QUALITY IMPROVEMENT ACTIVITIES IN HEALTH CARE VERSUS RESEARCH GUIDANCE

01/20/2021;Updated 07/31/2023

In general, a quality improvement (QI) project does not need to be submitted to the IRB. An IRB submission is needed by WakeMed students/trainees and faculty who are conducting quality improvement projects that require 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 Departmental policy or as a condition of a training program or by a journal or conference prior to acceptance of a health care related manuscript for publication or presentation. When Investigators and staff are seeking an authoritative determination, these proposed QI activities should be submitted through the IRBNet process for evaluation by the IRB. Investigators should request an exemption from further IRB review, resulting in a greatly shortened IRBNet application form (See the QI Application Template on the IRB website). Investigators and WakeMed staff may always consult with a WakeMed IRB Chair or the DUHS IRB Executive Director to discuss whether an activity does or does not meet the definition of research with humans and may require submission to the IRB. A checklist is found on page 3 that may be helpful in determining whether a proposed activity is a QI project and does not involve human subjects research. The IRB cannot issue retroactive approval of an activity that is conducted as a QI project and is later determined to be human research.

Typically, QA/QI projects are particularly focused on improving the performance of an institutional practice in comparison with an established standard or goal. They are focused on a local practice and consequently limit their scope to the specific institution. The results of the project are not intended to apply to anyone beyond the scope of the project, and conclusions are drawn only in relation to the particular practice at the institution. In other words, if the results of the project are shared outside the institution (i.e. published or presented), then it would only be for the purposes of sharing a successful improvement in practice; other institutions could then interpret the results and draw their own conclusions, but the key is that the institution conducting the QA/QI project is not drawing broad conclusions and is not using their participants as a representative sample.

For additional guidance, please refer to the following OHRP website on QA/QI: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html

Below are some criteria that tend to be representative of either QA/QI or research; this list is to be used as a guide and not a definitive determination:

Common Elements	
QA/QI	**Research**
The focus is local and specific, aiming to improve a particular institutional practice	Aims to explore a hypothesis or theory in order to draw general conclusions beyond the scope of the institution
Does not use participants as a representative sample of a broader population	Results or data from participants may be generalized as being representative of the population at large
Conclusions are intended to only be directly applicable to the particular institution; no claim that the results apply outside the institution	Conclusions are meant to be disseminated and applicable to people and institutions beyond the site where the project took place
Any publication or presentation on the project would still focus on the specific practice and improvement at the particular institution; it is only relevant to external institutions to the extent that they can draw their own conclusions about applicability at their institution	Publications and presentations aim to be applicable to the field more broadly. For example, if a particular intervention in the research study led to better outcomes, a publication would generalize those findings and suggest that they are applicable to other institutions as well.

WakeMed Institutional Review Board

Quality Improvement or Research Checklist*

In general, a quality improvement (QI) project does not require IRB review and approval because it is not research that is subject to the federal human subjects protection regulations. The following questions may be helpful in determining whether a proposed activity is a QI project and does not involve human subjects research. If all of the questions below can be answered as a Yes, **IRB review is not required.** If the answer to any of these questions is NO, please consult with the IRB for assistance since IRB review may be required.** An investigator or staff member may also request an authoritative determination from the IRB to confirm or assist with determining if an activity is a quality improvement project.

Project Description	YES	NO
Purpose Is the activity intended to improve the process/delivery of care while decreasing inefficiencies within a specific health care setting?		
Scope Is the activity intended to evaluate current practice and/or attempt to improve it based upon existing knowledge?		
Evidence Is there sufficient existing evidence to support implementing this activity to create practice change?		
Clinicians/Staff Is the activity conducted by clinicians and staff who provide care or are responsible for the practice change in the institutions where the activity will take place?		
Methods Are the methods for the activity flexible and include approaches to evaluate rapid and incremental changes?		
Sample/Population Will the activity involve a sample of the population (patients/participants) ordinarily seen in the institution where the activity will take place?		
Consent Will the planned activity only require consent that is already obtained in clinical practice, and could the activity be considered part of the usual care?		
Benefits Will future patients/participants at the institution where the planned activity will be implemented potentially benefit from the project?		
Risk Is the risk to patients/participants no greater than what is involved in the care they are already receiving **OR** can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented within a health care environment?		

***Adapted with permission from the Duke University IRB, January 2021**

****An inquiry can be made by email to the WakeMed IRB at irb@wakemed.org**
ckilday@wakemed.org

***** The QI Template is found on the IRBNet website under Forms Library.**