COLUMBIA UNIVERSITY
INSTIUTIONAL REVIEW BOARD

GUIDANCE FOR THE CLASSIFICATION OF QUALITY IMPROVEMENT ACTIVITIES VERSUS RESEARCH WITH HUMAN SUBJECTS

Effective Date: December 1, 2023

I. Background

The Columbia University **(Columbia)** Human Research Protection Office (**HRPO**) and Institutional Review Boards (**IRBs)** are 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. In recent years, there has been increasing recognition of the importance of quality improvement (**QI)** initiatives to improve the delivery of clinical care, behavioral interventions and educational programs. Under regulations of the U.S. Department of Health and Human Services (**HHS) (**45 CFR 46), IRBs are required to review and monitor research projects involving human subjects. However, there is no review process formally dictated by regulation for QI activities. Because of the different regulatory requirements, it is necessary to determine which of the activities undertaken by Columbia constitute research that requires IRB approval and oversight and which are QI activities that have no such requirement. Complicating the analysis is the fact that there are sometimes subtle differences and overlaps between research and QI; there is no bright line dividing the two and the categories of research vs QI are not mutually exclusive. Activities can in fact be either research or QI or a combination of the two. This Guidance is designed to assist investigators, educators and HRPO staff in making the distinction between QI activities and research.

In addition to comparing research and QI activities, and analyzing the differences between each, this Guidance also presents a simple tool that can be used to help differentiate when scholarly activities undertaken by researchers or educators do or do not require IRB review.

II. Basic Definitions

A. Research

Under the HSS regulations, **research** with human subjects is defined as a "systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge." **Generalizable knowledge** means information that expands the knowledge base of a scientific discipline or other scholarly field of study and that yields one or both of the following: (1) results that are applicable to a larger population beyond

the site of the data collection or the specific subjects studied and (2) results that are intended to be used to develop, test or support theories or principles or to inform policy beyond the study.

B. QI

Although there is no regulatory definition of QI, it can be summarized as ongoing efforts to make changes in practices and programs that will lead to better outcomes, system performance and professional development in a local setting.

With respect to healthcare QI, the Centers for Medicare and Medicaid Services (**CMS)** define QI as "the framework used to systematically improve care. Quality improvement seeks to standardize processes and structure to reduce variation, achieve predictable results, and improve outcomes for patients, healthcare systems, and organizations. Structure includes things like technology, culture, leadership, and physical capital; process includes knowledge capital (e.g., standard operating procedures) or human capital (e.g., education and training)." https;//www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/mms/quality-measure-and-quality-improvement-

QI projects are typically designed or intended to include one or more of the following factors:

- improve clinical care;
- improve behavioral interventions or educational or pedagogical programs;
- compare a program, process or system to an established set of standards such as standard of care, recommended practice guidelines, common teaching or educational strategies or other benchmarks;
- implement a practice or procedure for which there is expert opinion, a theoretical framework, or empirical evidence of potential benefit in order to have a local and immediate impact on outcomes; and
- improve the performance of institutional practices or local systems.

A commonly used approach for QI is to conduct Plan-Do-Study-Act (**PDSA)** cycles, where the "Do" phase consists of implementing an intervention for which there is evidence of effectiveness and the "Study" phase consists of the evaluation of the effectiveness of the process or system in the local environment.

In short, while research is designed to discover generalizable knowledge, QI focuses on translating existing knowledge into programs or practices to immediately improve the quality of services to individuals and populations within a local institution or setting.

C. Hybrid Activities

Many projects are clearly classified as research (e.g., a randomized trial investigating the effectiveness of a new medication) or QI (e.g., a survey of all students in a course to determine the outcomes and satisfaction of a change in pedagogical approach). However, in some cases QI activities are designed to accomplish a research purpose as well as the purpose of improving the quality of care or the delivery of services or education. For example, if a project involves

introducing an untested clinical intervention for purposes which include not only improving the quality of care, but also collecting information about patient outcomes to establish scientific evidence and determine how well the intervention achieves its intended result, that QI project may also constitute research. In some cases, when a QI project also involves research, IRB approval is required. When a person or team working on a QI projects are unsure if the projects requires IRB approval, they should consult with the IRB. (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html).

There are also projects that begin as QI, but become human subjects research at a later date. For example, if after a QI project is complete, there is an intent to utilize additional data and/or conduct additional analyses to generalize the outcomes beyond the initial scope of the QI project, this would usually constitute research and IRB review would be required before the second phase of the project is undertaken.

