are randomly assigned to have access to the Chronic Pain Onesheet may be able to access relevant medical record information more efficiently than they would otherwise.

q23303

State the potential benefits or information which may accrue to SCIENCE or SOCIETY in general as a result of this work.

This research will lead to an increased understanding of the impact that a decision support tool has on physician behavior and interaction with their electronic health record system. This may result in a clinician decision support system that benefits both clinicians and patients in terms of improved quality and improved outcomes associated with pain management in primary care.

F-Data Safety Monitoring

q23304

Describe the provisions for monitoring the data to ensure the safety of subjects.

Research staff will monitor (at least weekly) subject withdrawals and any complaints to ensure that study procedures are not harming the safety of participants. As part of this monitoring, this information will be shared with the PI for determination of any safety risks. We are in the process of forming a 3-person DSMB. These members are colleagues at current or former institutions. However, they do not stand to gain scientifically from participating (e.g., through publication or grant funding). Further, they do not have a financial interest in the study outcome. Because the CT is low risk, DSMB members will meet at least annually, by teleconference call. The DSMB will also have the option of expedited meetings to review unexpected SAEs or other urgent issues that arise over the course of the CT. Any recommendations related to the CT will be made in writing by the Board's Chairperson to the Principal Investigator in a report. The report will also include meeting minutes summarizing the discussions held during DSMB meetings. The DSMB members are of multidisciplinary backgrounds and have the necessary expertise in clinical medicine and pain management to serve on the DSMB for this CT. Additionally, because this is a multi-site CT, the DSMB is composed of one member from each site, as well as a third member, who is not affiliated with either study site. This ensures that decisions will be made impartially.

H-Informed Consent

q901

Will all or some subjects consent to participate in the research? Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.

q902

Explain which subjects will consent to the research, and which subjects will not.
The patients on which we are pulling clinical outcome data will not consent to research. The physicians, on whom we are collecting data, will consent to research.

q909

For those subjects who will consent to participate, explain how subjects (or subjects' legally authorized representative) will be presented with the information needed to decide to participate, including all elements of informed consent.
All subjects will be presented with a copy of the informed consent statement. A researcher will walk through the consent form with the subject and answer any questions that the subject might have regarding the study.

q903

Describe any informed consent tools which will be used to present information to potential subjects (i.e. consent documents, videos, brochure, drug/device information,

etc) and how they will be used.
An informed consent statement will be used to explain all the risks, benefits, and time commitments, and provide a description of how to stop participating in the study. All subjects will be walked through the consent form with a member of the research team. A Recruitment Handout will be given that contains a link to the REDCap consent form if subjects prefer to sign the consent at a later time after hearing about the study.

q925

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.
Clinician participants will be informed about the study, and provided a copy of the consent statement. A member of the research team will go over the sections of the informed consent statement with the potential subject and then allow time for questions and clarifications. The potential subject may sign the informed consent statement at that time, or they may complete it electronically (via REDCap) at a later time. The content of the electronic consent form will match the paper consent form.

q30127a

Will you include all required elements of consent in your consent process?
Yes

q921

Indicate in what language(s) the consent conversation will be conducted.
English

q926

Explain how you will ensure potential subjects understand the information you have presented to them before they agree to participate in the study.
The potential subjects are highly educated medical clinicians who participate in many trials and are familiar with the language of informed consent statements. To ensure potential subjects understand the specifics of this study, after reviewing the informed consent statement with participants, staff will prompt the potential subject for any questions that may have arisen during the review and provide any clarifications necessary.

q929

Briefly describe any training provided to investigators who are obtaining informed consent.
Investigators will undergo CITI training for social behavioral research practices. They will also be taught how to go through a consent form and prompt for questions that arise.
Investigators will have a thorough working knowledge of the research study and will be able

to answer subjects' questions. Any questions they are not able to answer, the investigator will refer the subject to the PI.

q931

Does the research include any minimal risk procedures to which subjects will not consent?
No

q23678a

For those subjects who will consent to participate, choose whether the consent process will be documented by a written signature from subjects.
All consented subjects will provide a written signature as documentation of consent.

