VA Consent Cover Letter

DESCRIPTION OF RESEARCH BY INVESTIGATOR

You are invited to participate in a research and implementation study on the impact of a reporting system for colonoscopy quality. We aim to evaluate the impact of report card feedback at VA sites, identify mechanisms of impact for national quality improvement, and to determine if the implementation increases adenoma detection rates compared to usual care. First, you will be asked to complete a baseline survey to assess site characteristics and colonoscopy practices prior to distributing the report cards. We will then provide all participants with a report card summarizing provider information regarding procedure outcomes (cecal intubation, bowel prep score, adenoma detection rate), and then at the 6 month and 12 month period following report card delivery, we will distribute follow up surveys to help assess adoption and implementation. We will conduct qualitative interviews via telephone 3 months post-implementation. The interviews will focus on identifying components of behavior change in order to help adapt and improve VA-EQuIP for future operational and research purposes.

The risks associated with this study are that healthcare providers may feel some inconvenience from time lost due to interviews and surveys. They may also feel some anxiety related to receiving VA-EQuIP report cards. Report cards will be distributed in a confidential manner. The benefit which may reasonably be expected to result from this study is an improvement of a quality metric outcome (ADR), which is directly associated with CRC incidence and death. **We cannot and do not guarantee or promise that you will receive any benefits from this study.** Your overall participation in this study is voluntary.

CONFLICT OF INTEREST

The investigator conducting the research study does not have any financial conflicts of interest to report.

CONFIDENTIALITY

Data collection, storage, management, and security for this project will be coordinated with the VA Veteran's Informatics and Computing Infrastructure (VINCI) research data server, which will provide the infrastructure necessary for proper data storage and security that adheres to all VA policies related to privacy and information technology security as established by VA ORD and the Salt Lake City VA. Access to the server is restricted based on security granted by this IRB. It is also password protected by VA administered user names and passwords. All analysis and temporary files will be performed on VA servers and no patient level information will be stored on portable storage devices or leave the VA secure firewall protection. Data will be treated in compliance with HIPAA guidelines. No reports will be released with patient identifiers at any time of this study. The PI, in conjunction with the VA ISO, will ensure that, upon completion of the research project, study data containing sensitive, confidential information will be treated according to VA policy. All affiliated personnel will be 12 months current on their VA Privacy and Information Security and Rules of Behavior training.

PERSON TO CONTACT

If you have any questions complaints or if you feel you have been harmed by this research please contact Andrew Gawron, MD, PhD at 801-582-1565 x2963.

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

University of Utah
Institutional Review Board
Exemption 12/5/2019

IRB_00119922

MEDICAL TREATMENT OR COMPENSATION FOR INJURY

The VA has the authority to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S. Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

COSTS TO PARTICIPANTS AND COMPENSATION

You will receive **no** payment for your participation.

A veteran participant will not be required to pay for care and services (treatment) received as a subject in a VA research project. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

It should take 2 hours (quantitative surveys are expected to take 10 minutes each, and the qualitative survey is expected to take 30-60 minutes) to participate in the study. Participation in this study is voluntary. You can choose not to take part. You can choose not to finish the questionnaire or omit any question you prefer not to answer without penalty or loss of benefits.

By returning this questionnaire, you are giving your consent to participate.

Thank you for your willingness to participate in this research.