Human Research Protections Program
MHC Institutional Review Board
2701 Cambridge Ct., Suite 110
Auburn Hills, MI 48326
Phone: (248) 484-4950 Fax: (248) 276-9732

GUIDANCE

Determining When Quality Assurance and Quality Improvement (QA/QI), Program Evaluation, Healthcare Innovation, and Other Similar Activities Require IRB Review

Overview

This document is intended to serve as a guidance to assist investigators and the IRB in assessing whether or not individual projects require IRB review and approval. While many QA/QI initiatives, program evaluations, and healthcare innovations do not meet the regulatory definition of human subjects research under the Common Rule or FDA and do not require IRB review, some projects may.

Because the line between quality and research can easily be blurred, an evaluation should be made on a case-by-case basis for each project using the regulations and guidance provided below. When a person engaging in an activity is unsure whether a project requires IRB review, is using coded private information or specimens, or is seeking a formal determination, they should submit to the McLaren Health Care IRB Office for a determination.

What is "Quality Assurance" and "Quality Improvement"?

There are no regulatory definitions of quality assurance and quality improvement, but generally quality assurance can be described as a comparison of performance or outcomes against a standard. In addition, quality improvement can be described as systematic, data-guided activities to bring about prompt positive changes in the delivery of health care and involve deliberate actions to improve care. Depending on the activity, QA/QI can look like practical problem solving, an evidence-based management style or the application of a theory-driven science of how to bring about system change.[i]

What is "Human Subjects Research"?

To determine whether an activity is research and whether that research involves human subjects, one must consider the regulatory definitions of "research" and "human subject". Research involving human subjects must be reviewed and approved by the IRB or determined to qualify for exempt status by the IRB Chair or designee, before it can begin.

Research

The Common Rule defines research as *"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities."* (45 CFR 46.102(l)).

The FDA uses the term "clinical investigation" instead of research and defines it is as *"any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit"* (21 CFR 50.3(c)).

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Activities deemed not to be research:

- **Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal
- research, and historical scholarship), including the collection and use of information, **that focus directly on the specific individuals about whom the information is collected.**
- **Case reports** – the external reporting (e.g. publication, poster, or oral presentation) of an interesting clinical situation or medical condition of up to three patients. The patient information used in the report must have been originally collected solely for non-research purposes as the result of a clinical experience.
- **Public health surveillance activities**, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during an event or crisis that threatens public health (including natural or man-made disasters).
- **Collection and analysis of information, biospecimens, or records by or for a criminal justice agency** for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- **Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions**

Human Subject

A human subject as defined by the Common Rule is *"a living individual about whom an investigator conducting research (i) Obtains information 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 or identifiable biospecimens"* (45 CFR 46.102(e)).

> **Note:** Human subjects may or may not be patients; for example, if your activity includes intervening with or gathering information about providers, the providers may be subjects.

- Intervention means *"both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes."*
- Interaction means *"communication or interpersonal contact between investigator and subject."*

  Note: Gathering data via questionnaires, surveys, diaries, etc. is considered interaction.
- Private information means *"information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)."*
- Identifiable private information means "*private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information*."

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- An identifiable biospecimen means *"a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen."*

For research covered by FDA regulations, *"human subject means an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. A subject may be in normal health or may have a medical condition or disease"* (21 CFR 50.3(g)). In the case of a medical device, a human subject also includes any individual whose tissue specimen an investigational device is used or tested (21 CFR 812.3(p)).

What are some differences between QA/QI and human subjects research?

	Research	QA/QI
Purpose	Test a hypothesis, establish standards where none are accepted, or advance knowledge in an academic, scientific, or professional community	To assess or improve a program or system (e.g., care delivery); compare or improve performance to accepted standards
Benefit	Designed to contribute to generalizable knowledge and may or may not benefit subjects	Most patients are expected to benefit from the quality improvement initiative
Risk	May impose risk or burden on subjects	By design, does not increase patient's risk, with exception of possible privacy/confidentiality concerns
Design	Leads to scientifically valid findings (control groups, random subject selection, statistical tests)	Established quality assurance or quality improvement methods (e.g., PDSA cycle) aimed at evaluating performance or producing change; does not typically include sufficient research design elements to support scientifically valid findings

When does QA/QI require IRB review?