q30129a

Will subjects participate in any study activity prior to physically signing a consent document?
No

q940a

Explain the process for obtaining a written signature from subjects.
Clinician participants will be informed about the study, and provided a copy of the consent statement. A member of the research team will go over the sections of the informed consent statement with the potential subject and then allow time for questions and clarifications. If this occurs in person, the potential subject may choose to sign the paper informed consent statement at that time. If this occurs remotely, the potential subject will be directed to the REDCap form where they may choose to electronically sign the consent statement. For clinicians who do not sign the consent statement at the initial contact, the study team will attempt to contact to recruit and consent a potential participant no more than 5 times, or until they state they do not want to participate.

q23764

Since some subjects will not consent to participation in the research, a waiver of consent is required. Choose the appropriate reason for waiving consent.
Research is minimal risk and obtaining consent is not practicable.

q904b

Explain how the research involves no more than minimal risk to the subjects.
The collection of outcome data is only meant to identify physicians who will be the subjects on whom we are actually collecting data. The physicians will be consented.

q906b

Explain how the waiver will not adversely affect the rights and welfare of subjects.
The identify of the patients will not be known by the study team. It is only meant to identify physicians. Data will not be used in any other way.

q907b

Explain how the research could not be practicably carried out if informed consent were required.
The research is concerned with the clinical behaviors of primary care providers when they are treating patients with chronic pain and using their EHR in daily practice. Because primary care providers see many patients with chronic pain on a daily basis, it would be impractical for researchers or clinic staff collaborators to intervene in each of these visits to obtain consent.

q30004d

Explain why the research could not be practicably carried out without identifiers.
The identity of the patients will not be known to the study team. They will be known by the hospital pulling the records. We will work with an honest broker who can act as a firewall between personally identifiable health data and the researchers, ensuring that the risk of loss of confidentiality is not greater than minimal.

q908b

Explain how subjects will be informed of pertinent results at the conclusion of the study, if appropriate. If subjects will not be informed, enter N/A.
N/A -- there not by any pertinent results for the patients because their data is only be used to identify the relevant physicians or OneSheet uses.

K-HIPAA

q23253

Are you part of a covered entity (health care provider that transmits health information electronically) or are you receiving information from a covered entity as part of your research?
Yes

q23254

Will protected health information be utilized, accessed, collected, or generated as part of the study?
Yes

q30347a

Select the electronic systems to be used for the collection and/or storage of protected health information (ePHI). Choose all that apply.

REDCap
Microsoft Teams
IU Box Health Data Account

q23257

Will you be accessing or collecting protected health information for RECRUITMENT purposes?

No

q23277

HIPAA applies to your study, and requires that you obtain authorization for PARTICIPATION in research, or that you request a waiver. Check all that apply.

I will not obtain authorization prior to their participation

q23650

List all data elements to be used or disclosed (do not refer to an attachment).

Patient demographics, Healthcare encounter location, type, provider, and date Chronic pain diagnosis and date Patient goal type and date Pain and function assessment (PEG) results and date of assessment PDMP check completion date Laboratory, procedure, medication, and referral orders Opioid risk tool results and date of assessment

q23651

A waiver of the requirement for a written signature must be approved by the IRB. Explain how this research involves no more than minimal risk of loss of confidentiality to the subject.

Because we will be collecting data on provider behavior, there is a risk that if a breach of confidentiality were to occur, and the provider's clinical behavior was criminal or otherwise objectionable, they would be at risk for criminal liability, loss of ability to be employed, and damage to reputation. However, because this data is already routinely collected in the Epic Electronic Health Record (EHR) system, they are already subject to these risks, and participation in this research does not increase these risks. Patients encounter the same level of risk that their identifiable data may be breached by simply being a patient in the hospital records systems. We will work with an honest broker who can act as a firewall between personally identifiable health data and the researchers, ensuring that the risk of loss of confidentiality is not greater than minimal. The health system will share the MRNs of qualifying patients, and dates of qualifying visits with the honest broker, who will collect outcome measure data, remove patient identifiers (with the exceptions of dates), and share this limited data set with the research team for analysis.

q23652

Describe the plan for protecting identifiers from improper use and disclosure.
We will work with an honest broker who can act as a firewall between personally identifiable health data and the researchers, ensuring that the risk of loss of confidentiality is not greater than minimal.

q23653

Describe the plan to destroy identifiers at the earliest opportunity appropriate for the research, considering the purpose of the research and local data retention requirements.

