QUality Improvement Publication (QUIP) Worksheet

Background: This document is designed to support initial evaluation by the Institutional Review Board (IRB) if an activity is considered "research" and requires IRB oversight for the protections of human subjects. It will also serve as IRB documentation if your project (e.g. quality improvement project, case report, etc.) is considered for publication, and enable communication with the medical library for literature searches and the Center for Health Care Improvement Science (CHCIS) for project evaluation assistance.

Part I: Define Project		
	Project Title:	Change in stage I-III rectal cancer therapy between 2006-2016
	Problem/process defect:	Variation in practices of chemotherapy, radiation, and surgery
	Key question/goal of project:	1. Describe rates of therapies given 2. Describe changes in therapy sequence (national trends toward increased preop radiation and increased preop chemotherapY0
	Initiating Investigator Name and Degree: Simianu/Kennecke	
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Part II: Human Subjects Research Determination		
	Federal regulations and Benaroya Research Institute at Virginia Mason (BRI) policy requires **ALL <u>research</u>** projects involving **<u>humans as subjects</u>** (including involvement of humans in one or more of the categories of research exempted or waived under the federal regulations), **<u>OR the use of identifiable protected health information (PHI)</u>** be reviewed and approved by an Institutional Review Board (IRB) **<u>PRIOR</u>** to initiation of any research related activities, including recruitment and screening activities. The BRI IRB is the sole body designated to make human subject research determinations at Virginia Mason. Some categories of research are difficult to discern as to whether they qualify as human subject research. The IRB will review the information provided to determine whether the project needs to be submitted to the IRB as Human Subject Research or qualifies as an activity outside the scope of IRB oversight (e.g. QI, QA, Case Report, etc.). You will be notified as to the final determination via email. **Please allow a minimum of 1 week for review and determination.**	
	Is this project being performed as part of the requirements for a graduate or nursing degree?	**YES** ☐ **NO** ☒ *(If <u>yes</u>, you will need advanced sign-off by the Department of Clinical Practice and Professional Development)* *Signature:*
	Describe the problem/process defect in the current state at VM.	Curable rectal cancer (stage I through stage III) can be treated with chemotherapy, radiation, or surgery. Often a combination of these therapies are needed to achieve cure. National trends suggest increased use in multiple modalities for rectal cancer, but the 'real world' impact of this is not well described.

What are the key questions you want to answer?	1. describe rates and factors associated with variation in receipt of chemotherapy, radiation, and surgery for stage I-III rectal cancer 2. describes trends over time (2006-2016) in receipt of multimodal therapy, specifically looking at treatments received before surgery 3. describe rates of survival and complete pathologic response of various treatment sequences across a national sample
What is the proposed intervention and method?	We will use de-identified data from the National Cancer Data Base (NCDB), Rectal Cancer Module, to create a retrospective cohort to address these questions.
Describe your target population/type of data you wish to use for your project. Indicate whether the data will be identifiable, de-identified, or coded.	Adult patients (age 18+) diagnosed with rectal cancer stage I-III from 2006-2016. Data is de-identified. Variable list attached.
Is any of your data originating from an IRB approved research study?	**YES** ☐ **NO** ☒ If YES, provide IRB#:
Sponsor or Funding Source (Identify all source(s) of funding for the project):	n/a
Do you intend to send data outside the Virginia Mason Health System? If Yes, you are required to provide documentation of an Institutional agreement with said entities to the IRB.	No
Electronic Signature:	☒ **By checking this box you are attesting that the above information is representative of the proposed activities. The IRB acknowledges this, and accepts it in lieu of your actual signature**.

IRB Determination
(For IRB Office Use Only)

☑ The proposed activity, as described**, DOES NOT** constitute Human Subjects Research per 45 CFR 46.102(d). Submission of a BRI IRB research application is not required.

☐ The proposed activity, as described, **DOES** constitute Human Subjects Research. Submission of a BRI IRB research application IS REQUIRED. IRB approval must be obtained before the investigator begins their research.

Chris Weir, CIP
Printed Name


Signature

Administrative Director, Research Protections
Title

04/22/2020
Date

Please submit the QUIP ELECTRONICALLY to the IRB in the Research Protections Department by saving and attaching it to an e-mail message and sending it to IRB@benaroyaresearch.org. Include all other relevant materials. If requested, an email acknowledgment of your submission will be sent. Copy e-mail to CHCIS@virginiamason.org to trigger a mentorship meeting.

If you would like assistance on literature search strategies, please complete the following and submit the QUIP ELECTRONICALLY to the Medical Library by saving and attaching it to an e-mail message and sending it to medlib@vmmc.org.

Part III: Library Review	Describe the problem/process defect in the current state at VM.	n/a
	What are the key questions you want to answer?	n/a
	What is the proposed intervention and method, if known?	n/a
	What are the timelines of your work?	n/a
	Have you done a search for articles on the topic? Are there key articles that contributed to planning? If so what are they?	n/a
	What terms could be used to describe the problem/project in the literature?	n/a
	Do you know of any external resources that may be searched? (i.e. professional organizations, government agencies and databases)	n/a
	What potential target journals would you publish in?	n/a
	Do you need to document your search strategies?	n/a