

COLUMBIA UNIVERSITY HUMAN RESEARCH PROTECTION OFFICE

Guidance for the Evaluation of Research versus Quality Assurance/Improvement Activities in Healthcare Settings

I. BACKGROUND

The Columbia University (CU) Human Research Protection Office (HPRO) is charged with the responsibility of ensuring that all research involving human subjects conducted by Columbia faculty, employees, and students is conducted ethically and in a manner that promotes the protection of human subjects' rights and welfare. Likewise, CU and NewYork-Presbyterian Hospital (NYP) are committed to improving healthcare for patients through quality assurance/improvement (QA/QI) activities, which are an important component of clinical practice and systems operations. Like research, QA/QI activities are generally data driven and involve human participants. Unlike human subjects research, QA/QI activities generally do not require submission to the IRB for review. However, due to the systematic nature of some QA/QI projects, there may be overlap with research methods and determining whether an activity is QA/QI, research, or both can be challenging.

Health Care is challenged with closing the 'Know – Do Gap' between consistently practicing what we know through research and implementing in practice. QA/QI relies on clinical research findings and evidence-based practices to guide health systems to set standards and continuously measure and work to improve performance. Differentiating between a research study and a QI project can be difficult, as both often involve defining a problem, developing and implementing an intervention or change to address the problem, and then analyzing the effect of that change on the problem of interest. While overlap exists between QI, research and program evaluation, there are differences that can help determine whether or not the work to be conducted qualifies as a research study or a QI project.

This guidance is designed to assist clinicians, investigators, their departments, students and their schools, and HRPO staff in making the distinction between QA/QI activities and research involving human subjects.

II. SCOPE

The checklist embedded in this guidance can be used to distinguish QA/QI projects from research with human subjects and to make an independent assessment regarding the need for IRB review. While an official determination by HRPO staff through review of a submission in Rascal for IRB review is not required for projects that meet the QA/QI criteria, many journals and conferences require an official IRB determination prior to acceptance of a manuscript or a presentation. It is important to consult journal or presentation guidelines in advance. If an IRB determination is required and there is any ambiguity about the project constituting research, IRB review is recommended. The IRB cannot issue retroactive approval of research.

III. EFFECTIVE DATE: December 1, 2020

IV. DEFINITIONS

CU HRPO GUIDANCE FOR THE EVALUATION OF RESEARCH VS QI

Terms used in this Guidance include the following, based on guidelines from the HHS Office for Human Research Protections (<https://www.hhs.gov/ohrp/regulations-and-policy/index.html>):

Research: A systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

Systematic Investigation: A process conducted under clearly specified and, where possible, controlled conditions that can be measured and evaluated.

Generalizable Knowledge: Information that expands the knowledge base of a scientific discipline or other scholarly field of study. While the term is not explicitly defined by OHRP, it includes activities designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program. The information is collected to share with others in a discipline and is created to make broad statements (conclusions) about a group of people, procedures, programs, etc.

Human Subject: A living individual about or from whom an investigator conducting research (i) obtains information (including, for example, through interviews, or observation) or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens or (ii) obtains, uses, studies, analyzes, or generates identifiable private information (including, for example, information from an individual's medical or school record), or identifiable biospecimens. Note: This includes use of data from records that an individual would consider to be private. If the data are abstracted in an identifiable format for research, even if they are coded at a later point (identifiers separated and replaced by a code linking to identifiable information), the individual about whom the data are collected is considered to be a "human subject."

Quality Assurance (QA) or Quality Improvement (QI): There is no regulatory definition, but often QA/QI are described as "systematic, data-guided activities designed to bring about immediate (or nearly immediate) improvements in health care delivery" which is guided by existing evidence (<https://www.thehastingscenter.org/briefingbook/quality-improvement-methods-in-health-care>), and the combined efforts of everyone to make changes that will potentially lead to better patient outcomes, better system performance, and/or better professional development. **The purpose is to address and attempt to resolve an issue recognized as impacting safety or quality care in a specific situation or location such as a single setting rather than to develop or contribute to generalizable knowledge.**

V. GUIDANCE

Health care institutions have evolved into systems that collect, aggregate, analyze and learn from patient-level data so that clinicians can make evidence-based practice decisions. The new knowledge generated from research or the collection of evidence-based practices often requires further evaluation when applied in a specific health-care setting. Therefore, while health care research is designed to discover generalizable knowledge, QA/QI focuses on translating existing knowledge into clinical practice to improve the quality of care for individuals and populations within a local health care institution or setting. QA/QI activities provide important information on the application of existing knowledge and changes that may be needed to achieve the best possible clinical outcomes. Note that the intent to publish the results of a project does not, by itself, mean that results would be generalizable (i.e., research) or require review by an IRB (<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>).

