Animal Regulations: So Far, So Good

Most institutions are reasonably content with new NIH standards but there is concern about forthcoming Agriculture regulations

In the spring of 1981, an unprecedented story captured headlines on the network news: animal activists had broken into a laboratory in Silver Spring, Maryland, and made off with 15 monkeys that had been used in some nerve-severing experiments.

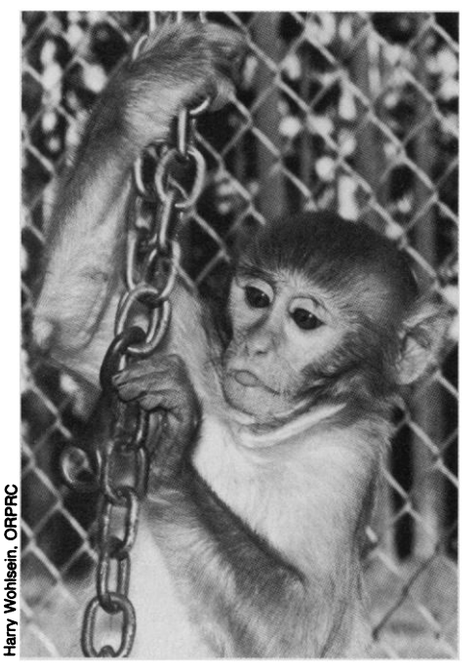
Charles McCarthy, head of the Office of Protection for Research Risks (OPRR) at the National Institutes of Health (NIH), who was in California at the time, remembers turning on the television in his hotel room and thinking that this was something "very new." For one thing, it was obviously planned with the media in mind, because TV cameras were already rolling inside the building when the police entered.

Indeed, the Silver Spring heist from the laboratory of investigator Edward Taub heralded the beginning of an era of animal activism unprecedented in this century. The break-in triggered a public response across the country that resulted in thousands of letters to NIH over a period of years. "What we perceived was not a small handful of activists but a nerve in the American public that was touched," says McCarthy. "I expect I will be long retired before we hear the end of the Taub case."

Much has occurred since the hapless Taub found himself in a much publicized trial which resulted in a verdict (later overturned) that some of his monkeys had received improper veterinary care. In 1985 Congress passed long-awaited amendments to the Animal Welfare Act that call for the Department of Agriculture to formulate new regulations on the care of laboratory animals. At the same time, the Public Health Service (PHS) issued new animal guidelines that must be followed by all recipients of PHS money (most of them NIH grantees).

In the world of ethics and science, the 1970s was the decade for overhauling policies on human subjects in research. The 1980s is the decade for animal subjects.

It is still a time of settling in. Scientists must become accustomed to the fact that research with animals is getting far more costly, and that stringent justifications will be required for any procedures involving animals. Nonetheless, judging from a recent conference sponsored by the Scientists Center for Animal Welfare (SCAW), held at New York's Rockefeller University in October, institutions are finding the new rules tolerable and many of the required changes even desirable.



Harry Wohlsein, ORPRC

Rhesus monkey. *What does it take to promote this primate's "psychological well-being"?*

Many institutions are discovering to their relief that NIH is being flexible in the interpretation of its guidelines. Much of the credit for this goes to McCarthy, who has been traveling furiously around the country, meeting with scientists and administrators to help them prepare for the changes. "We are seen as being reasonable," he says.

Basically, the new rules call for every research institution to set up an Institutional Animal Care and Use Committee (IACUC, pronounced as in "I, a cook"). Each committee has to have a scientist, a veterinarian, and a person otherwise unaffiliated with the institution. Duties are numerous, including inspections, semiannual reports, and review of the animal portions of proposed research protocols. The rules also contain detailed injunctions about personnel training, the conduct of painful procedures on animals, and specifications for living quarters. An immense amount of paperwork is required to demonstrate everything is in order. In the old days, the "assurances" that had to be submitted to NIH had little more than a signature on them. Now they must contain detailed information about the animal care program.

But McCarthy says that "it doesn't seem to me that an institution in compliance with the old policy should have trouble with the new one." Many institutions that saw which way the wind was blowing have made extensive changes in facilities and procedures since 1981. On the whole, undoubtedly spurred by fear of the activists, change has been remarkably fast. For example, only about half of the approximately 800 PHS-funded institutions had animal committees, and those that existed were not very effective. Now everyone has one—the average size is 11 members—and the OPRR receives several hundred calls a day from people seeking advice on compliance. "There is an atmosphere of good will," says McCarthy.

