Changes in Animal Care Policy Proposed

NIH is seeking to build a new consensus regarding the ethics of animal use in research, but some critics remain dubious

The National Institutes of Health (NIH) has proposed stricter guidelines for the treatment of animals used in research. The proposals, which offer some major concessions to animal welfare activists, would require institutions to establish committees with lay members to review individual grant proposals entailing use of research animals. As a last resort, NIH funding could be withheld if the guidelines are violated. They were announced at a recent meeting* and are being widely distributed for public comment.

Although NIH is hoping that these proposals will attract a broad consensus, it can expect continuing criticism from two disparate and opposing groups—animal welfare activists, who consider NIH the fox guarding the chickens (and other warm-blooded vertebrates to which the new policy would apply), and scientists and administrators from the research community, who regard tighter restrictions as unnecessarily burdensome. Nonetheless, their cooperation is being sought by NIH officials, who clearly would prefer welfare of research animals to be largely governed by guidelines instead of by proposed new federal laws (*Science*, 3 February, p. 468).

William F. Raub, NIH deputy director for extramural research and training, concedes that the proposed rules are, in part, the result of outside pressure. But he says that several other factors, such as the need to update and clarify current policies, prompted the changes. Another important factor emerged from site visits NIH conducted during the past 2 years, at ten randomly selected research facilities to evaluate the adequacy of their animal care programs.

Those visits resulted in an NIH report,† which is being distributed along with the proposed policy changes. Though largely complimentary, the report cites several problems and practices that added to the momentum for change. For example, although no incidents of animal abuse were noted, animal care committees were seen as "less than fully assertive" and auxiliary animal care facilities commonly had "deficiencies."

Two of the committees observed during the site visits had lay members, and their participation was deemed "extremely useful," according to the report. Thus, the proposed policy changes mandate the appointment of a lay person who is not affiliated with a research institution to its animal research committee (ARC). That is a recommended renaming from the current "animal care committee" to emphasize its more general role of reviewing research proposals instead of the traditionally more limited focus on animal facilities and care. Such appointments also are proposed in pending legislation, including Senator Robert Dole's (R–Kans.) amendments to the Animal Welfare Act, which influenced NIH's proposals. Because appointees may be drawn from among community members most interested in this issue, these appointments potentially would grant a major voice in reviewing research to animal welfare groups.

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James B. Wyngaarden

The federal government cannot deal with this issue by itself.

This particular change also epitomizes an underlying theme in NIH's proposals—that responsibilities for lab animal welfare be shifted more squarely into research institutions and the laps of individual researchers, who will be required to justify more explicitly in proposals their needs for animals. Along with an increased role in supervising their own use of animals, researchers also are being called on to participate more actively in the larger political contest. "The federal government cannot on its own adequately deal with the mounting pressure on this issue," NIH director James B. Wyngaarden said during the meeting. "It is the responsibility of the institutions and the investigators involved to become more active in responding to questions about the need for animals in research and . . . explain why animals are absolutely necessary in a given experiment." A similar plea was made by Edward N. Brandt, Jr., Assistant Secretary for Health and Human Services (HHS), who said, "Good research conduct only happens when the scientific community itself accepts its own larger share of the responsibility."

Several other proposed changes not only add new teeth to the guidelines but put greater responsibility for keeping them sharp at the institutional level. For example, an institution's ARC, which has first-line responsibility for reviewing and approving research proposals involving animal use before they are submitted to NIH (or any other agency of the Public Health Service) will have authority to halt experiments if they do not adhere to the policy. Moreover, federal grant support can be withheld or withdrawn if the "responsible institutional official," who would review the ARC's actions and has "authority for . . . the entire program of animal care and use," refuses to sign off on a project. Thus, the proposed policy changes would vest a local administrator with the principal responsibility for implementing good animal care practices, but leave open the not-so-local punitive option implicit in NIH's power of the purse.

Other proposals spell out stricter provisions for how an institution must qualify for NIH approval, what can be done to ensure an institution is correcting deficiencies, and under what general circumstances NIH is to intervene. Institutions, by qualifying for "option 1 status," will not be subject to random site visits by NIH. To so qualify, they must be fully accredited by the American Association

*National Symposium on Imperatives in Research Animal Use: Scientific Needs and Animal Welfare, 11 and 12 April 1984, Washington, D.C.

†Included in NIH Guide for Grants and Contracts, *Site Visits to Animal Care Facilities: A Report to the Director of the National Institutes of Health*, vol. 14 (No. 5), 1984, is the "Proposed PHS policy on humane care and use of animals by awardee institutions."

for Accreditation of Laboratory Animal Care, accept the principles of the new policy as "mandatory," and be in compliance with the Animal Welfare Act. Other institutions, which are not fully accredited, must submit annual reports to NIH, comply with all other preceding requirements, and are subject to site visits.

