FORT HAYS STATE UNIVERSITY
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INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS RESEARCH

NEW IRB SUBMISSION

I. Project Title and Research Team Members

Project Title:

Implementation of a Chronic Pain Protocol in a Rural Primary Care Clinic

Principal Investigator Name:

Cooper Rush

Faculty Research Supervisor (If student is the PI):

Dr. Tom Brady

Additional Team Members:

Sam Bradford

This form must be used to submit an application through the IRBNet system.
No other methods of submission will be accepted.

Access the system here: www.irbnet.org
Student and Adjunct Faculty researchers: Please note that Faculty Research Supervisor approval is required prior to submission to IRB. The Faculty Research Supervisor signature in IRBNet indicates approval and agreement with section XII.
For faster processing, ensure all research team members have completed all required CITI training through https://www.citiprogram.org/ prior to submitting this application.

II. Type of investigator and nature of the activity: (Check all appropriate categories.)

A. Faculty/Staff at FHSU:
- ☐ Submitted for extramural funding to:
- ☐ Submitted for intramural funding to:
- ☐ Project unfunded
- ☑ Quality improvement/program evaluation
- ☐ Quality assurance
- ☐ Other (Please explain)

B. Student at FHSU: ☑ Graduate ☐ Undergraduate ☐ Independent Study
☐ Thesis ☐ Specialist Field Study ☑ Graduate Research Paper

C. Class Project (Course Number and Course Title), explain activity:

N/A

D. Other than faculty, staff, or student at FHSU (Unaffiliated with FHSU)
Please explain:

N/A

III. Human Subjects Research Ethics Training: The IRB will not review submissions without verification of appropriate CITI training. The Principal Investigator and all members of the research team must complete the appropriate CITI training modules. Faculty Research Advisors, when listed above, must also complete CITI training. If the PI is not affiliated with FHSU, documentation of CITI or other comparable training must be provided.
Date completed CITI training:

Cooper Rush: July 2016; Tom Brady: August 2016; Sam Bradford: June 2017

IV. Project Information

A. Expected study period from: 9/4/17 To: 9/4/18

B. Describe the purpose of the research. Explain what is intended to be discovered, including goals, aims, and objectives and/or state the hypothesis to be tested. Background: provide a brief scientific or scholarly rationale for the research activities, and address gaps in current knowledge.

The purpose of this project is to improve the safety, timeliness and quality of the care provided to patients with chronic pain in a rural clinic through the use of a pain protocol by changing provider behaviors to be compliant with 2016 CDC guideline for chronic pain.

☐ Investigators NOT currently affiliated with FHSU will collaborate on this project.

C. (If checked above) Identify any cooperating institutions by name.

N/A

D. This study is being/has been reviewed by another IRB. Yes ◯ No ◉
If yes, please attach relevant documentation.

V. Subject Information

A. Number of subjects:

The participants will be the five full-time providers at the Pawnee Valley Medical Associates clinic

B. Subject Age (Check all that apply):

- ☐ 1-7
- ☐ 8-17
- ☑ 18-65
- ☐ 65+

C. Special Populations (Check all that apply):

- ☐ Minors
- ☐ Non-English speaking
- ☐ Prisoners
- ☐ Individuals with impaired decision-making capacity
- ☐ Individuals who are economically or educationally disadvantaged
- ☐ Individuals with Legally Authorized Representatives
- ☐ Individuals who are vulnerable to coercion or undue influence

D. Describe target demographic of proposed subjects; explain how you will ensure that selection is equitable and that all relevant ethnic groups, genders, and populations have access to the study.

The participants will be the five full-time providers at the Pawnee Valley Medical Associates clinic and will include a pre and post project implementation chart review of pain care patients who meet the inclusionary criteria and appropriate diagnostic code.

E. Describe any specific populations targeted for inclusion or exclusion: Justify criteria based on age, gender, race, ethnicity, sexual orientation, or origin.

