tember 2, Public Citizen and others again petitioned OSHA to issue regulations limiting residents' work hours to 16 per shift and 80 per week without averaging, arguing that "research has connected the typical resident work schedule to harm in four specific areas: motor vehicle accidents, mental health, pregnancy, and percutaneous injuries."[5]

A statement issued by David Michaels, assistant secretary of labor for occupational safety and health, suggested that OSHA may be more sympathetic to the petition now than it was in 2001, when it was under a Republican regime. Michaels wrote, "We are very concerned about medical residents working extremely long hours, and we know of evidence linking sleep deprivation with an increased risk of needle sticks, puncture wounds, lacerations, medical errors and motor vehicle accidents. We will review and consider the petition."

The ACGME initially said its "enhanced standards" would take effect in July 2011,[2] but it has come under pressure to delay the effective date until July 2012 because of the complexities of implementation. The council is considering this possibility — but recognizes that such a delay might not be well received by the public and could influence OSHA's consideration of the petition.

The IOM recommendations have so far spurred no action in Congress, where residency issues were placed on a back burner during the health care reform debate. If Democrats retain control of the House, its Energy and Commerce Committee, whose leadership requested the IOM study, might take testimony on residency hours in the context of Medicare funding of GME. If Republicans take control of one or both congressional houses, they may reexamine the rationale for Medicare's investment in GME as part of efforts to pare the federal deficit. Regardless of the election results or OSHA's decision on the petition, residents' duty issues will remain part of the ongoing private–public dialogue, given the interest of the populace, the concerns of policymakers, and emerging worries that too few doctors are being trained to treat the millions of people who will receive new health coverage under the Affordable Care Act.

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The Paradoxical Problem with Multiple-IRB Review

Jerry Menikoff, M.D., J.D.

The federal system for protecting research subjects was designed decades ago, when most research studies took place at a single institution. These days, if a study is conducted at multiple sites, an ethics review by an institutional review board (IRB) may be repeated many times. This practice has been criticized for both wasting resources and leading to inappropriate delays in the conduct of research.[1]

One might suppose that this resource-intensive effort at least substantially improves the ethical integrity of multisite studies. In fact, however, there is reason to believe that not only do these duplicative reviews provide relatively few benefits, but the current framework may actually reduce the likelihood that studies are in keeping with relevant ethical standards.

The current federal regulations for protecting research subjects require that studies be reviewed by an IRB, which must make various determinations regarding the risks and benefits of the study and the adequacy of the informed consent to be obtained from subjects. Each institution engaged in the research — and thus generally each individual study site — must obtain IRB approval.

Since the precursors to the current regulations were developed when multisite studies were few and far between,[2] they did not directly address the special issues

associated with such studies. Nonetheless, the regulations are somewhat flexible. Although each participating institution must get IRB approval, it need not have its own IRB perform the review — it can designate any IRB to do so. Yet many institutions that have their own IRBs are unwilling to rely on an outside IRB's review,[1] most commonly for reasons related to liability or control. Some institutions are concerned that if they use an outside IRB and it is later determined that the study was not in compliance with regulations, the institution will be tarnished — and possibly sued — even though its employees were not responsible for any misdeeds. Other institutions are simply uncomfortable with the idea of leaving such approvals up to an outside IRB.

The result is that a great deal of resources are devoted to the ethics review of multisite studies, including time spent on investigators' applications for approval, the administrative work and meetings of the IRB, any follow-up work the IRB requires for approval, and so forth. Nearly identical processes are repeated at many locations. And whereas the original IRB review system was very focused on local issues (e.g., the prevailing ethics of that community), such issues are relatively straightforward in most multisite clinical trials and usually do not play a major role in IRB deliberations.

So what does all this effort get us? Among IRBs' most important roles in reviewing studies are their review of the protocol (including the study design) and their review of the consent form and procedures related to obtaining consent. In terms of protocol review, the current system whereby multiple IRBs review a multisite study leads to a diffusion of responsibility and reduces the likelihood that appropriate changes will be made to protocols.

For scientific reasons, all sites conducting a given study must use essentially the same protocol. Permitting substantial variation in what happens to subjects at different sites introduces bias and risks rendering the study results uninterpretable. An IRB that reviews the protocol on behalf of a single site is well aware of this circumstance. If that IRB has serious concerns about the study design, it usually simply prevents the study from being conducted at that site, and the study sponsor finds another site or increases recruitment at the remaining sites. There is generally no change in the protocol[3] — and therefore no reduction in the number of subjects exposed to whatever risks the IRB identified.

