Quality Improvement vs. Research

Medical University of South Carolina

What is research?

Systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR 46.102(l)].

What is a generalizable knowledge?

Conclusions derived from a systematic investigation of a group of subjects (samples) that can be applied to populations beyond the one from which the sample is obtained.

Are you designing a project to contribute to generalizable knowledge?

Does your project design include:

- Power calculations to determine number needed to see a difference?
- Randomization to different conditions?
- Inclusion/Exclusion criteria?
- Ensuring adequate distribution of population demographics?

Quality Improvement (QI)

- Efforts to make changes that will lead to better patient outcomes and/or better system performance
- Considered to be part of healthcare operations
- Not subject to IRB review or approval
- Activities are limited to:
  - Implementing a practice to improve the quality of patient care
  - Collecting patient or provider data regarding the implementation of the practice for clinical, practical or administrative purposes

Research vs. Quality Improvement (QI)

	Research	QI
Purpose	To test a hypothesis OR to establish standards where none are already accepted	To assess or improve a process, program, or system OR improve performance as judged by established/accepted standards
Benefits	May or may not benefit current subjects, but may benefit future patients	Knowledge sought directly benefits a process/ program/ system, and may or may not directly benefit patients
Risks	May put subjects at risk	Does not increase risk to patients, except possible loss of confidentiality
Methods	Systematic data collection	Systematic data collection
Analysis	Statistically prove or disprove hypothesis	Compare a program/process/system to an established set of standards, or to establish internal benchmarks
Result	Answer a research question	Improves or creates a program/ process/system that results in greater safety, efficiency or satisfaction

QI Self-Certification Tool

QI Self-Certification Tool

- The MUSC IRB does not have purview over Quality Improvement Projects!
- Designed for projects that can be readily identified as QI
- Project information collected:
  - Date
  - Name of Project/Lead Investigator
  - Title of Project
  - Brief Description of Project/Goals
  - College/Center through which the project will be conducted
- 6 Potential (Yes or No) Questions

1. Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?

- The Research Decision Tool is based on the definition of research pursuant to the Common Rule (45 CFR 46.12(d))
- This question determines whether federal regulations beyond the Common Rule, such as FDA regulations, need to be applied
- If the answer is "**Yes**", IRB review is likely required
  - Please contact the IRB for additional guidance.

2. Has the project received funding (e.g. federal, industry) to be conducted as a human subjects research study?

- This question determines whether the project has received funding to be conducted as a research study and not QI or program evaluation
  - If you are unsure, consider contacting your program officer for the funding or funding entity to determine whether the funding source requires a specific level of IRB review and oversight.
- If the answer is "**Yes**", IRB review may be required

3. Is this a multi-site project (e.g. there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?

- This question determines whether the project is limited to local activities or whether multiple sites are conducting the same activities.
- If multiple institutions are conducting the activities, it's less likely that the outcomes will be used for quality improvement/program evaluation at the local institution.
- For multi-site projects, the QI tool is not a sufficient indicator of whether IRB review is required.

4. Is the primary intent to conduct a systematic investigation designed to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subject; comparative effectiveness research ; or comparable criteria in alternative research paradigms)?

- Publishing or presenting the results of a QI project DOES NOT make it research.
  - If the primary intent of the project is not generalizability OR the project is not designed in a way that the findings would be generalizable then the answer to this question is "**No**".
- The design of the project plays a key role in determining the intent.

5. Will the results of the project be published, presented or disseminated outside of the institution conducting it?

- This question determines whether, at the outset of the project, the intention is to disseminate results outside of the institution or program conducting the project.
- If there is no intention for disseminating results outside of the institution conducting the project, the answer should be "**No**"
- Intent to publish DOES NOT in itself make a project research. If there is potential for results to be disseminated outside of the institution or program conducting the project, then the answer is "**Yes**".

What if you want to publish?

Results from both QI and research activities can be published. However, it is the project's original design with its intention of applying the published findings beyond those being immediately studies that distinguishes QI from research.

6. Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program?

- If the intention upon designing and conducting the project is not to improve/evaluate a specific practice/program, then the answer should be "**No**".
  - IRB review is likely required.
- If the project is being conducted in a multi-site context with a common protocol across sites, then the results could be generalizable and thus constitute research. In this case the answer should be "**No**".
  - IRB review is likely required.

QI Tool Responses

- “Stop Here” Based on your responses to the IRB QI Self-Certification tool, it appears that your project may be deemed research and would require prospective IRB review and approval…please contact the IRB for more information.

or

- If you are not stopped before you get through all 6 questions, “This project appears to constitute QI and/or program evaluation and does not fit the federal definition of research. IRB review is not required.”

If your project is QI:

- It is not in the IRB's purview
- It should not be submitted to the IRB
- Informed Consent is not needed
- HIPAA regulations may still apply
- It may be published

If your project is research:

- It is subject to IRB review
- The type of review it will require will depend on the level of risk
- Informed Consent regulations will likely apply
- It must be reviewed and approved by the IRB prior to initiation of the project
- It is subject to HIPAA regulations (if using PHI)

Helpful tips:

- Do not minimize what is being done for your project to make it sound like it is NOT research, if in fact it is.
- If research questions in eIRB don't make sense for your project, STOP what you are doing and seek guidance.
- CLEARLY differentiate the RESEARCH procedures from those that would already exist in the clinical setting.
- If you lose your email with your QI certification letter, you will need to answer the questions to get a new letter.