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Manager
Department Research
Applicability Boston Children's
Hospital- Policies
& Procedures

Identifying Quality Improvement (QI)/Educational/ Competency Evaluations as Clinical Research Policy/ Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy applies to all Boston Children's Hospital (BCH) licensed locations, BCH operational and clinical departments, and staff (inclusive of W-2 employees, contracted staff, and members of the medical staff irrespective of their appointment category or employer). As applicable, the policy also applies to foundation practices leasing space at hospital-licensed locations.

Definitions

In accordance with the federal regulations, the Office for Human Research Protection (OHRP) defines:

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

Human subject as, "A living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual, or
2. identifiable private information

In accordance with the U.S. Food & Drug Administration (FDA) defines,

Research as "An experiment that involves a test article and one or more human subjects."

Human subject as, "An individual who is or becomes a participant in research, either as a recipient of a test article or as a control."

Item to note: The definition is very broad and open to some areas of interpretation.

Policy Statements

This guidance describes the quality improvement (QI)/education/competency evaluation activities that are considered research and subject to Institutional Review Board Review. The following represents consensus that was reached and has been endorsed by the Medical Staff Executive Committee (MSEC). It has been prepared to assist investigators in determining which of their activities require IRB review.

This guidance was developed to help clarify the confusion that anything published requires IRB review. The activities cited in this guidance do not represent **all** the QI and education activities performed at Boston Children's Hospital.

- There is often confusion in determining whether quality improvement (QI) activities fall under the jurisdiction of the Institutional Review Board (IRB).
- As an academic institution that is accredited by the Accreditation Council for Graduate Medical Education (ACGME), Boston Children's Hospital is required to continually evaluate and improve our training activities through quality assurance and performance improvement. In both situations, scientific methodology is used equally. Thus, activities that require IRB review cannot be easily defined by the methods they employ.
- Other attributes such as publication of findings, methodological design, selection of subjects, and hypothesis testing and generating **do not** necessarily differentiate research from quality improvement (QI)/educational /competency evaluation activities because these attributes can be shared by both research and non-research activities.
- The distinction between quality improvement (QI)/educational/competency evaluation activities and human subject research is challenging and evolving and as a result we have had to re-think our approach for making this distinction.

Procedures

What is the federal definition of research that is subject to Institutional Review Board (IRB) review?

The IRB is charged with reviewing research that meets the criteria for involving human subjects conducted under the auspices of Boston Children's Hospital.

What are the guidelines for determining whether a Quality Improvement project should be considered research and subject to IRB review?

The following principles should be used to define whether a quality improvement (QI) project should be reviewed by the IRB:

- Surveys whose primary purpose is to gauge the opinions and perceptions of internal and external "customers" (i.e. trainees, staff, patients, referring physicians, and others) are an integral component of organizational quality assessment and may be considered a quality improvement activity that does not require IRB review. Results of such surveys may yield new knowledge deserving of dissemination external to the organization through presentations and publications. Therefore, surveys performed within an institution's QI framework should not automatically require IRB consideration.
- QI projects that are designed to improve clinical care to better conform to **established/accepted standards** are not considered research.
- It may also help to think about quality improvement as activities based on existing knowledge about the enduring nature and function of people and their environment, rather than to develop new knowledge.

What are some examples of quality improvement (QI) projects, that may not require IRB review?

- Data guided efforts to ensure adoption of evidence based on practice guideline or introduce procedures to reduce medical errors, may be QI and not need IRB review.
- Clinical practice guidelines (CPGs) are intended to increase compliance with evidence-based or consensus-based practice. In general, CPGs and other QI projects that are designed to bring care in line with evidence or consensus-based standards will not require IRB approval.
- Rapid cycle continuous quality improvement projects (CQI) almost always are designed to bring care within accepted standards and may yield publishable data if conducted over a sufficient period of time for results to be statistically valid, or if the interventions are especially novel and successful. CQI activities are often required to meet accreditation and regulatory standards. Such CQI studies almost never should require IRB review.
- Questionnaires that are distributed to Boston Children's Hospital patient and service populations for the Purpose of determining their satisfaction with a service, program or clinic and for gathering information on how to improve the service, program or clinic does not require IRB review.