In many instances, the IRB's concerns are not even conveyed to IRBs at other study sites: the applicable federal regulations (apart from certain types of research involving emergency conditions) don't require such communication. Indeed, there have been anecdotal reports of sponsors' warning IRBs that discussing their concerns with other sites would represent a breach of confidentiality agreements.

Perhaps most important, not only does this arrangement discourage single-site IRBs from attempting to change the protocol, it results in an authority vacuum that leaves no IRB feeling empowered to change the protocol. As a result, often no IRB takes charge of identifying and making needed changes. The end result can be worse than it would have been if the study had been reviewed by only one IRB, which would have recognized and exercised its authority to shape the protocol.

By contrast, in approving the patient consent form to be used at their sites, IRBs do indeed have and regularly exercise the ability to make changes to the proposed template consent form for a multisite study. In a curious way, however, that discretion can create its own problems. On the one hand, that template may already have been fully compliant with applicable ethical and regulatory standards, in which case any changes that IRBs require would probably reflect relatively minor preferences as to word choice and grammar. The time that administrative staff members and researchers then expend on making those changes would not be particularly well spent.

If, on the other hand, an IRB correctly identifies serious problems with a consent form and asks for changes to be made in the version used at its site, these concerns are frequently not communicated to other IRBs, and inadequate consent forms may still be used at many or most sites. Moreover, if the changes to a consent form are meaningful, they will presumably have an effect on prospective subjects' decisions regarding enrollment in the study — which means that there will be differences among the populations enrolled at different sites. Now we are back to the problem that led to the requirement that the same protocol be used at all sites: if the creation of such meaningful differences among sites is permitted, bias is introduced into the study. And reducing the likelihood that a study will produce meaningful results reduces its ethical integrity, since there will be less justification for exposing subjects to risks.

There is little evidence that having multiple IRBs review a single study has led to the ethi-

cal improvement of protocols or consent forms.[3] On the contrary, this practice seems to pose a significant risk of diminishing studies' ethical integrity. Fortunately, some ways of changing this system are being explored. Recently, the Office for Human Research Protections put out for public comment a proposal to receive direct authority to take action against IRBs — as distinct from the institutions conducting the research — for noncompliance with regulations.[4] The intent is to encourage greater reliance on outside (and central) IRBs by assuring the individual institutions participating in multisite studies that they would not be blamed if an outside IRB were responsible for violations.

Another approach to reducing the number of IRB reviews would be to have sponsors require the use of a central IRB as a condition for participating in a study. Nothing in the existing U.S. regulations would prevent them from doing so. The Department of Veterans Affairs currently operates exactly such a system for a select group of studies. In an attempt to constrain the duplication of review efforts for international multisite studies, the European Union is taking a different approach: it now restricts each participating country to a "single opinion" representing the ethics review for that country, "notwithstanding the number of Ethics Committees" involved.[5]

Any one or a combination of these approaches may turn out to be satisfactory. But recognizing that the problem with multiple-IRB review relates not merely to wasted time and effort but also to less-than-optimal protection of people who volunteer to participate in research should add urgency to our efforts to solve this problem.

The views expressed in this article are those of the author and are not necessarily those of the U.S. Department of Health and Human Services or its operating division, the Office of the Assistant Secretary for Health.

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Public Release of Clinical Outcomes Data — Online CABG Report Cards

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On September 7, 2010, Consumers Union (publisher of *Consumer Reports*) reported the results of coronary-artery bypass grafting (CABG) procedures at 221 U.S. cardiac surgery programs.[1] The voluntary reporting of risk-adjusted outcomes in approximately 20% of U.S. cardiac surgery programs is a watershed event in health care accountability.

The reported ratings derive from a registry developed by the Society of Thoracic Surgeons (STS) in 1989. More than 90% of the approximately 1100 U.S. cardiac surgery programs participate in the registry. Registry data are collected from patients' charts and include key outcomes such as complications and death, the severity of preoperative illness, coexisting conditions, surgical technique, and medications. These data are maintained by the Duke Clinical Research Institute and are analyzed with the use of well-tested statistical methods. The data-collection and auditing methods, specifications of the measures, and statistical approaches have evolved over the course of two decades and reflect a substantial commitment by cardiac surgeons and their leadership.[2,3]

For years, participants in the STS registry have been examining these data and using them to make improvements. What does the public now get to see? Each surgical program that has chosen to make its data public is assigned a rating of one, two, or three stars. Stars are assigned on the basis of results on 11 performance measures (see table) that have been endorsed by the National Quality Forum. The rating depends on whether the risk-adjusted outcomes in a program fall be-