CAPE FEAR VALLEY HEALTH

IRB Guidance: Quality Improvement Projects

For the purposes of this document Quality Improvement includes Quality Assurance and Program Evaluation projects.

Determining if an activity is Research or Quality Improvement can be challenging. Federal regulations require human subject research to be reviewed and approved by the IRB, while strictly QI activities do not require IRB oversight. However, some QI activities may also be research and therefore need IRB approval.

Once you have determined your project is not research, requirements for submitting QI projects for IRB review are at the end of this document. The IRB cannot issue retroactive approval of an activity conducted as a QI project and is later determined to be human research.

Overview:

	RESEARCH	QUALITY IMPROVEMENT
INTENT	Develop or contribute to generalizable knowledge (e.g., testing hypothesis)	Improve practice or process within a particular institution or ensure it conforms with expected norms; not designed to contribute to generalizable knowledge
DESIGN	Systematic; follows a rigid protocol that remains unchanged throughout the research; may involve randomization	Adaptive, iterative design; may or may not be systematic; generally, does not involve randomization
MANDATE	Activities not mandated by institutional or program	Activity mandated by institution or clinic as part of its operations
EFFECT ON PROGRAM/PRACTICE EVALUATED	Findings are not expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional practice and identify corrective action(s) needed
POPULATION	Usually involves a subset of individuals; no obligation to participate; may involve statistical justification of sample size to achieve endpoints	Responsibility to participate as a component of the program or process; information on all or most involved in the practice or process is expected to be included; exclusion of some individuals significantly affects conclusions
BENEFITS	Participants may or may not benefit directly; often a delayed benefit to future knowledge or individuals	Directly benefits a process, program, or system; may or may not benefit participants
RISKS	May place participants at risk	Does not place participants at risk with the possible exception to risks to privacy or confidentiality of data
ANALYSIS	Statistically prove or disprove hypothesis	Compare program, process, or system to established standards
DISSEMINATION OF RESULTS	Intent to disseminate results generally presumed at outset of project as part of professional expectations, obligations; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies	Intent to disseminate results generally not presumed at outset of project; dissemination often does not occur beyond the institution evaluated; when published or presented to a wider audience the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks rather than to develop or contribute to generalizable knowledge.

Adapted in part from University of Wisconsin-Madison Health Sciences IRBs Comparison of the Characteristics of Research, Quality Improvement, and Program Evaluation Activities

Quality Improvement Projects

There is no regulatory definition for QI, however it is often described as “A systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of the product” by The Institute of Medicine.

QI in health care, unlike research, involves implementing previously proven/tested, planned and systematic activities from research into clinical practice to improve the quality of health care for individuals and populations.

The key difference between research and QI is research projects are intended to create new knowledge that can be generalizable to other populations and settings, while QI in health care uses existing knowledge to improve health care outcomes within a local health care institution or setting.

When an activity involving the inclusion of people is intended to evaluate an existing practice and attempts to improve it based upon existing knowledge, and if the data from the evaluation is not intended to be applied to populations other than the population under study, the IRB would not classify this activity as research, and the activity would not be subject to DHHS human regulations. Likewise, the intent to publish is an insufficient criterion for determining whether a QI activity involves research. Even planning to publish an account of a QI project does not necessarily mean the project fits the definition of research. People seek to publish descriptions of non-research activities for a variety of reasons, including, for example, if they believe others may be interested in what worked at another institution. A major priority for the National Quality Strategy is to develop and share methods for data collection, measurement, and reporting that support QI measurement and improvement efforts of both public and private sector stakeholders at the national and community level. Dissemination of QI efforts will require timely publication and sharing of information to create awareness of lessons learned, as well as what QI projects work will within each other's institutions.

The projects described below are examples of how evidence-based practice change implementation may be conducted without involving human subjects in research. Additional examples of QI projects that are not identified as research involving human subjects are found on the DHHS website.

Examples of QI activities that are likely NOT research include:

- The staff of an adult oncology clinic cares for patients receiving chemotherapy which commonly causes severe mucositis. The staff members implement a widely accepted oral care assessment tool as part of routine standard of care. An evidence-based training program on how to use the oral assessment tool is provided to the patient care team. A chart review a month later is used to evaluate whether a change in practice has occurred, measured by the number of oral care assessments performed and whether these assessments were performed with appropriate patients.
- A Resident project will evaluate the effect of standardizing care for patient presenting to the CFVMC Emergency Room with diabetic ketoacidosis using the evidence-based guideline published by the American Diabetes Association. An EPIC search identifies patients admitted for diabetic ketoacidosis a year before the evidence-based care guideline was implemented and for patients treated a year later in compliance with the guideline. Outcome measures include provider guideline adherence as well as clinically specific indicators which measure timely and efficient reversal of ketoacidosis. As required by the resident's program, the project is submitted to the IRB for an

authoritative determination that the activity does not meets the definition of research with humans.