The proposals also lay out various animal welfare principles, such as avoiding "all unnecessary suffering and injury to animals" and that a scientist "must be prepared to terminate an experiment." Here again, the specific implementation of these general principles rests with individual scientists to negotiate with their ARC's, but there will be several new ways for keeping an eye on them and, if need be, pricking their consciences.

To some extent, Sweden has been testing a similar set of principles since 1979. Experiences there with a secondary review of research proposals involving animal use generally have been good, according to Karl Johan Öbrink of the Biomedical Center in Uppsala, who helped establish the system. There are six regional review boards, and each has equal numbers of scientists, technicians, and lay members. Although only advisory, the committees are mandated to review all animal research proposals. "The underlying belief is that rules are not enough; attitudes are important," Öbrink says. Proposals are reviewed by subcommittees and then discussed with the investigators, who often have found the strongest criticisms of their use of animals coming from other scientists on the subcommittee.

The Swedish system faces two major problems, according to Öbrink. The first is a tendency to become less flexible and too institutionalized. The second, which is perhaps more worrisome, is that the committees cease to function effectively when they include militant antivivisectionists. The militants "have not done harm," he says, but they "make disturbances by discussing irrelevant things and so the work cannot go smoothly." The militants are being removed from the ethics review committees, he adds, but not surprisingly they are angry and are appealing their case to the government. Because Swedish law clearly states that research must continue and that animal experiments are "legal" despite the halt that radical antivivisectionist groups have sought, there is no assurance that their appeal will succeed. However, it does heighten Öbrink's worry that the issue will once again become highly polarized, leading to further losses in the new system's flexibility.

These same problems undoubtedly lie ahead for the proposed NIH system. Though aimed at attracting a consensus, the NIH system has gotten off to a somewhat shaky start. Representatives from the university community, for example, are concerned that implementing the proposals could become very costly, both in terms of time spent reviewing proposals and in improving physical facilities. However, there is general support for NIH taking the lead on this issue.

At another level, representatives from the animal welfare camp are saying that the NIH has presented its proposals in "too timorous" a light, noting that copies of the proposals "conveniently" were in short supply, hence precluding discussion of them during the meeting. Other more caustic critics, such as Constance Kagan who chairs the Animal Political Action Committee and Christine Stevens who is president of the Animal Welfare Institute, go farther.

Kagan says the whole NIH approach, with its emphasis on the role of individuals, is wrong. "Institutional accountability is really at issue," she says, and NIH's proposals do not correct the inherent conflict of interest of the ARC's. Kagan also accuses NIH of taking a "public relations approach to a moral issue." She is referring to the use of dramatic testimonials by surgical patients, who have benefitted from recently developed procedures, urging that animal research continue.

A similar appeal to the emotions—to achieve an opposite end in showing how lab animals sometimes suffer—has been used widely by activists in the animal welfare movement. Its use now by some researchers in this continuing argument, tied so closely to NIH's attempt to find a new consensus on the animal welfare issue, runs the risk of widening rather than narrowing the gap between the animal welfare and research communities.—JEFFREY L. FOX

Congress, DOE Battle Over British Plutonium

DOE refuses to give up the option of using plutonium from the civilian R & D program, including 4 tons imported from Britain, to make weapons

A battle between the Department of Energy and Representative Richard Ottinger (D–N.Y.) over the fate of about 8 tons of plutonium in DOE's civilian R & D program could embarrass the British government and cause strained relations between Britain and the United States. Ottinger, arguing that civilian and military nuclear programs should be kept separate, wants to stop DOE from using the plutonium to make weapons. DOE maintains, however, that the material may be needed for the Reagan Administration's weapons buildup.

Britain's stake in this dispute stems from the fact that about 4 tons of the plutonium was transferred from Britain to the United States between 1964 and 1971 under a 1958 agreement "on the uses of atomic energy for mutual defense purposes." It was bartered for highly enriched uranium and tritium, which was used in Britain's defense program.

Although DOE officials have said they do not know the source of the plutonium, British statements indicate that it came from civilian magnox reactors. The agreement provides for use of the bartered plutonium for military purposes, but the British government has repeatedly sought assurances that it would be used only in civilian programs.

The first of these assurances came in April 1964, when Sir Alec Douglas-Home, who was then Britain's Prime Minister, said in a statement in the House of Commons that "I am informed by the United States Government that they have no intention of using the plutonium received from us for weapons purposes." A similar commitment was given in 1982, when Britain's Secretary of State for Energy, John Moore, told Parliament that U.S. authorities had confirmed that the British plutonium was all in the civilian R & D program. Finally, on 5 March, U.S. Energy Secretary Donald Hodel said in a letter to Ottinger that