Inclusionary criteria will include providers' medical records that contain the following: 1) patient must 21 years or older, 2) must have a diagnosis of a type of nonmalignant chronic pain, 3) currently being treated for three months or longer with an opioid or other controlled substance, 4) must be able to be followed for the three months of the study, and 5) must have been seen for at least one maintenance visit for chronic pain in the six months prior to the protocol implementation.

Exclusionary criteria will include providers' medical records that contain the following: 1) pain related to current cancer treatment, 2) acute pain conditions, 3) patients managed by a pain specialist, 4) nursing home patients, 5) hospice patients, and 6) new patients who enter the practice after the protocol implementation.

VI. Recruitment

A. Describe the recruitment process for the study. Explain in detail how you will gain access to and recruit participants for participation in this project. Upload scripts, emails, letters, advertising, and all marketing materials with your application. Provide a step-by-step description of how potential participants will be recruited.

All providers that are full time at Pawnee Valley Medical Associates will be involved in implementing the project. No recruitment of providers or staff will be conducted. The providers will not need to be supervised and their involvement is voluntary.

B. Identify all applicable recruitment methods. (Please provide copies of materials).

- ☐ Flyers
- ☐ Purchased Sample List
- ☐ Email
- ☐ Telephone
- ☐ Newspaper
- ☐ Poster
- ☐ Class Announcement
- ☐ Departmental Communication
- ☐ Third Party (Professional or Charitable Organization)
- ☐ Internet
- ☐ Letter
- ☑ Personal or Professional Contacts
- ☐ Amazon MTurk
- ☐ Social Media
- ☐ SONA
- ☐ Snowball method (if used, must describe process in detail)
- ☐ Other (describe)

C. Are you recruiting students from a class you teach or for which you have responsibility? ◯ Yes ◉ No

D. Are you recruiting employees who directly or indirectly report to you?

◯ Yes ◉ No

E. If yes to either VI C or D, please explain why this population is necessary and describe what precautions have been taken to minimize potential undue influence or coercion.

N/A

VII. Compensation

- ☑ Participants will not receive compensation
- ☐ Students will receive extra credit or course credit
- ☐ Participants will receive monetary compensation
- ☐ Participants' names will be entered into a drawing for a prize

Describe the compensation or credit, including amount, scheduling and method. Explain what will happen if participants withdraw from the study.

N/A

VIII. Risks and Benefits

A. Describe the anticipated benefits of the research for individual subjects.

Currently, chronic pain management is a frustrating and time consuming process. The protocol is designed to simplify charting, improve flow, support provider decision-making, and decrease time constraints. The providers should have minimal risk and use of the protocol should improve the quality of care they provide to chronic pain patients as well and decrease their frustration levels in managing these patients. The project intends to provide the standard of care.

B. Describe the anticipated benefits of the research for society or the discipline. Explain how the benefits outweigh the risks.

The research may help investigate a new protocol for helping chronic pain patients and decrease the frustration levels in managing these patients.

C. Does this study involve any of the following? (Check all that apply.)

- ☐ Deception
- ☐ Omission
- ☐ Misleading Information/false feedback
- ☐ Physical or mental stress
- ☐ Collection of fluids or tissue
- ☐ Substances taken internally or applied externally
- ☐ Information pertaining to illegal activity
- ☐ Information relating to sexual attitudes, orientation or practice
- ☐ Private identifiable information
- ☐ Personal or sensitive information
- ☐ Private records (academic or medical)
- ☐ Social or economic burden to participants
- ☐ Mechanical or electrical device applied to subjects
- ☐ Information pertaining to substance use
- ☐ DXA Scan, X-RAY, MRI
- ☐ Information that, if released, could damage an individual's financial standing, reputation, employability, or cause social stigmatization, discrimination, or embarrassment
- ☐ Other
- ☑ **None of these**

D. Describe the nature and degree of the risk or harm checked above. If using deception, include a justification for the deception.

No deception will be used in the current study and there are no foreseen emergencies that should arise. The risk of harm or discomfort to any of the providers involved does not exceed that encountered in the daily tasks of the clinic on an everyday basis.