D. The Tool

Please use the schematic attached to this Guidance as **Annex A (Tool)** to help guide the classification of an activity as QI or research. The Tool identifies six major attributes that are key distinguishing factors: Intent and Background; Intervention; Methods; Intended Benefit; Applicability of Results; and Sharing and Dissemination. Although certain projects clearly fit into one category or the other, there is also a middle ground where some aspects of a QI project could be considered to be research. For each attribute, choose the column—QI or research—to which the project relates.

E. Examples

Examples of clinical and social, behavioral and educational QI, hybrid and research projects can be found in Annex B.

F. Review of QI Projects

If a project is either clearly a research study or is a combination of research and QI, it must be reviewed and approved by the IRB. If a project is clearly a QI study only, it is not required to be reviewed and approved by the IRB. We would suggest that schools, departments and divisions within the University establish an internal review process for the assessment of whether a project constitutes research or a QI activity. Such process can also assess potential risks to individuals and the need for disclosure about the project.

III. Publication and Dissemination of Results

Note that the intent to publish or disseminate the results of a QI project does not, by itself, mean that results would be generalizable or require IRB approval (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html). There are often compelling reasons to do so, and the publication or dissemination of the methods and outcomes of QI projects should be encouraged for the

betterment of individuals everywhere, and may be disseminated through conferences and peer-reviewed journals.

There are in fact established and published standards for the reporting of QI projects, such as the Standards for Quality Improvement Reporting Excellence (**SQUIRE)**, which provide a framework for reporting new knowledge about how to improve healthcare, expand knowledge of behavioral interventions or understand the impact of pedagogical improvements. There are also many high impact peer review journals that publish QI project results and some journals are dedicated to these topics (e.g., Journal for Healthcare Quality, American Journal of Medical Quality, etc.)

However, 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 conference guidelines in advance. If an IRB determination is required and there is any ambiguity about the project constituting research, initial IRB review is recommended because the IRB cannot issue retroactive approval of research.

In order to facilitate journal or conference acceptance, the Statement for Journal or Conference Submissions attached to this Guidance as **Annex C** may be included with submissions to journals or conferences.

IV. Privacy Issues

The HIPAA Privacy Rule generally prohibits the use or disclosure of Protected Health Information (**PHI)** unless it is authorized by the patient, or a waiver of authorization by a Privacy Board is granted. For research conducted at Columbia, the IRB serves as the Privacy Board. With certain qualifications, the use and disclosure of PHI for treatment, payment and health care operations is permitted without a HIPAA Authorization or Waiver of Authorization. QI activities, such as evaluating outcomes or developing clinical guidelines or protocols to support the core functions of treatment and payment for healthcare activities may fall under the category of "health care operations" under HIPAA where such Authorization or Waiver may not be necessary. See 45 CFR 164.506 and the Columbia IRB Policy on the Privacy Rule and the Use of Health Information in Research (https://research.columbia.edu/sites/default/files/content/HRPO/HIPAAPrivacyRulePolicyREVISEDFINAL1.22.18.pdf).

The Columbia Privacy Office (privacy@cumc.columbia.edu) can authorize the use of PHI for QI projects that do not require IRB review.

If a report of eligible patients or patient data will be needed in the study, they can be obtained through a request to the Tripartite Request Assessment Committee (**TRAC)** of Columbia, NewYork-Presbyterian Hospital and Weill Cornell Medical College by submitting a request form via https://webapps.nyp.org/trac after IRB approval or documentation that IRB review is not required.

If PHI will be disclosed to a person or entity outside of Columbia, if required by Columbia, a proper Data Use Agreement approved by the Columbia Office of Sponsored Projects Administration (**SPA)** must be in place prior to the release of information.

The Family Educational Rights and Privacy Act (**FERPA**) is a federal law that protects the privacy of student education records. The general rule under FERPA is that, with certain exceptions, access and use of identifiable student data from education records may not be disclosed without written consent of the student (or parent for minor students).

In certain situations, FERPA permits student data to be released without consent if "the disclosure is to other school officials, including teachers, within the institution whom the institution has determined to have legitimate educational interests in the data". It is within the University's discretion to determine what is a legitimate educational interest and whether student privacy considerations outweigh such interest. In some circumstances, FERPA permits educational institutions to share student data outside the institution with contractors, volunteers or other individuals performing services for the institution. In such cases, written agreements, such as Data Use Agreements, must be developed to protect student data.

Additional information about FERPA can be found at https://www2.ed/gov/policy/gen/guid/fpco/ferpa/index.html and the University's Policy on Access to Student Records (https://universitypolicies.columbia.edu/content/federal-family-educational-rights-and-privacy-act-ferpa).

ANNEX A

Tool to Assess the Differences between QI and Research with Human Subjects

The following table is intended to compare and contrast the general characteristics of quality improvement (QI) and research activities and is for use by Institutional Review Boards (IRBs) and investigators. This table is intended to guide discussion among these individuals but not to supplant the judgment of IRBs or local QI review committees.