According to McCarthy, the new responsibility to review animal protocols "may be the most difficult and controversial obligation imposed" on animal committees. These reviews require the committee to judge whether the experimental design is sufficient to yield important new knowledge, whether the animal model selected is appropriate (or whether nonanimal alternatives exist); the adequacy of procedures for pain control and euthanasia, environmental conditions, and qualifications for personnel.

Some people at the animal welfare conference thought this was going to be a problem. Sherman Bloom of the George Washington University Medical Center, for example, complained, "we are not constituted to do peer review. Can you judge a proposal from the department of obstetrics?" Another consideration raised by protocol review is confidentiality. This is largely the concern of those who use animals to test toxicity of industrial products. Richard A. Murphy of the University of Virginia School of Medicine observed: "Protocol review has created an enormous paper trail. . . . It has fundamentally changed the available information on every aspect of what you are doing."

But as time goes on, people seem to be developing their own solutions. Participants

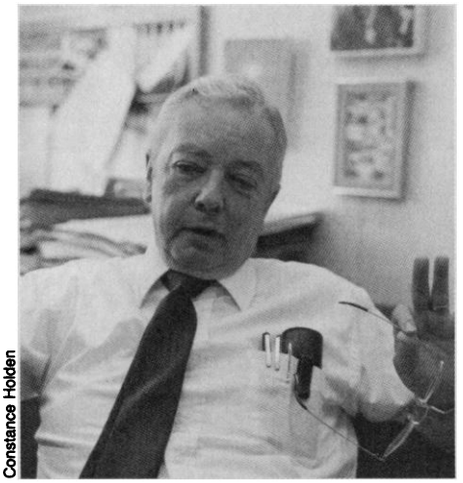
at the conference, for example, reported that protocol review can be expedited by calling in outside consultants or having the principal investigator present at the review. Some companies guard confidentiality by discussing each project under a coded number.

On the whole, it appears that institutions feel they can live with the new rules as interpreted by the NIH. At present, they are more concerned about threats from two other directions: the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), which administers the Animal Welfare Act, and the animal activists.

APHIS has to put out regulations governing virtually all of the country's animal labs. They were supposed to be out by the end of 1986. Last April, it published a preliminary set of regulations in the Federal Register that appalled many institutions and inspired a record 8000 responses. McCarthy reported at the SCAW conference that the proposed regulations were inconsistent with the PHS guidelines "in at least 135 ways." For example, he said APHIS had "misinterpreted" the animal welfare amendments to require committee inspections not just of animal facilities but of every lab and work area. This, he said, would make the committees "totally unworkable."

APHIS has now gone back to the drawing board (its administrator Bert Hawkins has been reassigned to the agriculture secretary's office). But according to Frederick A. King, director of the Yerkes Primate Center in Atlanta, there is a great deal of concern that if the new regulations are not substantially modified, they could result in almost doubling of the cost of animal care and facilities modifications—a cost which, using data from the Association for Biomedical Research, he estimates at about $500 million nationwide.

APHIS is supposed to be cooperating with NIH in creating the regulations but negotiations have been very difficult. APHIS reportedly has kind of a chip on its shoulder because animal research is not its main line of work, and it has suffered severe drubbings from critics who say its inspections are terrible. The agency is still short on money (the Administration wants to eliminate its laboratory inspection role altogether), and critics say its inspectors are poorly trained. They have been causing considerable distress by rigid adherence to the letter of the regulations. For example at Yerkes, animals are kept in a large corral and obtain water by licking a valve which sometimes dribbles to form a puddle 1 or 2 feet in diameter. Regulations prohibit standing water in animal facilities. King says APHIS inspectors demanded that a costly and totally unnecessary new watering system be installed. "We want fair, equitable inspections," says King—not people "looking for a speck of dust to protect their ass."



