

## **(1.4) IRB oversight of quality improvement initiatives**

Your department's Quality Improvement (QI) committee is planning a QI initiative to assess whether patients of a particular interventional procedure report less post-procedural pain following application of a newly described moderate sedation regimen within the literature. The committee intends to randomize one hundred patients to receive either the current or the new regimen over a one-month period and then analyze patients' reported pain scores to assess for a difference. The committee consults a biostatistician to assist in designing the initiative, including ensuring appropriate sample size. The committee does not intend to publish the results of the initiative, which is being conducted to help improve care for the department's own patients. During the initial planning phase of the initiative, the QI committee members consider the need to seek IRB approval. One member of the committee suggests that because data is being collected as part of the QI committee's local efforts rather than as a formal research endeavor at the time, and that results will not be published, that IRB review is not required. How should the committee best proceed regarding potential IRB review of this work?

### **Commentary**

Federal legislation (Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects; referred to as the "Common Rule") directs the conduct of IRBs. The Common Rule, implemented by the Office for Human Research Protections, provides specific criteria for activities that are considered "human subjects research" and that would potentially fall under the purview of an IRB. Namely, such activities must both deal with "human subjects" and represent "research." "Human subjects" refer to living individuals about whom the researcher either obtains data through an interaction or obtains identifiable private information, including content of a medical record when it is possible to identify the subject through captured medical record elements. "Research" refers to a systematic investigation that is intended to "develop or contribute to generalizable knowledge."

Because of the broad nature of "generalizable knowledge" in the definition of research, there has been uncertainty, if not confusion, regarding whether QI activities constitute research and thereby require IRB review. Indeed, IRBs at different institutions have addressed this issue in variable fashion. Thus, the OHRP has clarified its stance regarding the relationship between QI and research, with additional commentary provided by the Hastings Center. Based on these further clarifications, QI is considered a normal and integral component of healthcare delivery that benefits patients and is a responsibility of healthcare practitioners. QI seeks to immediately improve patient care in the local setting and is conducted in a flexible and integrated fashion, with ongoing monitoring and feedback of practice changes to allow prompt adjustments in an iterative fashion. In these regards, QI is distinct from research, comprising distinct methodology and processes. There is tremendous value in publishing the results of QI activities, in order to share the experience for the benefit of the radiology community at large.

While human subjects protection is the primary mission of the OHRP, the OHRP also supports the value of QI activities outside of the research setting. The OHRP deems QI activities that are applied internally within an organization for improving its healthcare delivery, or likewise for other internal clinical, practical, or administrative purposes, as distinct from research and therefore as not requiring IRB review. Given this distinction, practitioners generally do not need to seek IRB approval to perform standard QI or other operational activities that are only applied locally within the organization for improving the practice's clinical care.

With the above background in mind, the OHRP and the Hastings Center both also indicate that there can be overlap between these designations in that some QI activities also comprise research. In these circumstances, IRB review is required. Critically, the distinction is not influenced by the intent to publish the activity. QI activities may be published without requiring IRB review, and conversely, QI activities may require IRB review despite the lack of any intent to publish. Rather, potential designation of a QI activity as also being research depends on the design and characteristics of the activity at hand. The Hastings Center has identified various characteristics that may be assessed in considering the activity to represent research as well, including testing of a new treatment or intervention, random allocation of patients to different interventions, delayed feedback of data, involvement of researchers with no ongoing commitment to local care improvement, and funding or other substantial participation by a party outside of the clinical setting of the activity. The OHRP also notes introduction of an untested clinical intervention as a characteristic that would represent research beyond QI, as in such cases, additional generalizable scientific evidence regarding the new intervention would be established.

The description in the present case includes numerous characteristics that support a designation of research. For instance, patients are randomized, data are being evaluated after a prolonged window rather than on an immediate and ongoing basis, and an external investigator is involved in project design. Moreover, a new medication regimen is being tested in a clinical setting. Therefore, rather than being based on existing data, the activity will generate new data itself, thereby contributing to generalizable knowledge. Based on such project design, the activity represents research and requires IRB review. The lack of intent to publish the work is irrelevant to this designation.

Given the above assessment, the committee should seek approval from the IRB during initial planning, prior to beginning the activity. When unsure whether a given QI activity represents research and requires IRB review, individuals should consult their local IRB for guidance, allowing the IRB staff to make this determination. Even when the QI activity is deemed to not represent research, those involved still must follow strict ethical standards in conducting the initiative, in such cases under the professional supervision of their clinical practice rather than under the IRB.

## References

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