For each attribute, choose the column to which the project most closely relates: QI or research. You may only choose one answer. Leave the attribute blank if neither choice applies.

Attribute	Quality Improvement	Research with Human Subjects
Intent and Background	☐ Describes the nature and severity of a specific local performance gap ☐ Primary focus is to improve a specific aspect of healthcare delivery, behavioral interventions or educational programs currently not consistently and appropriately being implemented locally and to translate and rapidly introduce improvements into such practices or programs	☐ Identifies a specific deficit in scientific knowledge that can be studied ☐ Proposes specific hypotheses to develop new knowledge or advance existing knowledge of general benefit to society
Methods	☐ Procedures/practices may change over time (i.e., an iterative activity) in response to ongoing feedback ☐ A QI framework such as PDSA (Plan, Do, Study, Act) or DMAIC (Define, Measure, Analyze, Improve, Control) may be used ☐ Designed to improve local or regional standards or practices	☐ Interventions beyond standards or practices are generally studied
Intended Benefit	☐ Interventions are within the usual healthcare provider/patient therapeutic relationship or educator/student pedagogical relationship ☐ The intent is to be of direct benefit to participants or local setting (e.g., creating a safer institutional system) ☐ Goal is to increase efficiency, quality, or safety; or to decrease costs	☐ Intervention, interaction, or use of identifiable private information is beyond the usual healthcare provider-patient therapeutic relationship, standard operational use of data, or educator/student pedagogical relationship ☐ Direct benefit to the participants or the setting is not the primary intent ☐ Develops new or advances existing generalizable knowledge for societal benefit
Applicability of Results	☐ Implementation is immediate and review of results occurs throughout the process ☐ Extrapolation of results to other settings is possible, but is not the main intent of the activity	☐ Results and analysis may be delayed or periodic throughout the duration of the project and are intended to generalize beyond the study population
Sharing & Disseminating	☐ Results are mainly disseminated within the unit or institution in which the practice or process occurs ☐ Findings may be disseminated for healthcare or pedagogical reasons, but the extrapolation of results to other settings is not the principal reason for the QI	☐ It is expected that results will be published or presented to others through a peer-reviewed process

ANNEX B

Examples

Clinical Examples

Example #1

QI

A clinical team at a hospital wants to improve hand hygiene practices in the ICU where they work. Using staff members as coaches to provide feedback and support to colleagues about hand hygiene has been shown in the published literature to be effective in other settings. A staff member in the ICU has volunteered to be the coach and team members plan to monitor hand hygiene behavior before and after the coach is in place.

Hybrid

A clinical team at a hospital wants to improve hand hygiene practices in the ICU where they work. Using staff members as coaches to provide feedback and support to colleagues about hand hygiene has been shown in the published literature to be effective in other settings. A staff member in the ICU has volunteered to be the coach and team members plan to monitor hand hygiene behavior before and after the coach is in place. After trying the coach on their unit, the team has proposed expanding the intervention to other ICUs in the hospital system and collect data from staff members about their assessment of the program, what they perceive as barriers and facilitators to its success, and then link that data with characteristics of the individual staff member (e.g., discipline, job title, age, time working in the ICU, gender). All of the data would be used as the basis for a paper in a scholarly journal.

Research

A faculty member has received an NIH R01 grant to conduct a multi-center interventional trial in ICUs in four hospitals across the mid-Atlantic region. The aim of the study is to assess the impact of two interventions on hand hygiene practices. The ICUs are randomly assigned to one of these two interventions or a control (standard of care) arm. They intend to publish the results of the study in a peer reviewed journal.

Example #2

QI

A NYP quality expert who oversees QI issues relating to sepsis wants to improve sepsis treatment by testing a new sepsis screening alert. Sepsis screening is currently performed using screening criteria that trigger an alert in the EHR. At a recent conference, the quality expert

attended a session that presented data on the effectiveness of alerts sent to a physician's cell phone. The expert wants to see if using the same screening criteria to trigger a text message to the physician's cell phone will improve sepsis treatment. Physicians are alerted about the study and are randomized to receive either the EHR alert or the text message for three months. Statistical approaches are used to determine which method works better in improving the quality of sepsis treatment.

Hybrid

A NYP quality expert who oversees QI issues releating to sepsis wants to create a new risk model for sepsis screening that could potentially benefit patients at NYP, but will also be generalizable to other health systems. The expert obtains IRB approval to conduct a secondary analysis of the data from the QI project described above, using additional patient information such as demographics, comorbiditites, etc. to create the new model. The model is then used at other hospitals in the NYP network to obtain broader results.

