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Compliance Today - May 2024

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It's not research; it's quality improvement

by Mark J. Fox

Organizations often struggle to navigate the fine line between research activities and quality improvement activities. This can be complicated by a lack of coordination between the quality improvement and research departments in both large and small organizations. In this article, we will explore the differences between these two disciplines and how to appropriately determine if an activity is quality improvement or research.

Quality improvement defined

The Centers for Medicare & Medicaid Services define quality improvement as "the framework used to systematically improve [the ways] care [is delivered to patients]."[1] The Common Rule does not define quality improvement activities. The lack of a definition in the Common Rule requires individuals to rely on the definitions of research and human subjects. Because the lines between quality improvement and research often blur, it is imperative that there is interinstitutional collaboration and coordination between the quality improvement department, the human subject protection office, and the institutional review board (IRB).

Definition of research

The Common Rule defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."[2] The concept of generalizable knowledge is important as it is often the determining factor in defining an activity as research. There is often an argument that if you publish the activity, the activity is no longer considered a quality improvement because dissemination of results potentially promotes generalizable knowledge—especially when new findings are not previously published. IRBs can assist stakeholders by evaluating an activity.

Definition of human subjects

The Common Rule defines human subjects as "a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."[3] It should be noted that the application of the Common Rule is only required when the research is federally funded. However, most institutions apply the definition to all conducted research. Keep in mind that when the Common Rule is applicable, the definitions of both research and human subjects must be met. An example where the definition of human subjects would not be met is in a study where no information or biospecimens are captured through intervention or interaction, and no identifiable data or biospecimens are collected. As previously

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mentioned, IRBs generally have processes for determining nonhuman subject research. This documentation clears the ambiguity and is useful when one questions if an activity is human subject research or if the activity does not meet such definitions.

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