Constance Holden

Charles McCarthy of NIH. *"We are being seen as reasonable."*

King adds that APHIS has inadvertently been supplying fodder for use by such groups as People for the Ethical Treatment of Animals (PETA), which has been implicated in a number of laboratory break-ins. For example, he says PETA, which has made a special target of NIH primate centers, last year issued a list of APHIS-identified violations at Yerkes extending back to the 1970s. All the problems were old, trivial, and had been immediately corrected, says King. But since inspectors are only required to list negative criticisms, there were no indications in the report that conditions had improved.

So far, APHIS has not published proposed regulations on the most controversial aspect of its duties: specifying the proper conditions to further what the Animal Welfare Act calls the "psychological well-being of primates." King says a draft proposal, reviewed by a panel he is on, recommended that all primates housed individually must be taken out for 2 hours of exercise a day, 5 days a week. The panel found the proposal "unsatisfactory in the extreme" because in fact no one, least of all APHIS, knows what really promotes primate happiness.

Even if APHIS finally comes up with regulations compatible with NIH guidelines, institutions still have the animal activists to contend with. Institutions do not like to discuss how much they are spending on new security arrangements, but it is a lot. And, points out King, "money that should be going into scientific research is going into security systems."

McCarthy says the level of alarm is particularly high in New England and on the West Coast. "They are being nickled and dimed to death on the West Coast by these groups," he says, explaining that Stanford University and the University of California at Berkeley are both planning major new vivaria for their animals, but that activists are filing lawsuits to obstruct them.

Many people are also concerned that state laws mandating open meetings for policy-making bodies will be seized upon by activists to disrupt animal committee meetings, particularly when it comes to review of protocols. Frederick Cornhill of Ohio State University believes this would "significantly impair" the effectiveness of the review process and cause committees to be excessively cautious. Jean Dodds, a SCAW board member and chief of the New York State Health Department hematology laboratory, says "confidentiality is a major loophole in the system." According to Martin Stephens of the Humane Society of the United States, animal advocates have won court cases to gain access to state university meetings in Washington and Florida, are seeking to do so in California, and may launch a challenge in New York.

McCarthy acknowledges that sunshine laws could pose problems, but the only ones he knows of so far have been at the University of Florida, where last year protests helped squelch some research using dogs to test the Heimlich maneuver for drowning victims. Florida's solution, he says, is "committee members don't discuss anything any more."

In the long run, King and others believe that the threat posed by activists is enhanced by the complacency of scientists. "There are still too many scientists sitting in their labs saying it can't happen here," says King. "We still have a great need for scientists to be more forthcoming" in confronting critics and explaining their research.

That was also the theme of a speech by psychologist Neal Miller at the SCAW conference. Miller warned that even previously moderate animal organizations are getting more radical and that "terrorism" is on the increase. He said the tendency of researchers is to "lie low" when what they ought to be doing is inviting concerned citizens and members of the press into their laboratories to show how science works.

But investigators understandably do not want to become lightening rods for protesters. McCarthy relates that after one prominent scientist published some editorials criticizing animal rightsers, his office received a batch of material containing photographs and allegations of noncompliance at the scientist's institution.

King says the covert activities are a good deal more extensive than is suggested by the sporadic news coverage of illegal activities. At Yerkes, for example, there have been

offers to purchase information from employees. "We also have good reason to believe there is infiltration by activists" going on not only at primate centers but at universities and pharmaceutical companies, says King.

McCarthy notes that all the major breakins to date have been "inside jobs." He says investigation showed that the recent seizure of cats from a Department of Agriculture laboratory was done with the help of insiders because the fences had been cut from the inside. "The best security is training your own people," he told the SCAW audience.

The animal activism of the 1980s appears to be a major historical phenomenon. McCarthy, a former Catholic priest who taught philosophy and political science, sees it as the successor to the antiwar and human rights crusades of the 60s and 70s. He also notes that modern animal rightists come from a quite different philosophical strain than the old-line antivivisectionists, even though the goal of both groups is the total elimination of animal use in research. Whereas the antivivisectionists operate from principles of humaneness and the idea that doing harm to an animal degrades a person's humanity, the rightists embrace the idea of animal equality—a philosophy that contains a strain from Eastern religions and carries "cultural relativism" to its ultimate extreme.

Noting that the rightists tend to be young, McCarthy thinks they are largely urban types who have never known any animals other than family pets. This, he thinks, has led them to anthropomorphize animals, with help from television programs that show them acting like people. This view gets some support from the fact that McCarthy says the one group he has not seen much protesting from are those who know animals most intimately—the farm community.

