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Informed Consent Form
Study: "Rapid Process Improvement in Perioperative Surgical Home"

Principle Investigators: Jessica Hoge, MD and Bernadette McCrory, PhD, MPH, CPE

You are invited to participate in a study to evaluate the Perioperative Surgical Home (PSH) systems and its outcomes at a rural community hospital. This study is being conducted by Dr. Jessica Hoge, Hospitalist at Bozeman Deaconess Hospital, Bozeman Health Medical Group and by Dr. Bernadette McCrory, Assistant Professor of Mechanical and Industrial Engineering, Montana State University.

Before making your decision: Please read this information carefully and completely. Please ask questions about anything that is not clear. Feel free to take your time deciding whether you would like to participate. By agreeing to be in the study you will not give up any legal rights. We will provide you a printed copy of the consent form for your records.

Study Overview: PSH is a validated model used in urban and health systems to coordinate surgical care episodes. Limited PSH model fidelity currently exist for rural and remote care facilities due to inadequate communication, high cost, extended length of stay, and readmission. The study helps to assess the PSH model within a rural, community hospital to create a system-level model to adapt/customize PSH to meet the need of the staff, clinicians, patients, and communities served in rural counties in Montana. The study also aims to assess the system functionality by tracking preliminary clinical and rehabilitative patient outcome after initial PSH implementation at a rural community hospital.

Procedure
The standard procedures are followed by PSH care for patients prior to surgery. These procedures aim to gather as much important information from patients to give the best surgery results.

Pre-op Tests and Checkup with Doctors: The surgeon will want to make sure that other health conditions the patient have will not cause problems during the surgery. Pre-op is the time before the surgery and usually needs to be done within the month before the surgery. The patient may have to visit:

- Cardiologist (Heart Doctor): To check patient's history of heart problems. The results may vary for each patient based on their behavioral and age factors.
- Endocrinologist (Diabetes Doctor): To check patient's diabetes or sugar level in patient's blood. Extra measures would be taken during the surgery if the sugar level is too low or high.
- Sleep Doctor: To check patient's health prior to surgery if he/she have an obstructive sleep apnea problem. Extra measures would be taken during the surgery if the patient is having trouble breathing in sleep.

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- Primary Care Provider: To review patient's general health problems, exam, and any other tests needed before the surgery.

Risks and Discomforts:
There are no foreseeable risks involved in participation in this study. The possible discomfort is subject may experience an overwhelming amount of medical attention.

Benefits:
There are no immediate benefits but your contribution to this study will help the investigators to learn more about the PSH systems and improve the efficiency of perioperative surgical care at the rural hospital in the future.

Financial Responsibilities:
There is no costs associated with being a part of this research study. The only cost that is associated here is with your medical care.

Photo and Video Recording: This study may require still pictures and video recording of the subject for research purposes. The picture/video recording is only of you and will be kept confidential. The recordings will be stored securely and only Principle Investigators will have access to the recordings. Please know that you can choose to not be recorded or have your picture taken anytime during this study.

☒ **Yes,** I agree to photo and video recordings

☐ **No,** I disagree to photo and video recordings

Participation and Withdrawal from the study: Any person who is 18 years old or above is eligible to participate in this study. Please know that taking part in this study is completely voluntary. You have the right to leave at any time. If you withdraw from the study, you may request that your research information not be used by contacting the PI.

Confidentiality: Your identity will remain confidential and anonymous. All the information and the data you have provided in this clinical study will be stored in the secured database. The data will be accessed only by the PIs for research purposes and will be not be shared with anyone.

Questions and Concerns:
If you have any questions or concerns that may aid your decision to participate in this research, please contact Jessica Hoge or Bernadette McCrory (contact details on the next page). This study has been reviewed and approved by the Institutional Review Board (IRB) at Montana State University. Additional questions about the rights of human subjects can be answered by chairman of the IRB, Mark Quinn, 406-994-4707.

Conflict of Interest: The Principle Investigators have none to disclose.

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Authorization:
The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed consent documents should not be considered all inclusive in defining other methods of care and risk encountered.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subjected to change as scientific knowledge and technology advances and as practice patterns evolve.

I have read and understand the above consent form. I certify that I am 18 years old or older, and I, [redacted] (full name), agree to participate in this clinical study after knowing the discomforts, inconvenience and the risks involved.

☑ **Agree**

☐ **Disagree**

Signature [redacted] **Date:** January 20, 2021

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