What types of Quality Improvement activities require review by the IRB?

The above considerations notwithstanding, the following types of studies, which may be performed

under the general framework of QI, should be submitted for IRB review:

- Studies in which subjects or groups of subjects may be randomized to different interventions or treatments. When these interventions or treatments involve minimal risk, and particularly when informed consent would be impracticable, an IRB should consider a waiver or alteration of informed consent.
- Studies in which anonymity of participants cannot be assured. Participants are defined as individuals who are being asked to complete or provide feedback on a QI initiative not individuals or services that are being evaluated as part of the QI process.
- Studies involving care practices, interventions, or treatments that are not standard (neither consensus nor evidence-based).
- Studies that involve more than minimal risk to participants.

What principles should guide the decision as to whether evaluation of an educational activity or determining new methods of evaluating competency should be reviewed by the IRB?

- Boston Children's Hospital is required by the Accreditation Council for Graduate Medical Education (ACGME) to ensure that formal quality assurance programs are conducted. The ACGME indicates that residents and fellows should when possible, participate in performance improvement programs.
- Research done within the constraints of the training program and designed to evaluate or improve the quality of the educational experience for the trainees can be considered both quality assurance and performance improvement. Such research might include, but is not limited to, duty hours restrictions and their effect on resident/fellow learning, the effects of implementation of the General Competencies, the use of different curricula or evaluation tools; the effectiveness of measures implemented to improve patient safety; and the effectiveness of different teaching methods.
- If a proposed activity is developed to meet this ACGME requirement, it does not fall under the jurisdiction of the IRB for review. However, any activity conducted under this exemption must not adversely affect the quality of the training experience or cause the residents to vary from their normal course of training.

Are there other privacy and protection issues that need to be taken into consideration even if the QI/ educational/competency activity does not require IRB review?

Yes. In order to preserve privacy and mitigate sensitivity of members of the organization to adverse publicity, the following policies should be followed when IRB review is not conducted:

1. Any QI or educational survey results must be completely **anonymous**, and results should be presented as aggregate data.
 - a. Results must not be aggregated in such a fashion that the identity of respondents can be ascertained (e.g., identification of departments with very small numbers of staff members).
 - b. Therefore, all QI surveys must contain the following language:
This is an anonymous survey. Results of the survey will be presented only as aggregate data, with complete protection of individual anonymity.
2. The survey must not be **coercive**.
 - a. Individuals who do not wish to complete the survey may decline without fear of blame or punishment.
 - b. Therefore, all QI surveys should contain the following language:
Completion of this survey is entirely voluntary.
3. If there is any potential for publication of survey results, the survey must contain the following language:
The results of this survey may be published, using only aggregate, anonymous data. If you are concerned about publication of data from the survey and do not wish to participate, simply do not fill it out or hand it in.

What if I want to publish my experience with either a quality improvement activity as defined above or an activity developed for ACGME Purposes that fall within the criteria listed above?

- Intrinsic components of QI, educational initiatives, and competency assessment are shared learning. It is entirely appropriate to disseminate and replicate QI successes, including through channels that are external to an organization. This may include presentations at meetings and publications in professional journals. Therefore, the mere intent to publish the findings of a QI project does not obligate IRB review.
- As long as the publication does not refer to the activity as research and makes clear the publication is the result of a quality improvement or educational/competency assessment as defined above, there is no need for any action on behalf of the IRB. If a journal questions this determination, the IRB can provide the journal with the guidelines referenced above.

Further Guidance

There are other forms of education and quality improvement research that is subject to IRB review. If there are any questions, contact Susan Kornetsky at 5-7053.

References/Citations

Lynn, Joanne at al. [*The Ethics of Using Quality Improvement Methods in Health Care*](#), Annals of Internal

Related Content

- Department of Health and Human Services Regulations (HHS 45 CFR 46)
- U.S. Food & Drug Administration CFR – Code of Federal Regulations Title 21

Approval Signatures

Step Description

Approver

Date

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