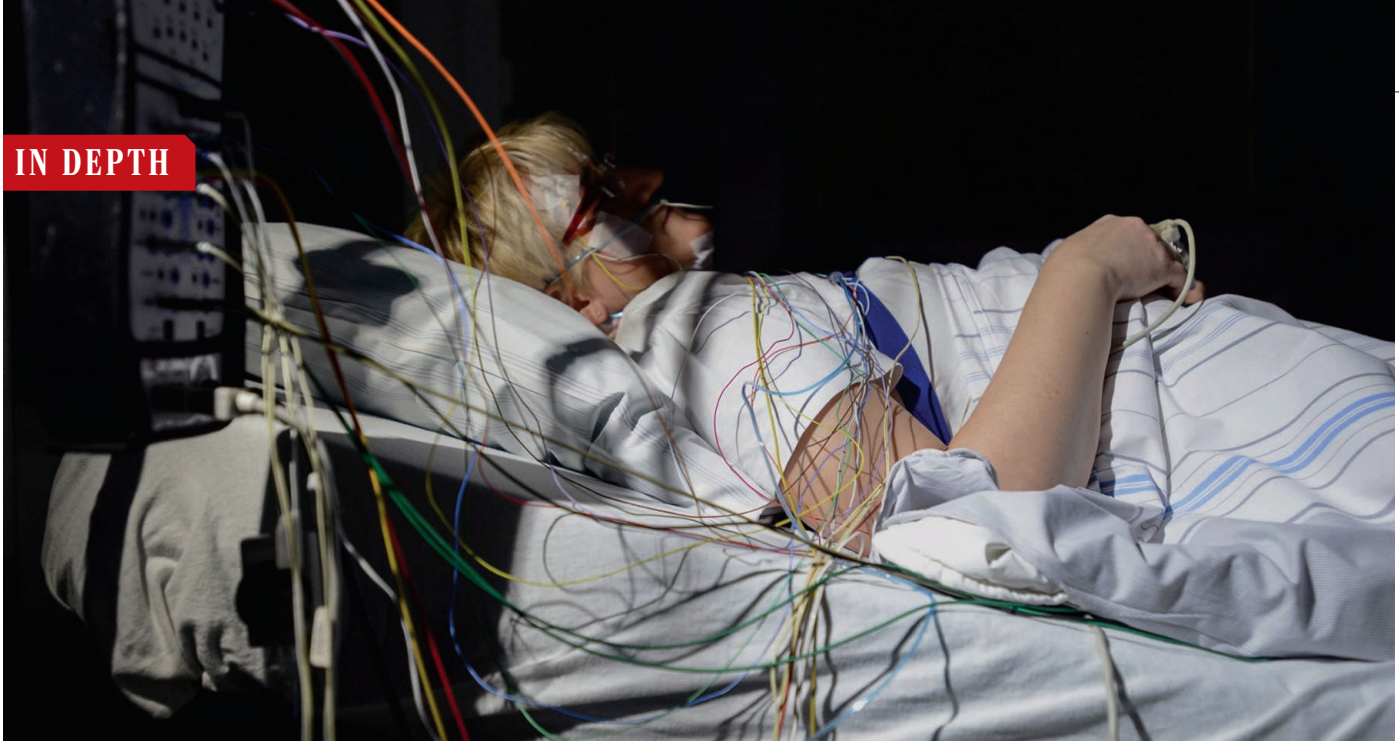

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RESEARCH REGULATION

Panel slams plan for human research rules

National Academies report urges creation of new national commission on ethical studies

By **David Malakoff**

In a surprise development certain to fuel a long-running controversy, a prominent science advisory panel is calling on the U.S. government to abandon a nearly finished update to rules on protecting human research participants. It should wait for a new high-level commission, created by Congress and the president, to recommend improvements and then start over, the panel says.

Policy insiders say the recommendation, made 29 June by a committee of the National Academies of Sciences, Engineering, and Medicine that is examining ways to reduce the regulatory burden on academic scientists, is the political equivalent of a comic book hero trying to step in front of a speeding train in a bid to prevent a wreck. It's not clear, however, whether the panel will succeed in stopping the regulatory express—or just get run over. Both the Obama administration, which has been pushing to complete the new rules this year, and lawmakers in Congress would need to back the halt—and so far they've been silent.

Still, many researchers and university groups are thrilled with the panel's recommendation, noting that they have repeatedly objected to some of the proposed rule changes as unworkable, but with little apparent impact. "We've been saying for some time that there is no rush to issue this rule by the end of this administration," says Lisa Nichols, director of research and regulatory reform at the Council on Governmental Relations in Washington, D.C., which represents universities and other research institutions. "The panel offers more support for the idea that we need further discussion among experts and stakeholders before we move ahead."

At the center of the debate is the so-called Common Rule, which sets ethical standards for federally funded researchers who work with human subjects. The rule spells out consent rules and governs how researchers can use data and tissue specimens from humans, alive or dead. Officials formulated the rule in 1981, with help from an influential 1978 study known as the *Belmont Report*, which was produced by a presidential commission. Since then, the rule has undergone periodic tweaks, but in 2009 more than a dozen federal agencies launched a major effort to modernize it, concluding that shifting ethical concerns and new biomedical and digital technologies had rendered it outdated. Late last year, the agencies asked for public comment on a draft rule that proposed scores of changes.

