NHSR Determinations

Purpose

This guidance is designed to assist in distinguishing projects that are related to health care operations from those that involve research and define the level of institutional oversight required in each case. Discerning when a project meets the definition of research is important since it affects the level of institutional review required.

Definitions

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

- Systematic Investigation - An activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. Often include surveys, interviews, data analyses, cognitive experiences, or medical chart reviews.

- Generalizable Knowledge - Knowledge from which conclusions will be drawn that can be applied to populations outside of the specific study population. This usually includes one or more of the following concepts: Knowledge that contributes to a theoretical framework of an established body of knowledge; the primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study; dissemination of the results is intended to inform the field of study (though this alone does not make an activity constitute research "designed to contribute to generalizable knowledge"); the results are expected to be generalized to a larger population beyond the site of data collection; the results are intended to be replicated in other settings.

Human Subjects: Living individual(s) 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. (CFR 46:102f) Human Subject (FDA Definition): An individual who is or becomes a subject in Research, either as a recipient of the test article or as a control. A Human Subject may be either a healthy human or a patient. [21 CFR 50.3(g), 21 CFR 56.102 (e)]. A Human Subject includes an individual on whose specimen a medical device is used. [21 CFR 812.3(p)].

FDA Definition of Research- 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 Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Food, Drug and Cosmetic 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, and Clinical Investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.10(c)]

Non Human Subject Research (NHSR) Determinations

Investigators are able to make a determination whether their project is Research with Human Subjects. Official IRB determination is NOT required. Guidance is available on the IRB website, with links to OHRP decision trees to aid investigators. However, if an investigator would like a formal IRB determination that a project is Non-Human Subject Research:

- Investigators should submit their project/protocol to the CHOA IRB using eIRB (tip sheet is on main IRB webpage)
- If a project is found to meet the definition of Research with Human Subjects, the IRB staff will work with the investigator to complete their full IRB submission for review.

Investigator Resources and Responsibilities

It is the responsibility of the investigator/physician to obtain appropriate institutional approval for non-research and non-human subjects projects and/or approval for accessing PHI for non-research projects.

If it is unclear what type of institutional review is required for a particular project, the investigator is encouraged to contact the appropriate department (Quality Improvement, Nursing Research, etc.) or the IRB for guidance.

Questions

Contact the IRB at irb@choa.org