

PRESIDENT'S COLUMN

Proposed Changes in the “Common Rule”: A Chance to Reframe Quality Improvement Research in Practice

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We cannot [create learning organizations] if QI (and CER) is hamstrung by obtrusive regulatory requirements or sidelined as ‘non-research.’



On July 22, when you learned that the Department of Health and Human Services (HHS) had released an Advanced Notice of Proposed Rule Making (ANPRM) to make changes in the Common Rule, it may not have been the opening remark in your very next conversation. In fact, many SGIM members are asking, “If the Common Rule is so common, why haven’t I heard about it?”. Yet, despite the arcane topic, details of procedures for protecting human research subjects—for the many SGIM members involved in quality improvement (QI) efforts—are important.

An attempt to streamline procedures for human subject research raises the fundamental issue about how human subject protections should relate to QI activities. Frequently asked in planning a QI intervention is “Is this project research?”. If yes, it must be considered for review by the institution’s human subjects investigational review board (IRB). If no—the project is just part of routine activities to improve and maintain performance—then it need not be reviewed by the IRB. Two questions often are used to determine whether the project is research: 1) Is the intent to create *generalizable knowledge* (is research), or is it just to provide local applicable knowledge (is not research)? and 2) Is the intent to *publish* results in a research journal (is research)? These questions can help in planning a project, but how they relate to the level of risk posed to human subjects—the focus of the IRB—is not clear. Clearly, even if not intended for publication, a potentially risky QI intervention should be carefully reviewed. Alternatively, even if

intended for publication, a risk-free QI intervention intended to enhance adherence to accepted practice should not be held up by IRB review and/or by the requirement for an obtrusive informed consent process. *Rather than focusing on whether a QI project is research or not, we should be asking about the risk to the human participants*, remembering that QI is a social good that should be facilitated, not impaired, in the interest of the public. The Common Rule and the proposed changes touch directly on this. Thus, it is worth reviewing the current framework and proposed changes as a basis for considering how SGIM members should be engaged.

The past several decades have seen important improvements in practices and regulations around human research. In 1974, HHS human subject protection regulations were first issued based on statutory authority under the Code of Federal Regulations (CFR) as 45 CFR, part 46. In 1978, the National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research (which included SGIM members) published “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” which identified three fundamental ethical principles that underlie human subject research: respect for persons, beneficence, and justice. The current HHS regulations include five subparts, of which two, Subpart A, which specifies the basic set of protections for all human subjects of research conducted or supported by HHS, and Subpart E, which requires registration of institutional review boards (IRBs) for human research studies, are most

relevant to clinical and health services research of SGIM members. In 1991, 15 federal departments and agencies issued a common “Federal Policy for the Protection of Human Research Subjects,” known as the “Common Rule,” based on 45 CFR, part 46, Subpart A. (In addition to the 15, an additional agency, the Central Intelligence Agency, is required to follow the Common Rule by executive order.)

This July 22, HHS announced that it was considering enhancements to the Common Rule to “...ensure the highest standards of protections for human subjects involved in research, while enhancing effectiveness of oversight.” The proposed changes can be found as an ANPRM, “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators,” in the July 25, 2011, *Federal Register* and at <http://www.hhs.gov/ohrp>, with additional information at <http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>. An excellent review of the initiative was published in the July 25, 2011, issue of the *New England Journal of Medicine*, titled “Reforming the Regulations Governing Research with Human Subjects,” by participants in generating the proposal, Dr. Ezekiel Emanuel and Dr. Jerry Menikoff. Comments on the proposed changes are invited at <http://www.regulations.gov>. SGIM members are encouraged to respond, and in SGIM’s behalf, the SGIM Health Policy Committee Research Subcommittee will be making specific comments. Your input is

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welcome.

Several of the proposed changes relate to SGIM members' research interests. One re-specifies what kind of human research requires IRB review, using three categories:

1. Research solely for the *collection of information*, without a study intervention, would be excused from IRB review.
2. Research in which there is an intervention, but only of *minimal risk* (as is the case in most QI research), would only require a brief expedited review by one person. Minimal risk is defined as posing risk no greater than "...encountered in daily life or during the performance of routine physical or psychological examinations or tests."
3. Research with an intervention of *more than minimal risk* would require full IRB review.

A second change proposes that when research includes multiple institutions, a single IRB at one institution (presumably that of the principal investigator) would be empowered to approve the study for the entire consortium. This would lessen duplicative work and delays by multiple IRBs and should eliminate confusion that can arise when different IRBs have divergent judgments on the same study.

A third proposed change is that after an intervention period is completed, annual reviews by IRBs would no longer be required. Once a study is only doing follow-up data collection and/or analysis, the current requirement for annual renewals of IRB approval would be eliminated. This would reduce the burden of many needless renewal reviews for investigators and IRBs.

These are all seemingly sensible and helpful changes and deserve our support. However, they beg the first question that is of importance to SGIM members for conceptual and

practical reasons: Should QI research be considered research? If we want to encourage the quality of and respect for systematic QI that seeks to improve care, then indeed we should consider it research. Then we can turn to the protections based on level of risk as required for human subject research. On one hand, this should help prevent studies with unwise, unjustified, or unsafe interventions. On the other, for the large bulk of QI that poses *no* risk beyond the collection of information about approaches that are consistent with usual care, no IRB review would be required. And for QI that poses only *minimal* risks, only one-person review would be required. Although some may have conceptual issues with this "all QI is research" approach, it provides clear guidelines and thus should reduce uncertainty among investigators and institutions. This ultimately should promote QI research—a very important objective.

Because designating QI as "research" under the Common Rule might be perceived as creating obtrusive requirements for informed consent, it is important that the implications of the proposed changes be understood. Beyond the implications for consent for the three levels of research risk, the use of a single durable short standard consent form signed at the outset of care has potentially enormous consequences. Once signed by a patient under care of an institution or practice, the investigator will be allowed use of all the patient's information (and biological specimens) for research purposes. Moreover, the combination of this consent mechanism with the operational definition of information collection research—and that usual accepted care is not considered an experimental intervention—has great impact on the conduct of QI (and comparative effectiveness research [CER]). For example, if a general medical clinic were to undertake a project to systematically compare,

such as by random assignment, outcomes of two alternative treatments that are part of usual accepted care (such as statins) and collect information to compare the outcomes, this project would be "excused" from IRB review and would have no further need for consent other than the initial global permission. (There is a proposal to have a one-week period during which a standard form is completed and is provided to the institution for general review, but this is not IRB review.) Thereby, it could be argued that the new framework, while designating this QI activity as research, would likely facilitate, not impede, such projects. This is very important; the proposed changes should not pose a barrier to well-constructed evaluations intended to move practice closer to preferred care and outcomes, as should be an ongoing focus in a learning organization. Were it to do so, it could undermine incorporation of QI (and CER) into routine practice, ultimately a bad thing for patients and the public.

Does this relate to SGIM members in their clinical care, education, and research activities? I believe it does for two reasons. First, QI and care improvement are central to our roles in clinical care, research, and education of students and trainees. Second, we need to create learning organizations—and a learning nation—that will continually improve the quality and efficiency of medical care. We cannot do that if QI (and CER) is hamstrung by obtrusive regulatory requirements or sidelined as "non-research." This very conversation engages us in public policy around improving care, which is good for our nation, our health care system, our profession, and our patients. Changes in the Common Rule should provide for the common good, and those proposed appear to do that. SGIM members should provide their insights as part of this conversation.

Postscript: Comments are expected to DHHS by October 26, 2011. **SGIM**