> ***The Common Rule proposal "is marred by omissions …"***
>
> Committee on Federal Research Regulations and Reporting Requirements

Although academic researchers generally support the intent of the changes, they have blasted many of the proposals as overly burdensome and counterproductive. One lightning rod has been a proposal to allow researchers to use anonymized tissue samples only if they come from people who have given explicit written consent—a plan critics say would create a paperwork nightmare and place many useful samples off limits (*Science*, 20 May, p. 878). Researchers also have argued that it isn't clear how key components might work, including what kinds of social science research—such as analyses of tweets—might be exempt from consent rules.

The National Academies panel, which was created to examine a range of federal regulations that affect academics, echoes those concerns. The Common Rule proposal "is marred by omissions, the absence of essential elements, and a lack of clarity," the report states, and should be withdrawn. The "inadequacies," it says, "signal a pressing need for a comprehensive review of the nation's ethical, legal, regulatory and institutional frameworks for protecting research subjects." To conduct that review, the panel calls for a national expert panel modeled on the one that produced the *Belmont Report*.

Debate surrounds rules to protect human research subjects, such as this person in a sleep study.

The idea for the new commission—and the Common Rule halt—largely arose from the committee's "realization that the past consensus over how we should regulate human research is broken," says panelist Arturo Casadevall, a microbiologist at Johns Hopkins University in Baltimore, Maryland. Now, said Larry Faulkner, chair of the committee and president emeritus at the University of Texas, Austin, in a statement, "Congress and the administration have an opportunity for a course correction."

Neither administration officials nor lawmakers, however, were immediately willing to buy in. A spokesperson for the Department of Health and Human Services, which is helping lead the reform effort, wrote in an email that officials planned to read the report, but suggested that the reform effort may continue. "If a final rule is issued this fall, it will be the first time in 25 years that the regulations governing research using human participants has been updated," the spokesperson said.

Senator Lamar Alexander (R–TN), who requested the panel's report and chairs the Senate's health committee, is still reviewing the recommendation, his press secretary Louie Brogdon told *Science*. But he says that Alexander believes the Common Rule "must strike a balance between allowing researchers access to biospecimens, such as blood or tissue, and ensuring the privacy of patients." Alexander's committee could be a potential launching pad for legislation creating the proposed commission.

Many critics of the Common Rule draft had essentially given up hope that the administration would back away from its push to issue a final rule this year. But the panel's unexpected move has raised "a glimmer of hope," says Emma Meagher, an associate vice provost for human research at the University of Pennsylvania. The "recommendation can't be ignored given the profile of this group and [its] thoughtfulness," predicts Elisa Hurley, executive director of Public Responsibility in Medicine and Research in Boston.

That doesn't mean the administration will agree with the proposal, Hurley adds. One possibility, observers say, is that the administration will withdraw particularly controversial elements and push ahead with the rest. Such a move could still leave room for a new commission to "really think logically about research regulations in general," Meagher says. And Casadevall says, "we are really in need of a comprehensive, fresh look at the problem." ■

With reporting by Dianne Lugo.

PHOTO: TILL MIDDELHAUVE/FAIR

PHYSICS

Long-delayed nuclear center looks set for construction

FAIR moves ahead despite remaining budget shortfalls

By **Edwin Cartlidge**

What was supposed to be a global beehive of nuclear physics is, for now, still a large, muddy field outside the German city of Darmstadt. The Facility for Antiproton and Ion Research (FAIR), an extension of the GSI Helmholtz Centre for Heavy Ion Research planned by a collaboration of eight European Union countries plus Russia and India, was first expected to open in 2009, and then in 2015. But a series of planning errors and other problems pushed the price tag up to some €1.7 billion—an overall rise of about 75%—and stalled construction.

The site reserved for the Facility for Antiproton and Ion Research near Darmstadt, Germany, pictured in 2014.

Now, however, FAIR may finally get built. At a council meeting on 27 and 28 June, the partner countries concluded that they have enough money to cover a €320 million budget gap that came to light in 2014, and they will now seek building permits from the German government. If all goes well, FAIR could be completed in 2025. "It is absolutely great news," says Carsten Welsch, a physicist at the University of Liverpool in the United Kingdom, which became an associate partner of FAIR in 2013. "The scientific community has been waiting for years for this project to go ahead."

Yet not all of the financial problems have been solved. Some countries still have to commit their share of the missing cash, including Russia, which had agreed to bear about 18% of FAIR's total construction cost, the second largest contribution after Germany's 70%. A statement issued by the FAIR council is short on details about the exact financial situation.

At FAIR, an 1100-meter-circumference synchrotron housed in a circular tunnel will propel extremely intense ion beams to very high energies and direct them to storage rings and detectors located above ground, allowing scientists to study everything from the origin of chemical elements to the cosmic imbalance between matter and antimatter (*Science*, 2 November 2007, p. 738).

In the first proposal, in 2001, FAIR was predicted to cost €675 million and to start operations in 2009. That was too optimistic. First, design additions, an increase in the cost of raw materials, and inflation upped the price to some €1.2 billion. Then, an additional roughly €100 million was needed to stabilize the unexpectedly sandy ground at the location. In 2009, the nine full-partner countries decided to commit just over €1 billion in 2005 prices for a scaled-back design with fewer instruments, to open by 2015.

Then the new €320 million hole emerged, mostly due to the introduction of tighter fire regulations in Germany that had major design consequences, says Ulrich Wiedner,

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