The movement has not yet plateaued, but McCarthy says he does not expect Congress will be passing any major new legislation. Rather, he says, policies will be worked out at state and local levels. Some localities, for example, have passed laws prohibiting the use of pound animals for research. And Cambridge, Massachusetts, which has already passed ordinances against the Draize test and the LD_{50} for toxicity testing (a move analagous to making a town a "nuclear free zone"), is now considering a law that would establish a city commission that would be empowered to review painful experiments, inspect research facilities, and even close laboratories. John M. Moses of the Massachusetts Institute of Technology, who described the proposed measure at the SCAW conference, said "no issue has attracted more letter writing in years." ■

CONSTANCE HOLDEN

Duke's Heart Center in Bureaucratic Jam

Duke got $14 million from NSF for an engineering center for cardiovascular research, but discovered it is contingent on co-funding from NIH

LAST March, the National Science Foundation (NSF) announced that it had "agreed in principle" to award Duke University $14 million to establish an NSF engineering center for cardiovascular research. Duke soon learned that its engineering center grant had an unusual string attached. Full funding, NSF officials reported, is dependent on Duke getting what amounts to a matching grant from the National Institutes of Health (NIH). If NIH money is not in the pipeline by next September, the 5-year, $14 million center at Duke will be shut down early.

"As of now, our present position is that if they cannot get NIH money the whole thing is over after this year," Marshall M. Lih, NSF director of cross-disciplinary research said recently. His stated position goes even beyond the strictures of the written agreement for the Duke center.

Duke researchers are stunned. Theo C. Pilkington, professor of biomedical and electrical engineering at Duke, has been negotiating with NSF through the spring and summer in the wake of NSF's co-funding demand. He was surprised by Lih's stark bottom line. "We expect this award to be made for the full 5 years and, I hope, for the maximum allowed, 11 years," says Pilkington.

NIH officials have not been happy from the outset with what appears to be a pressure play from NSF. NIH director James B. Wyngaarden recalls that NSF chief Erich Bloch approached him some time ago about a possible co-funding arrangement for the center, which represents a blend of engineering and medical research. But no agreement was struck.

"I indicated that I'd be willing to consider co-funding if I had a valid application [from Duke]," Wyngaarden said in an interview. "Duke would have to go through our valid review process. Having had previous conversations with [Bloch], I was rather surprised that the science board took that action." NSF officials sent Duke's engineering center application to NIH for its review.

On 1 April, Wyngaarden sent it back. "It is our recommendation that the NSF consider the application on its own merit without reference to possible co-funding by the National Institutes of Health," he wrote Bloch. "This recommendation is strongly influenced by the unilateral announcement by the NSF of conditional co-funding . . . ," said Wyngaarden, adding that the NSF co-funding demand was "particularly surprising" in view of President Reagan's budget request to increase NSF funding while decreasing NIH resources by 10%.

The unusual strings-attached grant to Duke was approved by the National Science Board (NSF's governing body) on 23 March when the Duke center for emerging cardiovascular technologies was one of three proposals the board selected from a list of 68 applications from 48 institutions. The board made commitments to the other two winners with no strings attached. An NSF center for hazardous substance control at the University of California at Los Angeles is slated to get $18 million over 5 years. A center for optoelectronic computing systems at the University of Colorado at Boulder was authorized at $14.5 million. Duke is expected to get one-third of its $14 million from NIH.

Apparently the interdisciplinary nature of the Duke cardiovascular center lies behind the demand that it receive NIH funding. Some of the officials responsible for this decision, including Bloch, have been unavailable for comment, but it is clear that the co-funding idea had support in the White House as well as at NSF. On 1 April, presidential science adviser William R. Graham wrote to Health and Human Services secretary Otis R. Bowen about Duke. "I view the Duke ERC [Engineering Research Center] as a natural opportunity to join the missions of the NSF and the NIH in our important national thrust to bring science and technology to bear on international competitiveness through centers," he said. "It is apparent that many benefits to NIH, NSF, and the country would be forthcoming if there were much closer cooperation between the agencies, particularly where engineering research and education activities may directly impact health care delivery."

Bowen replied 2 months later with a message like Wyngaarden's: to get money