Neither provider or patient names will be attached to their data. We will work with Regenstrief Data Core who can act as a firewall between personally identifiable health data and the researchers, ensuring that the risk of loss of confidentiality is not greater than minimal. The researchers will obtain a limited dataset containing dates of qualifying visits, but patient identifiers (with the exceptions of dates) will be removed by the honest broker.

q23654

Confirm that the study team will assure identifiable PHI will not be re-used or disclosed to individuals outside the study team, except as required by law.
The members of the study team conducting the analysis will access the limited dataset through a secure network drive, specifically created for that purpose. Only the members of the study team who are involved with the analysis will be granted access to the secure folder. Furthermore, all information collected will be stored in locked filing cabinets or password protected secure network drives on encrypted devices. Data will continue to be protected on secure network drives throughout the analysis and accessed only by members of the research team. All study dissemination activities, such as presentations and journal articles, will report data in the aggregate and not identify individuals.

q23655

Explain how the research could not be practicably conducted without waiver of authorization or alteration of authorization requirements.
The research is concerned with the clinical behaviors of primary care providers when they are treating patients with chronic pain and using their EHR in daily practice. Because primary care providers see many patients with chronic pain on a daily basis, it would be impractical for researchers or clinic staff collaborators to intervene in each of these visits to obtain HIPAA authorization.

q23656

Explain how the research could not be practicably conducted without access to and use of identifiable PHI.
Regenstrief Data Core will require MRNs and dates of qualifying visits to create the limited dataset that will be shared with the study team. The limited dataset will include dates of

healthcare services provided. The limited dataset is required to complete our analysis determining if access to the OneSheet changes clinician behavior regarding pain medication prescriptions, treatment referrals, the setting of pain and function goals, and the assessment of opioid related risks (PDMP checks, urine drug screens, and PEG scores). Specifically, dates are required to analyze the effect of the OneSheet over time, and to measure guideline-concordance of clinician behavior (e.g., was the PDMP checked within the time span required by guidelines).

IRB Amendments

Approval date	Summary of changes
7/8/20	Added WF as a site, Dr. Mazurenko named PI, Dr. Hurley as site specific PI, Limited dataset instead of deidentified, updated recruitment process, added demographic survey, ICF edited, e-Consent added - a003
7/29/20	Updated recruitment talking points - a004
9/16/20	Individual randomization instead of clinic level, updated ICF total number of participants - a005
8/6/21	Adding second recruitment at both sites to increase sample size due to provider turnover-v5

Administrative Details Form

Protocol Details

9031

Protocol Type

Expedited

Billing Account #

Study Status

Submission Details

9000

Submission Review Level

Expedited

9030

Expedited Category.

Category 5: Data or specimens that have been or will be collected for nonresearch purposes

Category 7: Survey, interview, focus groups, human factor, group behavior or characteristics

9002

Criteria for Approval. Select to confirm.

Approved: The criteria for approval of the research are satisfied in accordance with IU HRPP Policies, and applicable federal regulations.

Protocol Determinations

9003

Protocol Level of Risk.

Minimal risk

9020

Is renewal required for this research?

No

9004

Check all determinations that need to be made.

Informed Consent Waiver
HIPAA Waiver
Certificate of Confidentiality

9005

Informed Consent Waivers

Waiver of informed consent granted in accordance with IU HRPP Policies

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9006

HIPAA Waivers

Participation

9010

Brief description of PHI - Participation

Patient demographics Healthcare encounter location, type, provider, and date Chronic pain diagnosis and date Patient goal type and date Pain and function assessment (PEG) results and date of assessment PDMP check completion date Laboratory, procedure, medication, and referral orders Opioid risk tool results and date of assessment Patient MRN

9009

Participation HIPAA Waiver

Waiver of authorization criteria satisfied in accordance with 45 CFR 164.512(i)(2)(ii). Waiver of authorization approved in accordance with 45 CFR 164.512(i).

9025

Certificate of Confidentiality.

The research is subject to the NIH Policy for Issuing Certificates of Confidentiality and therefore has been issued a Certificate.

9028

Other Determinations.