- CFVMC implements an evidence-based approach to reducing pharmacy prescription errors and collects prescription practices by chart review. Adherence to this approach and medication error rates are evaluated after implementation. The team plans to submit to a journal that requires IRB review, and the project is submitted to the IRB for an authoritative determination that the planned activity does not meet the definition of research with humans.

Please see HHS guidelines and FAQs or DHHS Health Resource and Services: Quality Improvement for more information.

A QI activity may also constitute non-exempt human subject research if it meets the definition of research.

Examples of Activities that are likely QI and Research

- A project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collection information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results.
- Collaborative (multi-site) – All sites are trying to improve some aspect of clinical care (ex. Implementing an application to help improve making clinical decisions). The whole department decides this app with improve care, and implement the app. They collect data as the app is implemented, and in addition, analyze this data for generalizable knowledge.

Examples of Activities that Begin as QI and Become Research

- A QI project is implemented, and upon completion, the investigator realizes they want to do research about the project, and interview clinicians. The data collected from the interviews will be used for research purposes, therefore, the investigator would submit to IRB before beginning the interviews.
- A team uses biospecimens to compare two different types of tests to determine which is better and therefore which one should be used at CFVMC (intent to improve care at CFVMC). After the comparison is complete, the team realize they want to share the successful results because they believe it will help other institutions (intent to contribute to generalizable knowledge). And request to use the data collected for the QI project as secondary data for research.
- A surgeon believes a certain technique will improve their own practice, so they implement the technique and record results as part of clinical practice. The surgeon then decides this technique would help others, so he systematically analyzes the data collected and generalizes outcomes and results. The surgeon needs to submit to the IRB prior to review of the collected data.

Resources:

Institute for Healthcare Improvement

- Education
- Resources

Register and download the QI essentials Toolkit

IHI's QI Essentials Toolkit includes the tools and templates you need to launch a successful quality improvement project and manage performance improvement. Each of the ten tools can be used with the Model for Improvement and includes a short description, instructions, an example, and a blank template

Worksheet for Developing Your Quality Improvement Project

If you have further questions, please contact the Research/IRB Office at 910-615-5839 or sleming@capefearvalley.com.

Submission Procedures:

An GME or IRB submission is needed by anyone conducting QI projects requiring an authoritative determination of whether an activity does or does not meet the definition of research with humans. An authoritative determination might be required by a journal or conference prior to acceptance of a health care related manuscript or poster for publication or presentation.

CFVH Investigators/Staff: Quality Improvement projects generally do not require submission to the IRB, this includes any QI project which falls under Institutional oversight (e.g. the Quality Council/Patient Safety Team, hospital mandated initiatives, or departmental/program initatives) and projects which do not require an authoritative determination.

If an authoritative determination is required, submit an ***IRB NHSR Protocol Application Form*** to the IRB Administrator.

Note: *QI projects conducted for a master's degree or PhD are considered generalizable and therefore, research and must be submitted to the IRB using the appropriate application form. Please contact the GME Program Administrator/IRB Administrator for details on working with your school.*

Investigators and staff may always consult with the IRB Chair, Co-Chair, or IRB Administrator to discuss whether an activity does or does not meet the definition of research with humans and may require submission to the IRB. The IRB cannot issue retroactive approval of an activity conducted as a QI project and is later determined to be human research.

Residents and Trainees must submit the ***GME: Quality Improvement Project Form*** to the GME Research Program Administrator for tracking and acknowledgement purposes, whether or not an authoritative determination by the IRB is required. If an IRB authoritative determination is required, the Research Program Administrator will forward your submission to the IRB Administrator for review.

Note: Projects conducted at a non-CFVHS site must follow that clinic's or institution's policies

and procedures regarding QI/QA activities.

Advisors, Residents and Students may always consult with the Research Director, Research Program Administrator, and IRB Chair to discuss whether an activity does or does not meet the definition of research with humans and may require submission to the IRB. The IRB cannot issue retroactive approval of an activity conducted as a QI project and is later determined to be human research.