NIH Plans Peer-Review Overhaul

After a long debate, NIH director Harold Varmus has ruled that grant proposals should be judged on "innovation." Next, NIH plans to revamp the structure of the study sections

SPECIAL NEWS REPORT

The National Research Council—the operating arm of the U.S. National Academies of Sciences and Engineering and the Institute of Medicine—has been hit by two lawsuits and is grappling with declining federal revenues. A Special News Report on the NRC begins on page 900. News and Comment and Research News are combined into a single section for this issue.

If you have been arguing that the peer-review system for biomedical research is in trouble and needs to be fixed, be forewarned: You may get your wish. This month, the National Institutes of Health is embarking on an overhaul of the entire network of peer-review panels that selects winners of the more than $5 billion worth of grants NIH doles out each year. The effort—if carried out as intended over the next 18 months—would go beyond the relatively minor tinkering with procedures that has taken place over the past 3 years. And, like all previous attempts to modify the system that determines who gets funded and who doesn't, this effort is already proving controversial.

NIH took the first step in its attempt to bring substantive change to its peer-review procedures on 5 May, when NIH director Harold Varmus announced that he has ended a long-running debate over proposed new criteria for judging the quality of grant proposals. Varmus overruled some of NIH's top leaders by deciding that, beginning next year, the study sections will rate proposals on a new criterion: innovation. It joins four other newly defined criteria reviewers will use to come up with a single score that determines whether a proposal will be funded or not. The next steps will come over the next few months, as agency staffers begin exploring changes in the structure and membership of the study sections—the peer-review panels that will implement these new criteria. They have already begun experiments that could lead to the assignment of some research fields to new panels (see sidebar).

Revamping the criteria should have been the easy part. But, for almost a year, leading NIH program officers and academic advisers have been mired in a stalemate over the question of creativity. On the one side are some outspoken academics—led by Keith Yamamoto, a molecular biologist and former colleague of Varmus's at the University of California (UC), San Francisco—who believe that the degree of originality in a proposal should be explicitly weighed by study groups. On the other are research leaders, mostly at NIH, who are skeptical about singling out this quality for special attention, arguing that it could lead to discrimination against proposals from areas such as clinical research.

Yamamoto, who chairs the advisory panel for the NIH's Division of Research Grants (DRG), has been lobbying for creativity as a criterion since 1994, shortly after his colleague Varmus took the helm at NIH (*Science*, 4 March 1994, p. 1212). Like many others in the biomedical community, Yamamoto feels that the funding crunch is having a detrimental impact on science by making reviewers too cautious. Reviewers often endorse proposals by scientists who have already established a successful track record or who propose a modest extension of work they have already published, he says. "When money is very tight," agrees DRG advisory-committee member Elizabeth Theil, a biochemistry and physics professor at North Carolina State University in Raleigh, people favor "the sure bet" and neglect "the innovative possibilities."

NIH institute leaders themselves concede that reviewers have become risk-averse in the 1990s, favoring grants with the best pedigrees rather than those taking on the biggest challenges. At a meeting of NIH's Peer Review Oversight Group (PROG) this week, for example, Howard Schachman, a professor of molecular and cellular biology at UC Berkeley and a special adviser to Varmus, said that reviewers do "too much nit-picking." They harp on technical weaknesses, Schachman claimed, rather than focus on substance.

To counter that trend, Yamamoto suggested last year that NIH instruct reviewers to rate grants explicitly on "creativity" or "innovation" as well as on several other traditional measures. His suggestion was one of several new grant criteria that were debated at NIH over the winter and have been included in Varmus's list. A few outsiders weighed in on Yamamoto's side, including Stanford University biologist Paul Berg, who, as an officer of the American Society for Cell Biology, "wholeheartedly" urged Varmus to adopt the creativity standard to show that "innovative ideas are valued" at NIH.

The notion did not get wholehearted endorsement among senior NIH staffers, however. Although they gave their support to most elements of the revised set of grant-review cri-

DOES YOUR GRANT MEASURE UP?

RICK KOZAK

Stamp of approval. Varmus released these criteria on 5 May.

SIGNIFICANCE

Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

APPROACH

Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

INNOVATION

Does the project employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

INVESTIGATOR

Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

ENVIRONMENT

Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Review Panels Under Review

"My e-mail box has never been as full," says National Institutes of Health (NIH) director Harold Varmus, discussing the intense reaction from biomedical researchers to relatively modest changes in the criteria used to judge grant proposals (see main text). Varmus's e-mail may reach another high-water mark this spring, for NIH is now considering changes that would revamp the structure of the study groups that will apply these new criteria.

NIH is doing this, Varmus says, because he would like to "loosen the rules" a bit, in an attempt to make the review system more flexible and more focused on scientific concepts. He also wants to ensure that the same review standards are applied across all fields of research. And he says he hopes to attract more senior scientists to serve on peer-review panels, perhaps by letting busy researchers serve on a study section just once rather than three times a year as rules now require.