CU HRPO GUIDANCE FOR THE EVALUATION OF RESEARCH VS QI

Schools, clinical or academic departments/divisions or clinical facilities such as hospitals or outpatient clinics may establish an internal review process for assessment of projects proposed by their employees, faculty or students to assist in making decisions as to whether a project constitutes research with human subjects or is a QA/QI activity. The HRPO encourages individuals and departments to use this guidance for that purpose.

When QA/QI activities are designed to accomplish BOTH a research purpose AND improve the quality of care locally, the regulations for the protection of subjects in research (45 CFR part 46 and 21 CFR part 56) apply. In that case, a submission in Rascal for IRB review is required. Use the “Checklist to Differentiate Quality Assurance/Improvement and Research with Humans” below to determine whether certain activities are QA/QI or research.

In order to facilitate QA/QI projects and to facilitate journal acceptance, the Statement for Journal Submissions (see below) may be included with submissions to a journal or conference.

VI. ADDITIONAL CONSIDERATIONS:

What if I need to access Protected Health Information (PHI)?

The HIPAA Privacy Rule generally prohibits the use or disclosure of Protected Health Information (PHI) unless authorized by the patient, or a waiver of authorization by a Privacy Board, but with certain limits and protections, the use and disclosure of PHI for treatment, payment, and health care operations activities is permitted. QA/QI activities, such as looking at outcomes evaluation or development of clinical guidelines or protocols to support the core functions of treatment and payment of health care activities, may fall under the category of “health care operations” where HIPAA Authorization or Waiver of Authorization may not be necessary. See a list of permitted PHI disclosures without authorization, or waiver thereof, at <https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>.

The Privacy Office (privacy@cumc.columbia.edu) can authorize the use of PHI for QA/QI projects that do not require IRB review. In addition, faculty, employees, and students must have appropriate departmental leadership approval before engaging in any form of QA/QI activities. If a report of eligible patients or patient data will be obtained from the Tripartite Request Assessment Committee (TRAC), the TRAC request form can be submitted via <https://webapps.nyp.org/trac> after IRB approval or documentation that IRB review is not required. Further, if PHI will be disclosed to an entity outside of CU, the proper data use agreements endorsed by the Office of Sponsored Projects Administration must be in place prior to the release. For additional information regarding HIPAA regulations, see https://privacyruleandresearch.nih.gov/pr_08.asp.

Checklist to Differentiate Quality Assurance/Improvement and Research with Humans

Use the following checklist to determine whether a quality assurance/improvement project also meets the definition of research. Follow the instructions to determine if a submission in Rascal for IRB review is required.	Yes	No
Does the project use existing evidence designed to bring about immediate or nearly immediate improvements in health care delivery within a local health care institution or a setting such as a clinical unit?		
<i>If you answered, “Yes” to the question above, submission in Rascal may not be required. In order to confirm, please complete the following series of questions.</i>		
1) Is the intent of the project to develop or contribute to new knowledge that can be generalized to other populations and/or settings?		
2) Does the project involve collaboration between more than one institution?		
3) Is the project funded by an outside organization that has a commercial or financial interest in the use of the results?		
<i>If you answered “Yes” to any of the questions above, a submission in Rascal for IRB review is required. If you answered “No” to all 3 questions above, a submission in Rascal for IRB review is not required. If your QA/QI project does not require submission in Rascal but does involve use of PHI, please contact the Privacy Office (privacy@cumc.columbia.edu) to obtain the required clearance.</i>		

Statement for Journal Submissions

The manuscript being submitted to your journal is a description of a quality assurance/improvement (QA/QI) project. In 2020, the Columbia University Human Research Protection Office (CU HRPO) implemented guidance on the review of QA/QI projects to distinguish those that constitute QA/QI from activities that meet the federal regulatory definition of research.

The CU HRPO Guidance is based on guidelines established by the United States Department of Health and Human Services, Office for Human Research Protections (DHHS-OHRP). The guidance notes that quality assurance/improvement activities do not meet the definition of Human Subjects in Research (45 CFR Part 46) if their purposes are limited to implementing a practice to improve the quality of patient care and collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes. Additionally, DHHS notes that the intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research. (<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>).

Using the criteria developed and approved by the HRPO, individual healthcare professionals or their department administrators assess whether the proposed activity meets the definition of QA/QI. In that case, review by an institutional review board (IRB) or the CU HRPO is not required. Because the project described in this manuscript meets our prescribed criteria as QA/QI, review by the CU HRPO or IRB was not required.