When the QA/QI activity is designed to accomplish a research purpose as well as the purpose of assessing or improving the quality of care or evaluating the success or value of a program or system, IRB review is required.

In addition, when QI initiatives lack a sufficient evidence base, you are engaging in the development of evidence and conducting research. The only time these activities may not be research is when the results are dependent on a set of characteristics unique to the organization or unit and the results are unlikely reproducible in another setting (i.e., not generalizable).

When does healthcare innovation require IRB review?

The Belmont Report (Section A. Boundaries Between Practice and Research) provides the following guidance to help distinguish between practice and research:

> *"For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to individuals. By contrast, the term "research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to*

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develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships)."

Because research and medical practice often go hand-in-hand, it can be difficult to identify when innovation is or should be research. Generally, *"[a] practitioner should move an innovation practice into formal research if the innovation represents a significant departure from standard practice, if the innovation carries unknown or potentially significant risks, or if the practitioner's goal is to use data from the innovation to produce generalizable knowledge."*[ii]

When do educational activities or assessments require IRB review?

Educational activities or assessments undertaken as part of the normal education or training process for practitioners, staff, or trainees, will ordinarily not require IRB review. However, if the intent is to compare the effectiveness of educational practices, or to collect data to support the development of new or refined practices, the activities are likely to meet the definition of human subjects research and IRB review may be required. In such cases you should confer with the IRB Office for a determination.

What if I intend to publish or present my results?

The intent to publish is an insufficient criterion for determining whether a QA/QI activity involves research. When QA/QI is published or presented, the intent is usually to discuss potentially effective models, strategies, assessment tools or to provide benchmarks, rather than to establish scientific evidence or otherwise develop or contribute to 'generalizable' knowledge. Conversely, an activity may involve research even if there is no intent to publish the results (e.g., the data may be used to develop or inform research).

What if I am receiving funding for my project?

Funding may make a difference in distinguishing between QA/QI and research. For example, when the grant type is for research, the grant application describes the activity as research, or the activity is described as research in a notice of award, terms of a grant, or in a contract, it is unlikely that McLaren IRB could issue a determination that an activity is not research.

What if I don't know if my project requires IRB review?

MHC IRB makes the determination whether an activity constitutes research involving human subjects. Investigators CAN NOT make the determination that the activity is not human subject research.

A "Request for Determination of Non-Human Subject" Research should be made prior to beginning the activity or research. The IRB Office will provide a letter documenting the outcome of the determination. If it is determined that your project does not require IRB review, the determination letter can be provided to publications or for a conference presentation, if such documentation is requested.

Activities that meet the federal definitions for both "research" and "human subjects" as outlined in this document must be submitted to the MHC IRB for review via the e-Protocol electronic submission system.

How do I submit for a Human Subjects Research Determination?

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The investigator must complete the "*Request for Determination of Non-Human Subject Research*" form and send it to MHC IRB via e-mail. Based on the definitions listed in this document, the MHC IRB chair, or designee, will determine whether the activity meets the definition of human subject research based on federal regulatory definitions, 45 CFR 46.102(d), 21 CFR 50, or 21 CFR 56.

[i] Baily, MA, *The Ethics of Using QI Methods to Improve Health Care Quality and Safety*, A Hastings Center Special Report, July-August 2006, p. S5, http://www.thehastingscenter.org/uploadedFiles/Publications/Special_Reports/using_qi_methods_to_improve_health_care_quality_safety.pdf

[ii] *Innovative Practice: Ethical Guidelines,* ACOG Committee Opinion, Number 352, December 2006, http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Innovative-Practice-Ethical-Guidelines