lected and stored for testing should a problem develop.

These experts considered only Ildstad's proposal, but several other baboon marrow transplants are waiting in the wings. And researchers want to try using other types of xenotransplants to get around shortages of human hearts, livers, and other organs (*Science*, 18 November 1994, p. 1148).

Although the FDA currently has authority to regulate only the transplant of cells and not of solid organs, it is developing guidelines to address concerns about all xenotransplant experiments. The agency will continue to evaluate cellular xenotransplant proposals, but will rely on local research oversight committees to use these guidelines for judging the merits and risks of solid organ xenotransplants.

Based on the committee's recommendations, these guidelines, a draft of which will be available this summer, will require that donor animals be as free as possible of specific pathogens, specify care and quarantine standards for suppliers of donor animals and transplant centers, and urge that blood samples from the donor and recipient—and perhaps those who care for the transplant recipients—be screened for the appearance of unusual pathogens and archived. These data should become part of an international registry. The scientists at this meeting thought these guidelines should preclude the need for a national oversight group similar to the Recombinant DNA Advisory Committee or for new regulations.

–Elizabeth Pennisi

Elizabeth Pennisi is a free-lance science writer in Takoma Park, Maryland.

CONFLICT OF INTEREST

Final Rules Put Universities in Charge

Researchers funded by the National Institutes of Health (NIH) or the National Science Foundation (NSF) will soon have to follow new rules intended to make sure that their financial interests don't influence their research. But it will be up to the researchers and the universities, not the federal government, to decide what constitutes a conflict of interest and what to do about it. As a result, the new policies, announced last week by the Public Health Service (PHS), NIH's parent agency, are drawing a round of applause from universities, which have been fighting a 6-year battle for that authority.

"I think that we got most of what we wanted," says Julie Norris, director of sponsored programs at the Massachusetts Institute of Technology. "It puts the burden where it belongs—on the institution."

The rules require researchers to inform their institutions if they, their spouses, or their dependent children have financial interests—exceeding $10,000 or 5% ownership—in companies that might be affected by their research. It is then up to the institution to decide whether those holdings constitute a conflict of interest, take the appropriate steps to eliminate the conflict, and tell the government that the problem has been resolved. That's how it should be, says George Galasso, NIH's associate director for extramural research and a veteran of past battles. "[University officials] said they didn't want us to call the shots, but we still reserve the right to step in and look at what they have done if we suspect there's a problem," says Galasso.

PHS's effort to develop these rules dates to 1988, after several researchers involved in a clinical trial of tissue plasminogen activator, a genetically engineered anti-clotting agent developed by Genentech, were found to have financial ties to the company. Congress urged PHS to come up with regulations governing such situations. Its first attempt spelled out what constitutes a conflict of interest and put the government in charge of enforcing the rules (*Science*, 29 September 1989, p. 1440). A wave of complaints from the biomedical community led to the withdrawal of that draft, but PHS came up with a more acceptable one a year ago (*Science*, 8 July 1994, p. 179). Last week it issued the final version with a few minor changes. On the same day, NSF announced technical changes to its policy—adopted last year—that bring it in line with the PHS rules. The rules go into effect on 1 October.

Under the new rules, researchers are free to decide which holdings over the threshold "would reasonably appear to be affected by the research," although PHS suggests a broad interpretation, including, for example, holdings in competing companies as well as interests in specific products or processes under study. The next step is up to the institution. Earlier drafts would have required university officials to decide whether a financial conflict existed before a grant proposal was submitted to a funding agency. But the new rules require universities to review conflict of interest materials only if the government decides to fund a proposal.

If the university determines that there is a conflict, it has several options, including public disclosure of the relationship, outside monitoring of the research to ensure its impartiality, modifying the research to avoid any conflict, removing the scientist from the research, or requiring divestiture. "Our preference would be that they get rid of the financial interest," says Galasso. "But that's not always necessary or fair. The important thing is that [the institution] tells us it's taking care of the problem."

PHS estimates that 20,000 researchers each year—about half of those receiving PHS awards—will have financial interests to disclose, but that institutions will only find about 200 cases where a conflict exists. NSF guesses only 23% of the 10,000 investigators it funds will have to file disclosures, and that there will be "significantly fewer" cases of conflict to resolve because the research it funds "is less likely to affect the financial interests" of the individual scientist.

The rules contain some loopholes, federal officials admit. NSF's policy, for example, allows institutions to waive any conflict if they decide that the researcher is uniquely qualified to perform critically important work, and neither set of rules addresses a situation in which the school itself has a financial interest in the outcome of federally funded research on campus. Both sets also assume a good-faith effort by the grant recipients. "It's really an awareness regulation," says Christopher Ashley of NSF's general counsel office. "We expect schools to take their responsibility seriously."

–Jeffrey Mervis

CONFLICT OF INTEREST AT A GLANCE

What's covered:
A significant financial interest means anything of monetary value, including but not limited to salary or other payments for services (*e.g.*, consulting fees or honoraria); equity interests; and intellectual property rights (*e.g.*, patents, copyrights, and royalties from such rights).

What's at stake:
A conflict of interest exists when the designated official(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of Public Health Service (PHS)–funded research.

What can be done:
Examples of conditions or restrictions that might be imposed to manage conflicts of interest include: public disclosure of significant financial interests; monitoring of research by independent reviewers; modification of the research plan; disqualification from participation in all or a portion of the research funded by the PHS; divestiture of significant financial interests; or severance of relationships that create actual or potential conflicts.

SOURCE: FROM THE PHS REGULATION ON OBJECTIVITY IN RESEARCH, *FEDERAL REGISTER*, 11 JULY 1995.