E. What steps will be taken to minimize risks or harm and to protect the subject's welfare (when risk is greater than minimal)?

There are no foreseeable risks involved with participation in this study. Participants (providers) work within the clinic of the investigator. The investigator will be able to keep in close contact with all providers involved and will be available for any unanticipated event. Due to the nature of the project, minimal risk, if any is anticipated. The provider staff will be provided with the number of the PI and information regarding contact with FHSU faculty. IRB will be notified within 10 days of any event that occurs by the FHSU faculty lead. Every effort will be made to protect the confidential medical information and the project will comply with all HIPAA regulations. Patient information will be de-identified.

IX. Emergencies

How will emergencies or unanticipated events related to the research be handled if they arise? (Please note that this refers to an emergency situation associated with the research activity not an emergency such as a fire alarm.)

No foreseen emergencies should arise. Any emergencies which occur during the study will be handled through the PVCH emergency room. However, as this study is a change in documentation and not directly intervening in patient care, there should be minimal risk. If an emergency does occur, the IRB will be notified immediately.

X. Data Collection and Security

A. Procedures: Describe the setting and tasks subjects will be asked to perform. Describe the frequency and duration of procedures, tests, and experiments. Include a timeline or a step-by-step description.

The project will include the following steps of implementation:
Step 1: A retrospective chart review will be completed on all patient charts who have been seen in the clinic between July 1, 2017 and September 30, 2017 which meet the inclusion criteria. IT will identify charts for review by doing a search of charts seen in the time frame with an ICD-10 diagnosis code for chronic pain (G89.4), chronic low back pain (M54.5), and fibromyalgia (M79.7). Charts will be de-identified and a random code assigned for data collection.
Step 2: An educational program will be developed for providers and support staff covering the 2016 CDC Chronic Pain Management Guideline for patients with chronic nonmalignant pain and an introduction of the EHR "chronic pain protocol." The protocol will include specific requirements for:

- Screening for opioid abuse/misuse
- Documentation of medication side-effects
- Documentation of risks associated with long-term opioid use
- Documentation of completing a K-TRACS (Kansas' pharmacy controlled substance monitoring system) search
- Documentation of a review of the controlled substance agreement
- Documentation of a urine drug screen

Step 3: An electronic template will be placed in the medical record by the IT department.
Step 4: Once the protocol development and the EHR template is completed, two educational sessions will be developed to educate the clinic providers, nurses and certified nursing assistants on the CDC guideline recommendations and the use of the protocol. One session will be held during the monthly provider meeting, and one will be held during the monthly nurse's meeting in September, 2017.
Step 5: The protocol will then be implemented into use with the chronic pain patients. It will be linked to the ICD-10 diagnosis code for chronic pain. Staff will be educated to choose this diagnosis code for any maintenance visit where the patient receives a narcotic medication or other controlled substance for any form of chronic nonmalignant pain. The protocol will be used for three months.
Step 6: A second chart review will be completed over all patient charts who were seen from October 1, 2017 through December 31, 2017 who meet the inclusionary criteria. IT will repeat the process of identifying charts from the time-line with the appropriate ICD-10 diagnosis codes. Charts will identified by the IT department and all identifying information will be de-identified and a random code assigned for data collection.
Step 7: After project completion and data analysis, results will be disseminated to the providers and staff in the clinic.
An educational session will be done for the providers and staff participating in the study to discuss results and receive feedback. All debriefing will occur within the organization.

B. Describe the steps that will be taken to secure the data during storage, use, and transmission. How and where will the data be stored, for how long will it be kept, when will it be destroyed, what safeguards are in place for data with identifying information? Include a description of physical and electronic security.

The data will be stored on the primary investigator's laptop for three years. The laptop is password protected. Any paper material of data that has been collected will be stored in a locked container for three years.

C. Identify any direct identifiers like name, unique identifier, address, email, etc. that will be kept with the records. Explain why it is necessary to record the identifiers and describe the coding system to be used.

