RESEARCH ETHICS

Studies Trace Patchwork Of Conflict Policies

For more than a year since the September 1999 death of a teenager in a gene-therapy clinical trial that had industry connections, scientists, ethicists, and government and university officials have been fretting about conflict of interest. But no one could say just how the nation's universities are policing such conflicts. Now, the answer is finally emerging: It all depends on a researcher's home university.

Requirements for disclosure of outside financial interests vary widely from university to university, according to three recently published studies. Penalties for violations vary, too. Although most policies provide penalties ranging all the way up to termination, university officials have broad discretion in imposing them. All three research teams—headed respectively by S. Van McCrary of Baylor College of Medicine in Houston, Bernard Lo of the University of California, San Francisco, and Mildred Cho of Stanford University—found existing policies wanting.*

McCrary's team collected information from 250 institutions that received at least $5 million in grants from the National Institutes of Health (NIH) or the National Science Foundation in 1998—about an 85% response rate. Cho's group targeted the top 100 institutions receiving NIH grants that year and obtained information from 89. Lo's team analyzed the policies of the top 10 medical schools in terms of NIH grants.

Astonishingly, 15 institutions that received NIH grants in 1998 told McCrary's group that they have no conflict-of-interest policy—a flat violation of the 1995 Public Health Service (PHS) conflict-of-interest regulations. NIH deputy director for extramural research Wendy Baldwin calls this "a little mystifying"—and she is looking into it. Among those that have a policy, 91% in McCrary's survey adopt the PHS threshold that requires disclosure to local administrators of financial interests of $10,000 in annual income or equity, or 5% ownership of a firm whose prospects might be affected by a scientist's research. But only 34% require disclosure of research support from corporations, 73% ask about intellectual property such as patents, and 89% demand disclosures of potential conflicts relating to a researcher's spouse and minor children.

In Cho's survey, 49 institutions require all faculty members to disclose financial interests, but 40 ask for such data only from principal investigators or those conducting research. Only 78 require family members to disclose. Several institutions ban any financial interest in companies that might be affected by a researcher's work, but one allows a researcher to own up to 50% of such a company.

Lo's top 10 medical schools require all faculty members to file disclosures. Five demand information on all financial interests, not just interests above the federal threshold. One bans any financial ties to a company that manufactures the drug or device being studied in a clinical trial. Another prohibits trading in stock or stock options while a trial is under way (a practice that, at some point, would also violate Securities and Exchange Commission insider trading rules). Six require disclosure to the Institutional Review Boards; two of these demand that clinical-trial patients be told, too.

Lo and his colleagues believe that university clinical researchers should be prohibited outright from holding any stock, stock options, or decision-making position in a company that might be affected by the trial. That standard is endorsed in a separate editorial in the same issue of *The New England Journal of Medicine (NEJM)* by Greg Koski, director of the Office for Human Research Protections in the U.S. Department of Health and Human Services, and Jeffrey Drazen, editor-in-chief of *NEJM*. Right now, it would be a hard standard to enforce: According to Lo and his colleagues, only one of the 10 schools even comes close.

SURVEY OF 235 UNIVERSITY CONFLICT-OF-INTEREST POLICIES

Policy Aspects	% Requiring Action
Disclosures required from:	
Investigators	100
Spouse or partner	89
Minor or dependent child	89
Adult child	23
Type of financial interest:	
Income	91
Equity	93
Intellectual property	73
Appearance of conflict	66
Corporate support of research	34

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* The McCrary and Lo studies appeared in the 30 November issue of *NEJM*, and Cho's study appeared in the 1 November issue of the *Journal of the American Medical Association.*

–BRUCE AGNEW

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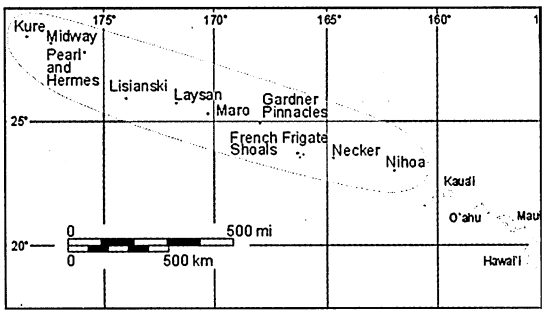
MARINE ENVIRONMENT

Clinton Creates Huge Hawaiian Coral Haven

A 2000-kilometer-long necklace of remote, coral-fringed Pacific islands has become the United States' largest ever protected area. President Bill Clinton last week signed an executive order creating the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve. Marine scientists say that the mega-reserve, which holds nearly 70% of the nation's reefs, will help protect some of the globe's most pristine ocean habitats.



Coraled jewels. The new Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve holds 70% of U.S. reefs.

Last May, acting on a suggestion from a White House Coral Reef Task Force, Clinton ordered Administration officials to devise a plan for protecting the chain of small, mostly uninhabited islands that harbor endangered monk seals, sea turtles, and other fragile populations. After months of meetings with local fishing, conservation, and tourism interests, a committee crafted a plan designed to reconcile opposing views while strengthening protection.

The new 35-million-hectare reserve, for instance, will allow commercial, recreational, and native Hawaiian fishers to maintain current catch levels, but will ban most other new exploitation, from drilling to coral harvesting. In addition, about 5% of the reserve will be set aside in 15 "preservation areas," where most activities will be severely restricted. A council of scientists, fishing officials, and state leaders will shape its future, including a research agenda.

The new reserve encompasses reefs that are "relatively undisturbed," says invertebrate zoologist Scott Goodwin of the Bishop Museum in Honolulu, a recent visitor during a research expedition (explorers.bishopmuseum.org/nwhi). "This is what the main Hawaiian islands must have looked like before there was so much impact from human habitation," he says. "A lot of species are probably going to benefit."

–DAVID MALAKOFF