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of Higher Education

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GOVERNMENT

Federal Overhaul of Rules for Human Research Hits Impasse

Massachusetts General Hospital

E. Greg Koski, a former director of the Office for Human Research Protections, says the government should ask basic questions about what exactly it is trying to achieve, rather than "tinkering around the edges" of the current rules.

By Paul Basken | MARCH 07, 2013

PREMIUM

After nearly two years of effort, a bid to rewrite the federal rules governing research involving human subjects appears to be stuck, with little optimism for a way forward.

Universities and researchers pressing for changes in the Common Rule, which governs the ethics of biomedical and behavioral human-subjects research, gained an apparent breakthrough in July 2011, when the federal government's Office for Human Research Protections formally outlined some proposed revisions and asked for public comment.

The time seemed ripe. Social scientists, in particular, were frustrated by rules that often left simple attempts at public-opinion surveys bogged down in bureaucracy for months. And the Obama administration, upset by recent revelations that federal scientists in the 1940s intentionally infected Guatemalans with gonorrhea and syphilis, was also eager for changes.

But now, after months of trying to reconcile the sometimes competing goals of making the rules both simpler and tougher, while engaging 17 different federal agencies affected by the Common Rule, participants are describing the process as stalemated.

"I think it's dead, pretty much," said E. Greg Koski, a former director of the human-research-protections office, reflecting assessments he's heard from key players in the process.

The office has a published timetable suggesting it will formally propose a new set of regulations next month. In a written statement, the current director of the Office for Human Research Protections, Jerry A. Menikoff, said he intended to keep trying.

"This is, of course, a complicated undertaking, as was stated from the outset, and it takes time," Dr. Menikoff said.

At least one governmental colleague is more blunt. Attempts to modify the Common Rule "have become stalled, at least for the foreseeable future, if not permanently," J. Thomas Puglisi, a former division chief in the protections office, wrote in a January commentary for *The Hastings Center Report.*

Divided Mission

The Office for Human Research Protections, part of the U.S. Department of Health and Human Services, was given lead responsibility for coordinating the regulatory overhaul involving the 17 federal agencies that abide by the Common Rule.

The process began when the office asked for public comment on the idea, in 2011. The Common Rule, in place since 1991, establishes a system of institutional review boards, or IRBs, that monitor and approve plans for studies involving human beings. The idea dates to a time when most medical trials involved university settings and single locations.

As part of that initial request, Dr. Menikoff's office published a list of seven recommendations and more than 70 questions on which it wanted advice before it actually developed a set of proposed new rules. Its suggested changes include making the

restrictions on experiments more closely tied to expected risk, and letting a single IRB set the policy for all the domestic sites of a single study.

Then, in December 2011, the Presidential Commission for the Study of Bioethical Issues wrapped up its review of the case in the 1940s—discovered by a Wellesley College historian—in which federal scientists intentionally infected hundreds of people in Guatemala with sexually transmitted diseases as part of a public-health research project.

The presidential commission responded to the case with several recommendations for improvements in rules and procedures, including a requirement that universities treat and compensate anyone who is harmed in experiments that involve human subjects.

From the start, the July 2011 notice from Dr. Menikoff's office seemed to reflect the divided mission that now seems to be snarling the process, Dr. Koski said. The preamble of the notice spoke of both strengthening protections and easing burdens, but the actual recommendations seemed almost entirely devoted to the latter, he said.

More important, by assuming the current structure of federal attention to human-subjects protection will remain in place, the government appears to be "tinkering around the edges of what most people acknowledge to be a slow, costly, dysfunctional system that in many instances is more of an impediment to research than it is to truly protecting human subjects," Dr. Koski said.

Rather than try to adjust the current rules on human-subjects protection, Dr. Koski said, the government might want to form a commission to ask fundamental questions about what exactly it is trying to achieve, across a variety of clinical and research settings, and then figure out an approach that best fits that need.

Costly Review Boards

Mr. Puglisi, now director of the Office of Research Oversight at the U.S. Department of Veterans Affairs, suggested in his *Hastings Center Report* commentary that frustrated federal agencies might start figuring out and observing their own interpretations of the Common Rule. The VA, for its part, is already carrying out a policy intended to make distinctions between the treatment of medical practice and medical research, he wrote.

The apparent stalemate is likely to drive frustration among university researchers, said Zachary M. Schrag, a professor of history at George Mason University who helped the American Association of University Professors draft its recommendations on the proposed rules changes.

Among its criticisms of the current process, the AAUP has argued that IRBs consist of members with no special expertise in the research subjects they are being asked to judge. And for all their cost and regulatory burden, Dr. Koski said, the review boards rarely reject submissions, and usually make minor administrative revisions to comply with statutory requirements.

The government has received more than 1,100 public comments on the rule-change ideas, suggesting heavy interest in change, Mr. Schrag said. The fact that the revision process involves multiple agencies helps explain why success may be even tougher in this case than in rules changes involving a single agency, he said.

But the suggestion by Mr. Puglisi that agencies pull back and devise their own interpretations of the Common Rule could be especially bad for universities, he said. "It won't do much for researchers at universities and other federally supported institutions who do not receive direct funding and thus may be left squabbling with their IRBs about which Common Rule to apply," he said.

At least one party is pushing ahead. The National Academy of Science, the federally chartered provider of independent scientific advice, has formed a panel of experts in the behavioral and social sciences to consider changes in the Common Rule. The panel, which is intended by the National Academy "to inform the current efforts of the federal government to update the Common Rule," is scheduled to hold a two-day workshop this month.