Patient data will be de-identified. The primary investigator will have access to the patients' medical records of patient numbers that present during the time frame of the project. Patient numbers will be utilized rather than names to collect the data on the spreadsheet. Every effort will be made to protect their confidential medical information and comply with all HIPAA regulations.

D. If retaining a link between study code numbers and direct identifiers after data collection is complete, please explain why this is necessary, how long the link will be kept, how it will be stored, and when it will be destroyed.

N/A

E. Data collection methods (check all that apply)

- ☐ Observation
- ☐ Interviews
- ☐ Focus groups
- ☐ Surveys/Questionnaires
- ☐ Psychological tests
- ☐ Educational tests
- ☐ Blood draw, saliva swab, or other biological sampling
- ☐ Audio recording (see section X. F)
- ☐ Video Recording (see section X. F)
- ☐ Previously collected data (no individual identifiers)
- ☐ Previously collected data (with individual identifiers)
- ☐ Internet-based methods
- ☑ Other (describe)

The EMR template will be utilized which is currently in the medical record, as a tool to document the necessary charting requirements and assess

F. If using audio or video recording, describe how the recordings will be used, how confidentiality will be maintained, who will have access, and how and when the recordings will be destroyed or completely deidentified.

N/A

G. Protected data to be collected (check all that apply)
☐ Protected health Information (see Section X, Part H)
☐ Unique ID number (e.g. employee ID, driver's license number, student ID number, etc.)
☐ Academic records
☐ Social security number
☐ Other personally identifiable information

H. If the research involves protected health information, it must comply with the HIPAA Privacy Rule.
Select one:

☐ The research does not involve protected health information

Do you plan to use or disclose identifiable health information outside FHSU?
◉ Yes ○ No

If yes, the consent form must include a release of protected health information.

The IRB may make a waiver of authorization for disclosure if criteria are met under the HIPAA Privacy Rule. *If a waiver of authorization is being requested, the researcher must contact the IRB administrator prior to submitting this application.*

Will the protected health information to be used or disclosed be deidentified, or will a limited data set be used or disclosed? *Please describe*:

Patient data will be de-identified using a coded number assigned as the patient chart number. No identifying factors will be retained. Only data related to the documentation of the measurable outcomes will be retained on the laptop. The laptop is password protected. Every effort will be made to protect their confidential medical information and comply with all HIPAA regulations.

I. Sharing results with subjects (Indicate if results, like tests or incidental findings, will be shared with the subject or others, and if so, indicate how it will be shared.)

Information of the purpose and design are not going to be withheld from the subjects. Subjects will have an educational session on CDC guidelines and new protocol before implementation and a debriefing at the end.

J. Withdrawal of subjects (Describe the procedures to be followed when subjects withdraw from research or under what circumstances subjects may be withdrawn without their consent.)

N/A

XI. Informed Consent

A. Specify the type of informed consent you will use with this research project.

☐**Signed Consent**

Consent forms included with this submission:

☐Adult ☐Assent Script/Procedures ☐Parent/Guardian

☐Foreign Language Version ☑Agency Consent

☐**Oral Consent** (Waiver of documentation of consent, include script with application)

☐Signed consent form would be the only record linking the subject to the research, and the principal risk of signing a consent form would be the potential harm resulting from a breach of confidentiality.

☑The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

☑**Information Statement** (include with application)

☑**Debriefing Statement** (include with application)

B. Describe any potential concerns with obtaining informed consent (Foreign language, minimizing possibility of coercion, etc.)

Informed consent is not needed in this quality improvement project because the collection of data is through a noninvasive procedure normally employed in practice, i.e. chart review.

C. Describe the process you will follow to obtain consent and/or assent. Include names of individuals on the research team who will obtain consent, where and when the process will take place, and how you will ensure the subject's understanding.

Informed consent is not needed in this quality improvement project because the collection of data is through a noninvasive procedure normally employed in practice, i.e. chart review. Subjects will have an educational session on CDC guidelines and new protocol before implementation and a debriefing at the end.

