Is My Project Research/Human Subject Research?

The purpose of this document is to provide guidance on Children's Hospital of Wisconsin ("CHW") organizational position on what does or does not constitute a research activity. The following are definitions used to consider what projects constitute research activities within CHW. To request a written determination, please complete the form entitled ***Request for Determination of Human Subject Research*** found on the CHW HRPP website at https://connect.chw.org/departments-services/clinical-departments/childrens-research-institute/human-research-protection/Forms or call the Research Integrity Manager at 414.337.7705.

WORKING DEFINITIONS (for this guidance)

Research (OHRP) means a ***Systematic Investigation***, including research development, testing and evaluation, designed to develop or contribute to ***Generalizable Knowledge***. [45CFR46.102(d)]

Case studies: A "single" case report (3 or fewer cases) does not require review by the CHW IRB. If a clinician would like to request the CHW IRB review the activity to see if it meets the Organization's definition of research or human subject research, the individual should submit a written request following the process described in this guidance. A case series (more than 3 cases) likely meets the definition of human subject research and will require submission of an application in IRBNet. NOTE: Case reports for publication must be prepared in accordance with the requirements of the HIPAA privacy regulations. Publication of a case report containing PHI is a disclosure of PHI. The Privacy Officer in CHW Corporate Compliance should be consulted prior to submission of the case report to assure proper authorization was obtained.

Clinical investigation (FDA) means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the 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 later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms *research, clinical research, clinical study, study,* and *clinical investigation* are deemed to be synonymous for purposes of this part. [21CFR56.102(c)].

Generalizable Knowledge: Knowledge that could be applied to populations outside of the population served by CHW. Generalizability is not specifically described or defined in the regulations. For purposes of this Guidance, **generalizable knowledge** is information that expands the knowledge base of a scientific discipline or other scholarly field of study. The primary beneficiaries are other researchers, scholars and practitioners in the field of study

Systematic investigations designed to develop or contribute to generalizable knowledge constitute research. Thus, a systematic investigation designed to produce information to

expand the knowledge base of a scientific discipline or other scholarly field of study constitutes research.

Common ways of disseminating results include publishing or presenting. HOWEVER, intent to publish is not the sole criteria. If the published materials will be limited to only documenting or reporting on events, situations, policies, institutions or systems without the intent to form hypotheses, draw conclusions, or generalize findings, this does not make the project research. Most now agree publication does not make a project 'research' *per se* (OHRP even recognizes this fact in its Quality Improvement Activities FAQs).

Examples of activities that typically are ***not*** generalizable include:

- Biographies
- Oral histories that are designed solely to create a record of specific historical events
- Service or course evaluations, unless they can be generalized to other individuals
- Services, or concepts where it is not the intention to share the results beyond CHW or any agency supporting the research
- Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the primary intention to share the results beyond the CHW community

Human Subject (OHRP) means a living individual about whom an investigator conducting research obtains:

1. data through intervention or interaction with the individual, OR
2. identifiable private information. [45CFR46.102(f)]

Human subject (FDA) for FDA-regulated products means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. [21CFR56.102(e)]. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

Operations Activity: Operations activities are certain administrative, financial, legal, quality assurance, quality improvement, and public health endeavors that are necessary to support an organization's mission of delivering health care and performing medical education. Operations activities may or may not constitute research.

Outcome Analysis: Term that may be used to describe a variety of projects in which medical records are reviewed to evaluate the outcome of medical treatment or the course of patients with a specific medical condition.

Quality Improvement: Activities aimed at improving local systems of care. The intent is to promote "betterment" of a process of care or clinical outcome within the institution.

Quality Assessment: Activities that are designed to determine whether aspects of medical practice are being performed in line with established standards within the institution.

Quality Assurance: Process of reviewing, analyzing or evaluating patient or provider specific data that may indicate the need for changes in systems or procedures that improve quality of care. The knowledge generated is typically for local, immediate application within the institution.

Systematic Investigation: A systematic investigation is an activity that is planned in advance and that uses data collection and analysis to answer a question. Although research must include systematic investigation, non-research operations activities also include systematic investigation to ensure reliable outcomes. Systematic investigation does not, in and of itself, define research. Projects that are not systematic investigations include :

- oral histories
- journalism
- phenomenological activities.

Internal CHW operations activities (which may include some data collection and analysis) are not considered research when:

- The purpose of the activity is to assess/evaluate the success of an established internal process/procedure/program in meeting objectives and goals.
- The intended results are to improve the practice/process/program within CHW.
- The evaluation is used as a management tool for monitoring and improving practice/process/program at CHW.

If a project is originally initiated as a local QI project, but the findings are of interest and the project investigator chooses to expand the findings into a research study, IRB review is required at that time. The submission should clearly indicate that the data were originally collected as part of a QI project.