Marshfield Clinic

Program Evaluation, including Quality Assurance and Quality Improvement: Determining the Need for IRB Review

1. SCOPE

1.1. System-Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1 Engaged in Research:

- To intervene or interact with human subjects, or obtain individually identifiable private information about human subjects, for purposes of research.

2.2 Generalizable Knowledge

- Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside the specific study population), to inform policy, or to provide general, applicable conclusions.

2.3 Human Subject

- A living individual about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information.

2.4 Quality Assurance (QA)

- An activity designed to determine if aspects of medical and/or institutional practice are being performed in accordance with established standards.

2.5 Quality Improvement(QI)

- A data-guided, system-oriented activity designed and intended to bring about positive change in the delivery of health care within an institution. Improving the quality of care of patients is a fundamental obligation of health care providers. The QI process involves evaluating and learning from experience.

2.6 Research

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

2.7 Systematic Investigation

- An activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.
- Activities are not research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.

3. RESOURCE GUIDE BODY

This document is to be followed to determine whether quality improvement (QI) and/or quality assurance (QA) activities (hereinafter "program evaluations") qualify as human subjects research, and require Institutional Review Board (IRB) review and approval as a consequence. Any activity meeting the definition human subjects research is subject to the federal regulations on human subjects research, and must be submitted to the IRB for prior review and approval unless it qualifies for an exemption under 45 CFR 46.101(b).

The HHS Office for Human Research Protections (OHRP) has issued a document, "Quality Improvement Activities – FAQ," confirming that most QI activities do not meet the definition of human subjects research because the goal of protecting subjects in research, and the goals of measuring and improving quality of care, are distinct. However, OHRP recognizes "in some cases, quality improvement activities are designed to accomplish a research purpose, as well as the purpose of improving the quality of care, and in these cases the regulations for the protection of subjects in research (45 CFR 46) may apply."

3.1. Most program evaluations do not qualify as human subjects research.

a. Activities that implement a practice aimed to improve the quality of patient care, and collect patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes, are not human subjects research. This includes activities that have the limited purposes of delivering health care, and measuring and reporting provider performance for clinical, practical, or administrative use.

b. National Bioethics Advisory Commission, "Ethical Issues in Research Involving Human Participants" (August 2001) explained that:

- "[P]rogram evaluation or quality improvement, are not intended to have any application beyond the specific organization in which they are conducted. . . . [I]f the purpose is to assess the success of an established program, and the information gained from the evaluation will be used to improve that program, the activity should not be considered research. . . ."

c. Having the Intent to publish or share the results of a program evaluation does not necessarily mean that the evaluation qualifies as human subjects research.

- OHRP stated in its document "Quality Improvement Activities – FAQ," (Q. 5) that planning to publish an account of a quality improvement project does not necessarily mean that the project fits the definition of human subjects research.

- Elizabeth Bankert and Robert Amdur, in their publication, Institutional Review Board Management and Function Vol. 2, explained, "There are many situations in which academic forums are used to share the results of a non-research activity with interested colleagues, in the hope that they will benefit from this information. . . . Education, not research, is the most accurate term for these kinds of activities . . . . It is appropriate to inform project investigators that non-research activities can be published, but it is necessary to remind them that the word research cannot be contained within the publication. If research is used to describe the project, IRB review is required, and journal editors may inquire about the status of IRB review."

3.2. However, some program evaluation activities meet the definition of human subjects research and require IRB approval and oversight.

a. When a program evaluation involves human subjects or their identifiable data, and is primarily intended to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective and can be used locally and elsewhere, the activity is considered QI research, a subset of human subjects research.

b. When a program evaluation is a component of a larger project that has already been determined to be research, it is subject to the regulatory requirements, including IRB oversight.

c. If a program evaluation does not initially meet the definition of research, but its results are interesting, and it is decided to expand the findings into a research project, IRB review is required before initiation of the research project.

d. The Hastings Center Special Report, "The Ethics of Using QI Methods to Improve Health Care Quality and Safety" (2006), also recognized the hybrid nature of some QI projects:

- ". . . [M]ost QI activities are not research as understood by those who framed the human subjects protection regulations. However, some QI activities are genuine hybrids: systematic investigations designed to bring about local improvement and develop generalizable knowledge simultaneously. . . . Certain issues might trigger the requirement for formal [IRB] review of a proposed QI project: randomized designs, novel treatments, involvement of researchers, delayed feedback of monitoring, or external funding." (S28, S34)

3.3. MCRF Program Evaluation Determination

a. When there is uncertainty as to whether a proposed activity is human participant research or involves their identifiable information qualifies as human subjects research, or QA/QI an MCRF "IRB Review Determination Request" should be filled out and submitted to ORIP. The IRB Chair, IRB Administrator, or designee within ORIP will use the information provided to make a determination. Determinations will be made and communicated in writing promptly (normally 5 working days). If it is determined that the activity is human subject research or quality improvement research the investigator will be instructed to submit an application for IRB review. If it is unclear whether the proposed activity qualifies as human subject research, the individual attempting to make the determination may ask the investigator to complete an IRB application or otherwise provide additional written information in order to make a final determination.

b. Some program evaluation activities determined to be human subjects research may, after an initial IRB determination of exemption, require no further IRB review. See the IRB document, "Exempt Projects, Review of" for detailed information on IRB Exemption.

4. ADDITIONAL RESOURCES

Points to Consider	Human Subjects Research	Quality Improvement (QI)/ Quality Assurance (QA)
Purpose	To Test a hypothesis OR establish clinical practice standards where none are accepted	To assess promptly improve a process, program or system; OR Improve performance as judged by accepted/established standards
Starting Point	To answer a question or test a hypothesis	To Improve performance
Design	Follows a rigid protocol that remains unchanged throughout the research	Adaptive, interactive design
Benefits	Might or might not benefit current subjects; intended to benefit future patients	Directly benefits a process, system, or program; might or might not benefit patients
Risks	May put subjects at risk	Does not increase risk to patients with exception of possible patient's privacy or confidentiality of data
Participant Obligation	No obligation of individuals to participate	Responsibility to participate as component of care
Endpoint	Answer a research question	Improve a program, process or system
Analysis	Statistically prove or disprove hypothesis	Compare program, process or system to establish standards
Adoption of Results	Little urgency to disseminate results quickly	Results rapidly adopted into local care delivery
Publication/Presentation	Investigator obliged to share results	QI practitioners encouraged to share systemic reporting insights

4.1. References:

- Amdur, Robert and Elizabeth Bankert, Institutional Review Board Management and Function Vol. 2 (Jones and Bartlett, Sudbury MA 2006).
- DHHS OHRP, "Quality Improvement Activities – FAQ"
- The Hastings Center, "The Ethics of Using QI Methods to Improve Health Care Quality and Safety" (July 2006).
- National Bioethics Advisory Commission, "Ethical Issues in Research Involving Human Participants" (August 2001).

4.2. Supporting documents available: None

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control system transferred from Policy & Handbook Library - #1907.1 (no changes made)
2.0	Added Hyperlinks to document; Sect. 3.3 revised to include IRB Review Determination process. Sect 4. Add Comparison Chart
3.0	

6. DOCUMENT PROPERTIES

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