All materials related to this study must be uploaded into your IRBNet study workspace. Instructions for using IRBNet are located at the FHSU IRB website. Required materials may include, but are not limited to:

- Completed application
- Copies of all recruiting materials, including scripts, emails, letters, posters, advertising, etc.
- Copies of all measurements, instruments, surveys, interview questions being used, etc.
- All consent forms and assent forms or scripts (for children).
- Debriefing materials, if used.

Please note that all materials and scripts to be used for this study need to be reviewed and approved by the IRB.

XII Certifications:

I am familiar with the policies and procedures of Fort Hays State University regarding human subjects in research. I subscribe to the university standards and applicable state and federal standards and will adhere to the policies and procedures of the Institutional Review Board for the Protection of Human Subjects. I will comply with all instructions from the IRB at the beginning and during the project or will stop the project.

AND

I am familiar with the published guidelines for the ethical treatment of human subjects associated with my particular field of study.

Statement of Agreement:

By electronically signing and submitting this application package, I certify that I am willing to conduct and /or supervise these activities in accordance with the guidelines for human subjects in research. Further, I certify that any changes in procedures from those outlined above or in the attached proposal will be cleared through the IRB.

If the Principal Investigator is a student, the electronic signature of the Faculty Advisor certifies:
1) Agreement to supervise the student research; and, 2) This application is ready for IRB review. The Student is the "Principal Investigator". The Faculty Research Advisor is the "Advisor". Designees may not sign the package. It is the student's responsibility to contact their Faculty Research Advisor when the study is ready for the Advisor's signature.

I certify the information provided in this application is complete and correct.
I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects and strict adherence to any stipulations imposed by the IRB.
I agree to comply with all FHSU policies, as well as all federal, state and local laws on the protection of human subjects in research, including:

- Ensuring all study personnel satisfactorily complete human subjects research training.
- Performing the study according to the approved protocol.
- Implementing no changes in the approved study without IRB approval.
- Obtaining informed consent from subjects using only the currently approved process and form.
- Protecting identifiable health information in accordance with HIPAA Privacy rule.
- Promptly reporting significant or untoward adverse effects or unanticipated problems to the IRB.

Recruitment Message: Implementation of a Chronic Pain Protocol in a Rural Primary Care Clinic

Hello,
My name is Cooper Rush, and I am a graduate student in the Nursing Department here at Fort Hays State. Your clinic has decided to be involved in implementing a new protocol to improve the safety, timeliness, and quality of the care provided to patients with chronic pain and decrease the frustration that may come with caring for these patients. You are being asked to follow the new protocol that will be implemented in order to compare the previous chronic pain protocol with the outcomes following the new protocol. The overall purpose of this research project is to find a new, easier protocol for caring for patients with chronic pain. This will happen over the course of a few months. Thank you for participating in this research project!

Thank you!

Cooper Rush
clrush@mail.fhsu.edu

Dr. Tom Brady
tepbrady2@fhsu.edu
(Faculty Supervisor)

Debriefing Form: "Implementation of a Chronic Pain Protocol in a Rural Primary Care Clinic"

You have just completed a study titled "Implementation of a Chronic Pain Protocol in a Rural Primary Care Clinic." The purpose of this study was to examine a new protocol for caring for chronic pain patients. You were asked to adopt a new protocol when working with patients in order for the researchers to compare care and outcomes of the previous protocol and the new protocol. The information provided will help researchers understand how this new method for chronic pain may be treated compared to previous protocol plans used. This information could also aid in further development of new protocol.

The research team greatly appreciates your help with this project! If you have questions about the process of this research project, you may contact the Office of Scholarship and Sponsored Projects at 785-625-4349. For more information about the research project, you can contact the principal researcher, Cooper Rush. You may also contact the faculty supervisor, Dr. Brady.

Sincerely,
Cooper Rush
clrush@mail.fhsu.edu

Dr. Tom Brady
tepbrady2@fhsu.edu
(Faculty Supervisor)