Human Subject Protection Program
Investigator Guidance
June 2, 2020

DIFFERENCES BETWEEN RESEARCH AND QUALITY IMPROVEMENT ACTIVITIES

Overview

- A frequent question to the CHLA HSPP office is whether quality improvement activities constitute research involving human subjects, and whether these activities require review by the IRB.

- Investigators planning quality improvement activities should submit an iStar application to the IRB. Under the category “Type of Study Review” the PI should indicate that the study falls under the category “Expedited Review”. If the HSPP office concurs, a determination letter will be issued confirming that the activity is quality improvement and not research.

- **IMPORTANT NOTE:** CHLA HSPP determinations that an activity is not research must be obtained **before** the activity begins. The CHLA HSPP office does not grant retroactive determinations for activities that have already been performed.

Definitions of Research

Activities that meet the definitions of “research” as defined by DHHS and FDA regulations require IRB review or an exemption determination from the HSPP office.

- **Research as Defined by DHHS:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- **Research as Defined by FDA:** Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

  - ☐ Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
  - ☐ Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
  - ☐ Any activity 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.

Distinguishing Characteristics of Research

Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- **Investigation:** a searching inquiry for ascertaining facts; detailed or careful examination
- **Systematic:** carried out according to plan
- **Designed:** with intent
- **Develop:** following a behavior devised
- **Contribute:** add to
- **Knowledge:** facts and understanding

Research as Defined by FDA

- Quality improvement activities that involve a clinical investigation of a test article (drug, biologic or device) **are always "research"** as defined by the FDA.

Definitions of Quality Improvement

Quality improvement activities can involve systematic data collection designed to bring about immediate improvements in health care delivery:

- A systematic, data-guided activity designed to bring about immediate improvements in health care delivery in particular settings (can also establish a new clinical practice).

- An intrinsic part of good clinical care, in which data from clinical settings guide improvement in clinical practice.

The HHS Office for Human Research Protections (OHRP) has issued frequently asked questions (FAQs) that indicates quality improvement activities are limited to:

- Implementing a practice to improve the quality of patient care and collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes.

  - ☐ The purposes of quality improvement are limited to delivering healthcare and measuring and reporting provider performance data for clinical, practical, or administrative uses. Under these considerations QI activities are not considered to be research.

Distinguishing Characteristics of Quality Improvement

Quality improvement activities have these features:

- Can be (and usually are) systematic investigations, and the results are usually published.

  - ☐ **Key Difference:** They are **not designed** to develop to contribute to generalizable knowledge.

- Designed to implement knowledge by assessing a process or program as judged by established/accepted standards.

- Knowledge learned is integral to an ongoing system for delivering healthcare.

- Directly benefits a program, process system.

- Improves a program, process or system.

- Compares a program, process or system to established standards.

- Results can be used to change/improve local care delivery.
- Quality improvement describes the nature and severity of specific existing local performance gaps and proposes improvements to specific aspects of health care or health care delivery with an emphasis on study of health care methods.
    - In contrast, research involves hypothesis testing to develop new generalizable knowledge or advance existing knowledge.
- Quality improvement involves assessment of a system, flexible designs, and reliance on protocol changes based on feedback, with the goal of improving a program or system and comparison of a current program to established standards.
    - In contrast, research involves interventional methods such as randomization, blinding, control groups, and comparisons between groups described in a rigid protocol to answer a research question or evaluate a research hypothesis.