Research

A NYP quality expert who oversees QI issues relating to sepsis wants to improve sepsis treatment in the ER. Instead of letting the physicians follow the standard practice, he wants to test whether giving all partients an antibiotic on arrival will improve sepsis outcomes. The NIH awards a grant to fund the study and IRB approval is obtained. After consent is obtained, patients are enrolled in the study and are randomized, with half receiving the early antibiotic dose. Statistical analysis is performed to see whether the early antibiotic dose improved outcomes.

Additional research example, derived from the QI example above:

A NYP quality expert who oversees QI issues relating to sepsis wants to improve sepsis treatment by testing a new sepsis screening alert. Sepsis screening is currently performed using screening criteria that trigger an alert in the EHR. The expert wants to see if using the same screening criteria to trigger a text message to the physician's cell phone will improve sepsis treatment. The study will be sponsored through a federal grant for which the primary objective is to improve local healthcare; however, the results of the study could be applied to other hospital systems using the same EHR. Physicians are alerted about the study and are randomized to receive either the EHR alert or the text message for three months. Statistical approaches are used to determine which method works better in improving the quality of sepsis treatment.

Social, Behavioral and Educational Examples

Example #1

QI

A project to encourage better study habits is implemented by college. A nationally distributed guide for improving study habits will be distributed to all college undergraduates. Students are administered surveys before and after using the guide to assess its impact on their study habits.

Hybrid

Faculty in the Political Science Department at a college have over the years assessed teaching strategies in political science courses. There are departmental guidelines on pedagogical methodology. Professor A in the Department attended a conference that discussed a newly develop methodology that evidences some value in a particular teaching strategy that involves more student participation in the course. Professor A is curious as to the impact this new methodology would have on students in her class and decides to use it in her class. She therefore administers pre- and post- course surveys to measure the effectiveness of the new teaching method. After the results of the survey are in, she sees that the increased student participation may have an effect on the students' perception of political parties in the US and hypothesizes that it would In order to test her hypothesis, she proposes to send out an additional survey to her students with questions aimed at the students' perception of such parties and whether the course contributed to a change in perception. She believes that the results would be applicable to other institutions and plans to disseminate them through presentation at both a departmental meeting and a political science education conference and submission to a professional journal.

Research

The chair of an academic department at a large university administers a survey to assess student perceptions regarding gender parity within the department. This is of interest both internally, to see whether the university should increase its hiring of women faculty, and nationally, where the discipline has an interest in gender parity across different types and locations of schools. The chair has hypothesized that students and faculty see gender parity issues very differently. After the survey is administered, the chair and a graduate student plan to analyze the data and author a paper to share the data with other scholars in the field.

Example #2

QI

A biochemistry professor decides to encourage better study habits by sharing a newly published guide with evidence-based recommendations with his students and encouraging them to use it during the course. Before distributing the guide, he administers a test to see what each student knows or does not know. A similar test is given at the end of the course to measure learning gain. Several questions in the anonymous section of the test ask students to comment on how useful the guide was, how it could be improved and whether there was advice to be shared with next year's students. The professor decides that, in order to educate other biochemistry course directors, it would be helpful to share the results of the tests and the student comments at a national conference to show others how the guide can help improve student learning.

Hybrid

The following year the professor uses the same study guide and measurement process, but also sends the previous year's students an anonymous survey to get a sense of what changes students make to their study behaviors after using the guide and, in general, what additional insights might be helpful to share at a second national conference. His presentation at the conference includes an analysis of the data he received from the students both years.

Research

After presenting the findings of the survey at the second national conference, several colleagues in the field approach the professor to ask him to collaborate on further studying the impact of the guide on student learning. They all want to share and analyze data together in order to write a scholarly paper on the perspectives on the implementation and impacts of sharing evidence-based study strategies with students.

ANNEX C

Statement for Journal or Conference Submissions

This manuscript/proposal being submitted to your journal/conference is a description of a quality improvement (QI) project. The Columbia University Human Research Protection Office (HRPO) provides guidance on the review of QI projects to distinguish those that constitute QI from activities that meet the federal regulatory definition of research. The HRPO guidance is based on guidelines established by the United States Department of Health and Human Services, Office for Human Research Protections (DHHS). The guidance notes that QI 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, behavioral interventions or educational programs, and collecting data regarding the implementation of the practice for clinical, pedagogical, 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 Columbia healthcare professionals, behavioral scientists or educators, or their administrative staff, assess whether the proposed activity meets the definition of QI. If so, review by an institutional review board (IRB) is not required. Because the project described in this manuscript/proposal meets Columbia's prescribed criteria for QI, review by an IRB was not required.