SUBJECT: Quality Improvement Activities **POLICY:** RA:HRPP:09.08

DATE EFFECTIVE: **PAGE:** 1 of 2

I. POLICY

It is the policy of the Children's National Medical Center (CNMC) Institutional Review Board (IRB) to review activities which qualify as human subjects research under the Federal regulations. Activities for the purpose of quality improvement or for the evaluation of educational methods or competencies may not meet the definition of human subjects research and therefore not require IRB approval and oversight.

The IRB and the Office for the Protection of Human Subjects (OPHS) provide guidance to investigators to assist in ascertaining whether a proposed activity constitutes quality improvement or research with human subjects. The final determination is to be made by the IRB Chair.

II. ACCOUNTABLE EXECUTIVE AND REVIEWER(S)

A. Accountable Executive: Chief Academic Officer/Institutional Official for the Federalwide Assurance
B. Department Responsible for Review: Office for the Protection of Human Subjects
C. Committee Responsible for Review: Institutional Review Board Executive Committee
Research Policy/Procedure Working Group

III. APPROVAL

Approved by:

IRB Executive Committee — 3/22/2010
Date

Research Policy/Procedure Working Group — _____
Date

_____ — _____
Mark L. Batshaw, M.D., Chief Academic Officer — Date

IV. APPLICABILITY

Areas where the policy and procedure applies: Children's Research Institute, Children's National Medical Center

Persons to whom the policy and procedure applies: Investigators, Chair of the Institutional Review Board

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Element(s):

SUBJECT: Quality Improvement Activities **PROCEDURE:** RA:HRPP:09.08P

DATE EFFECTIVE: **PAGE**: 1 of 5

I. PROCEDURE

A. Introduction

1. There is often confusion in determining whether activities designed for Quality Improvement (QI) or to evaluate educational methods or competencies fall under the jurisdiction of the Institutional Review Board (IRB). Scientific methodology is used equally in both circumstances, thus activities that require IRB review cannot be easily defined by the methods they employ. In addition, other attributes such as publication of findings, methodological design, selection of subjects, and hypothesis testing and generating do not necessarily differentiate research from QI and educational evaluation activities because these attributes can be shared by both research and non-research activities. The distinction between quality improvement, education/competency activities, and human subject research is challenging and evolving.

2. The following guidelines were developed to assist investigators in determining which of their activities require prior review and approval by the IRB. ***Please note that publication of findings is NOT a direct indicator of the need for IRB review.*** Much depends on the details of the activity. The examples listed below do not represent all of the quality improvement and education/competency activities performed at Children National Medical Center. Contact the Office for the Protection of Human Subjects (OPHS) if you have any questions regarding your activity.

B. Definition of Research that is Subject to Institutional Review Board Review

1. The IRB is charged with reviewing human subjects research conducted under the auspices of Children's National Medical Center (CNMC). In accordance with the Federal Regulations (45 CFR 46.102(d)(f)), the IRB and OPHS apply the following definitions:
    a) Research -- "A systematic investigation, including research development, testing and evaluation, designed to develop and contribute to generalizable knowledge."
    b) Human Subject -- "A living individual about whom an investigator (whether professional or student) conducting research obtains:

i. Data through intervention or interaction with the individual, or
ii. Identifiable private information."

2. The definitions under the Food and Drug Administration (FDA) regulations (21 CFR 50.3(c)(e)) are applied by the IRB and OPHS to FDA-regulated activities:
    a) Research -- "An experiment that involves a test article and one or more human subjects."
    b) Human Subject -- "An individual who is or becomes a participant in research, either as a recipient of a test article or as a control."

3. The definitions in the Federal regulations are very broad and open to some areas of interpretation. The IRB Chair is to make the final determination as to whether an activity is considered research with human subjects or quality improvement. (See RA:HRPP:02.01 and 02.01P, *Human Subjects Research: Definitions and Determinations*)

C. Quality Improvement Activities

In addition to the regulatory definitions cited above, the following principles should be used to determine whether a quality improvement (QI) project should be subject to Institutional Review Board review.

1. Surveys whose primary purpose is to gauge the opinions and perceptions of internal and external "customers" (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.

2. QI projects that are designed to improve clinical care to better conform to **established/accepted standards** are not considered research.
    a) **Example 1 --** 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.
    b) **Example 2 --** 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. Such CQI studies almost never should require IRB review. CQI activities are often required to meet accreditation and regulatory standards.

c) **Example 3 --** Questionnaires that are distributed to CNMC 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 do not require IRB review.

3. 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:
    a) Studies in which subjects or groups of subjects will be randomized to different interventions or treatments. When these interventions or treatments involve minimal risk, and particularly when informed consent would be impractical, an IRB should consider waiver or alteration of informed consent.
    b) Studies in which anonymity of subjects cannot be assured. Subjects 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.
    c) Studies involving care practices, interventions, or treatments that are not standard (neither consensus- nor evidence-based).
    d) Studies that involve more than minimal risk to subjects.

D. Evaluation of an Educational Activity or Determining New Methods of Evaluating Competency

Research done within the constraints of an institutional 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.

E. Subject Privacy and Protection when Institutional Review Board Review is <u>Not</u> Required

1. 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 and approval is not required:
    a) Any QI or educational survey results must be completely **anonymous**, and results should be presented as aggregate data. 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). Therefore, all QI surveys must contain the following or equivalent language: “This is an anonymous survey.

Results of the survey will be presented only as aggregate data, with complete protection of individual anonymity."

b) **The survey must not be coercive**. Individuals who do not wish to complete the survey may decline without fear of blame or punishment. Therefore, all QI surveys should contain the following or equivalent language: "Completion of this survey is entirely voluntary."

c) If there is any potential for publication of survey results, the survey must contain the following or equivalent 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."

F. Publication of Quality Improvement Activities as Defined 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 it 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's editors question this determination, the Office for the Protection of Human Subjects can provide them with the guidelines referenced above.

G. IRB Submission Requirements

Investigators must complete and submit the IRB Application Form with sufficient information for it to be determined whether the proposed activity constitutes research with human subjects or quality improvement. An IRB Regulatory Analyst will review the submission and make an initial determination as part of the protocol pre-review. The final determination will be made by the IRB Chair.

Investigators are encouraged to contact the OPHS prior to completing of the IRB application for additional guidance.

H. Determinations as to whether a proposed activity is human subjects research or quality improvement will be communicated to investigators in writing, with a copy of the determination to be retained in the IRB records.

II. REVIEW OR REVISION DATE

Original:

III. REFERENCES

AAHRPP Element(s):

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.102(d)(f)
Food and Drug Administration (FDA) 21 CFR 50.3(c)(e)

Policies and Procedures: RA:HRPP:02.01 and 02.01P, *Human Subjects Research: Definitions and Determinations*