Spearheading this reform effort is Elvera Ehrenfeld, a molecular biologist and former dean of biological sciences at the University of California (UC), Irvine. She joined NIH officially in January, picked by Varmus to head NIH's Division of Research Grants (DRG). Ehrenfeld oversees a network of 1800 extramural scientists who sit on 105 study sections, each focused on an arbitrarily defined area of scientific turf. At a meeting of DRG's advisory council on 28 to 29 April, Ehrenfeld sketched out a plan to achieve some of Varmus's goals, which she said could lead to a "much bigger and broader overhaul" of these peer panels than has been attempted before. She has retained one consultant—pediatrician Michael Simmons of the University of North Carolina—to serve as liaison to the clinical-research community and is looking for another to link up with behavioral researchers. DRG's advisory group, chaired by molecular biologist Keith Yamamoto of UC San Francisco, endorsed the broad proposal, and Ehrenfeld and her staff are now working out a concrete agenda.

Ehrenfeld told Yamamoto's committee that in addition to trying to lure more senior scientists into the system, she is concerned about reports that competition for funding is much more intense in some study sections than in others. Ehrenfeld said some grantees complain that "too much of the hottest, most active" science may be crowding into "too small a subset of study sections." At the same time, she said, other panels may be responsible for proposals from "not-so-productive" fields. As Donald Cleveland, a member of DRG's advisory council and professor of medicine at UC Los Angeles, notes, panels in both the hot and the not-so-active fields can give fundable scores to the same percentage of grants. Ehrenfeld also mentioned a third problem: "the orphans"—the emerging areas of science that have no proper home and "may not be getting the best review." They should be better provided for, she says, perhaps by creating entirely new study sections.

Judging the judges. DRG chief Elvera Ehrenfeld.

Ehrenfeld told the advisory group that her office will look into the flow of grant applications, the principles that guide the assignment of proposals to specific study sections, and how "hot" areas of science fare in review. DRG staffers have already started a set of "pilot projects" to judge how well the judges perform. They are looking over the shoulders of seven study sections in cell development and function, and 22 recently reorganized study sections in the field of neuroscience, to see how efficiently they handle grant applications and how well they have done at picking winners. As the DRG gathers the information, it will begin drafting recommendations.

Ehrenfeld and Yamamoto say they hope the DRG will be able to come up with a concept for reorganizing NIH's study sections within 18 months. It is an ambitious goal. But, as Ehrenfeld said last week, many committees have studied peer review at NIH, and "we suffer ... from talking a lot." This time around, she said, "'we will see a bunch of experiments and hopefully some solutions" to these long-debated problems. **–E.M.**

teria, some NIH research chiefs balked at the idea of judging grants on originality.

Claude Lenfant, director of the National Heart, Lung, and Blood Institute, led a working group that surveyed staffers at NIH on this question last winter and concluded that they "would not find it helpful" to have grants rated on their innovativeness. Lenfant conceded in a report that new ideas in science are often "controversial" and that "there is a perception ... that such work is not well received in review groups." But his panel was against using creativity as "an explicit review criterion" because doing so might "create the awkward situation" in which a proposal's failure to address the criterion, even when it was not applicable, "could carry a negative connotation." In addition, Lenfant said clinical researchers might feel it put them at a disadvantage. The Lenfant panel's skepticism was shared by other NIH program officers, including Wendy Baldwin, deputy NIH director for extramural research. When discussions reached an impasse in February, Baldwin bumped the matter up to Varmus.

Now, after a 2-month review, Varmus has given an unequivocal endorsement of the creativity principle. In a statement Varmus read to the PROG meeting this week, he said that, starting in fiscal 1998, proposals submitted to NIH should be reviewed on five criteria—made explicit for the first time—including the degree of "innovation" they exhibit. To judge innovation, Varmus explained, he would ask: "Does the project employ novel concepts, approaches, or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?" (See table on previous page for other criteria.)

Varmus handed out copies of the new criteria at the PROG meeting and brushed aside the arguments against evaluating proposals on innovation. "I take umbrage at the suggestion" that clinical research would score poorly on innovation, he said. "There's plenty of imaginative clinical research and plenty of me-too-ism in laboratory research." He complained that the "whole issue" of grant criteria "got overly wound up" and pleaded for "a more dispassionate treatment" of it. The reason for adopting new standards, he explained, is to shift reviewers' attention away from "technical details" and toward substantive research concepts.

Varmus made it clear that he doesn't want to debate the criteria any longer. He said he would entertain proposed "refinements" of wording over the next "couple of days." But apart from that, he said, "we should get on with the business of trying" the new standards. With the first skirmish over, NIH now begins the bigger task of revamping the structure of the peer-review network.

–Eliot Marshall