Quality Assurance/Improvement Activities
A Guidance Document

Purpose

This document provides guidance on when quality assurance/improvement activities may fall under the jurisdiction of the UMH-West Institutional Review Board.

Regulatory Guidance

45 CFR 46.102(d): *Research* is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

42 CFR 480.101(b): *Quality review study* is defined as an "assessment, conducted by or for a Quality Improvement Organization, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up."

45 CFR 164.501(1): The HIPAA regulations define *health care operations* to include "conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of ***generalizable knowledge*** is not the primary purpose of any studies resulting from such activities; patient safety activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment."

Discussion

"Generalizable" Debate; the federal regulations governing the protection of human subjects (45 CFR 46) define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." The section of this definition that causes researchers and IRBs the most confusion is the "designed to develop or contribute to generalizable knowledge." Research activities tend to focus on creating new knowledge for the scientific community to benefit future patients and focus less on the immediate care of the individual patient. [1] Quality improvement activities tend to focus on improving systems and organization performance based on findings from internal quality assurance activities (internal audits/gap analysis) with the intention to improve outcomes to benefit current and future patients. A randomized clinical trial with a control arm is clearly designed to develop or contribute to generalizable knowledge because the

[1] Newhouse RP, Pettit JC, Poe S, Rocco L. The Slippery Slope: Differentiating Between Quality Improvement and Research. JONA 2006:36(4):211-219

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results will be applicable regardless of setting. [2] On the other hand, a quality improvement project designed to improve patient care in a specific nursing unit using established guidelines or recommendations from credible publications and measuring the outcome and sharing the results is not intended or designed to contribute to generalizable knowledge. Some individuals may interpret the latter to fall under "generalizable knowledge," but the majority does not since the original intent and study designed was only to improve the quality of patient care at the local setting using existing knowledge.

Intent and Design

Perhaps a more accurate way of determining if the ***research*** is subject to human subject regulations may be to consider why the research is being done and what it is designed to achieve. The federal regulatory definition of research includes a consideration to whether or not the study is designed to develop or contribute to generalizable knowledge. Clinical trials are intended and designed to generate knowledge, that is applicable regardless of specific settings, by testing the effectiveness and safety of an intervention or treatment in two or more groups of patients (e.g., those who receive the intervention/treatment and those who do not) with the same medical condition/disease. Significant findings from clinical trials are often published and may alter how physicians treat a medical condition/disease in future patients. Clinical trials are considered human subject research and must undergo IRB review and approval prior to initiating the research.

Alternatively, ***quality improvement*** activities are intended and designed to improve the quality of the health care patients receive locally by identifying opportunities for improvement in the delivery system through audits of the current state and then addressing the identified problem areas based on existing knowledge in literature. Quality improvement is a continuous process of evaluating the current state, identifying problem areas, proposing solutions, (e.g. changing internal processes, staff re-education), and then re-evaluating if the change made an improvement the intent to publish and share the data from an internal quality improvement project does not automatically make the activity human subject research. Other hospitals and health care systems may benefit from learning how our hospital addressed a specific institutional problem. Thus, quality improvement activities may be published and presented to other external parties without the requirement of initial IRB approval and oversight. However, quality assurance/improvement activities are still required to receive approval to be conducted by the UMHW Quality Improvement Department. In addition, any submission of abstracts/manuscripts to journals for publications or proposed presenting of quality improvement activities to external parties requires

[2] Lynn J, Baily M, Bottrell M, et al. The Ethics of Using Quality Improvement Methods in Health Care. Ann Intern Med. 2007; 146:666-673

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prior review by the UMHW Quality Improvement Department. (For helpful information on writing a manuscript to share the results of quality improvement activities, refer to the SQUIRE 2.0 guidelines found at their website: www.squire-statement.org.)

Ethical Distinctions of Quality Improvement

The Hastings Center, a nonpartisan bioethics research institute, convened leaders and scholars to address ethical requirements for quality improvement and their relationship to the human subject regulations. This convened group defined quality improvement as a systematic, data-guided activity designed to bring about immediate improvements in health care delivery in particular settings and concluded quality improvement is an intrinsic part of normal health care operations. [2] They went on to further clarify quality improvement generally aligns with the patient's best interest, because it presents lower risks than continuing with the usual care and demands the participation of all to be effective, and has no history of ethics scandals. [2] For this reason, informed consent to participate in quality improvement activities is not usually a necessary ethical requirement for participation, because patients expect their health care provider to continually improve the quality of care provided. The HIPAA regulations place quality assurance/improvement activities under normal healthcare operations and thus do not require covered entities (i.e. hospitals) to obtain authorization from patients for this valid use of their health information. [3]

Indicators of Research Activities

In general, quality improvement activities are not designed to create new knowledge, but instead use existing knowledge to improve patient care. [2] There are rare situations when quality improvement activities may meet the definition of human subject research, thus requiring IRB review. *There is no simple algorithm to distinguish quality improvement from human subject research.* Depending on the situation, any of the following **may** tip the quality assurance/improvement activities into the realm of research [4]:

- Study aim is to evaluate an innovation to an existing process, study something new, or analyze a process that has not yet been subjected to rigorous scientific analysis (not proven effective),
- Substantial deviations from established/proven clinical practice,
- Substantial funding or funding from a historically research driven organization, agency
- Conducting the project specifically to meet a research requirement for an advanced degree,
- Use of non-therapeutic/control arms/groups, randomization and/or blinding of treatments,
- Multiple institutions are involved,

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- Focusing on how the intervention affected the individual subject vs. the overall delivery system/process,
- Staff or patients incurring any additional risk and/or burdens (i.e. additional time commitments) in order to produce measurable results,
- Involvement of extensive extra data collection above and beyond normal health care practice for the purposes of analysis,
  Includes in the project design hallmark research activities such as controlling for extraneous variables that may affect the outcome, uses measures that have established validity, sample size calculations to determine statistically significant differences in comparison groups, use of a research protocol to ensure a high degree of standardization and evaluating outcomes over a longer period of time (years vs. months).

[3] 45 CFR 164.506
[4] Lynn J When does quality improvement count as research? Human subject protection and theories of knowledge. Qual Safe Health Care 2004:13:67-70

Indicators or Quality Improvement Activities

In contrast, some of the general attributes of quality improvement activities are the following:

- Intent of the project is a formal process to identify, manage, and improve the quality related to a **specific problem** identified by administration, providers or staff in a service area/unit/program,
- Project will benefit the patients or providers directly affected by the identified problem,
- Use of quality assurance/improvement methods/models: audits, gap analysis, benchmarking, surveillance activities, iFADE, PDSA, DMAIC- Six Sigma, CQI, or TQM,
- Focusing on common quality improvement topics: increasing patient satisfaction, increasing staff efficiency, reducing medical errors, reducing work-related injuries, decreasing morbidity and mortality, etc.
- Data collected is needed to assess and improve the service area/unit/program and the health of the individual patient,
- Knowledge that is generated does not extend beyond the scope/purpose of evaluating the success of the quality improvement initiative for the particular service area/unit/program,
- Project activities are not experimental.

Conclusions

- Focus on *intent, design, and methods* of the quality improvement activity when questioning if IRB review is needed.

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- Email research@umhwest.org if you are uncertain if your quality assurance/improvement activity needs IRB review.
    - The IRB will instruct you if you need to submit an IRB application for review to make a formal determination.
- Inform the IRB if changes occur to your quality assurance/improvement activity that may alter the initial determination via irb@umhwest.org
- Contact the IRB if you have any questions about your quality assurance/improvement activity at irb@umhwest.org or by phone at 616-252-5026

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