NIH cash tied to compulsory training in good behaviour

Rex Dalton, San Diego

A sweeping new government policy requiring US researchers and other laboratory staff to undergo training in the "responsible conduct of research" was issued last week. It will begin to take effect late next year.

Under the policy, institutions receiving grants from the National Institutes of Health (NIH), which supports most biomedical research in the United States, must have a plan in place next October to deliver the training in their laboratories.

Courses that researchers will have to take include instruction on ethical scientific conduct, work with human and animal subjects, conflicts of interest, and authorship rules. The health department's Office of Research Integrity (ORI), which drew up the policy, says that a three-hour course, available on compact disc, can meet its requirements. But more comprehensive courses, including group dialogues on case studies, are expected to become the norm.

By October 2003, all personnel involved in research — principal investigators, postdocs, students and lab technicians — must have been trained to conduct studies under a Public Health Service (PHS) grant (the NIH is part of the PHS). Institutions or laboratories that fail to implement the training face losing all PHS research funds.

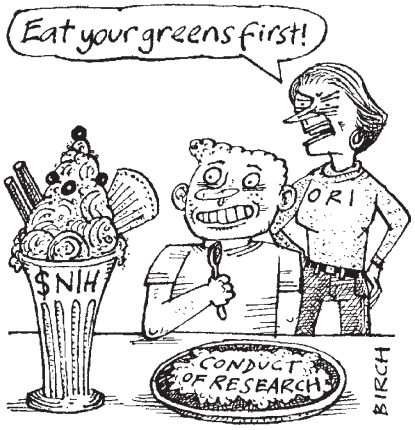
Chris Pascal, the ORI's director, says he hopes his agency has struck an appropriate balance in the new training policy. "We don't believe institutions will fight it," he says.

But when researchers learned of the development last week, they expressed some concern about the time the training would take. At the Salk Institute in La Jolla, California, virologist Matthew Weitzman said that junior principal investigators such as himself may consider the training unnecessary. "As junior investigators, we are already overburdened," he says, adding that the training may be perceived as just another burden.

But neuropharmacologist Michael Kalichman, director of the research ethics programme at the University of California at San Diego, says he expects the new training courses to win converts at all levels — as have voluntary courses in research ethics.

For Sheldon Krimsky, a professor of urban and environmental policy at Tufts University in Massachusetts, the new policy represents "an important first step" in acknowledging the problem of scientific misconduct. Proper ethics "have to be built into the scientific culture", says Krimsky.

The ORI, which monitors scientific conduct for NIH grants, issued the policy



after several months of discussions with universities and institutions that had followed several years of informal debate.

The National Science Foundation, which supports most non-biomedical research at US universities, is not planning to introduce similar training. But, historically, other research agencies in the US government have sometimes followed the ORI's lead on issues related to scientific misconduct.

For nearly a decade, the ORI and associated government agencies have relied on research institutions to monitor, investigate and report on the conduct of scientists receiving grants. The ORI oversees this process, which can lead to penalties — from warnings to debarments — for misconduct.

High-profile incidents in recent years — including instances of mistakes in clinical trials, researcher conflicts of interest and data fabrication — have prompted the government to add the more stringent training requirements in a bid to strengthen scientific ethics, officials say.

Although some universities are already planning their own training programmes on the conduct of research, only a handful of the 300 major research institutions operate them now. Some of those that do, such as the University of Minnesota, set them up as part of a remedial plan after particular instances of research misconduct.

The new policy was welcomed by leaders of research institutions and by organizations that had criticized earlier ORI proposals. An official at the Council on Governmental Relations, which represents leading research universities, called the proposal "well-researched and thoughtful". Some university representatives had rejected the training proposal as overly prescriptive and bureaucratic. But concessions by ORI on the timing and extent of the training proposal appears likely to blunt university opposition. ■

http://www.ori.hhs.gov

France opens door to use of embryos in stem-cell research

Declan Butler, Paris

The French government is to submit a bioethics bill to parliament that would lift its ban on human embryo research.

The decision was widely expected, but some observers are surprised that the bill does not expressly prohibit therapeutic cloning of human embryos to create embryonic stem cells. Last month, advisers to the European Union concluded that such a move would be "premature" (see *Nature* 408, 277; 2000).

But the bill will state that it should "not be excluded *a priori*", says Roger-Gérard Schwartzenberg, the research minister and chief sponsor of the measure, as it may become necessary should other techniques fail. He points out that cells or tissues derived from embryonic stem cells produced by cloning for transplantation would not be rejected by the patient's body.

The bill — an update of France's 1994 bioethics legislation — would allow research on embryos left over from *in vitro* fertilization procedures. Research would be restricted to embryos less then 6–7 days old and to circumstances in which no effective alternatives existed.

Protocols would be evaluated and overseen by a proposed new government-appointed body. This would be responsible for human reproduction, developmental biology and genetics, and predictive medicine.

The bill has been drafted largely by the pro-science research ministry. Government officials predict that it will face a rough ride through the conservative senate, and perhaps even the parliament, where a Socialist-led coalition holds a majority.

Opponents will argue that creating embryos for research runs counter to the European convention on bioethics, which France has signed, and that the proposed therapeutic cloning provisions would prevent France from ever ratifying the convention.

AFP

Research minister Schwartzenberg will not rule out cloning.

Others say that the bill is calculated to defer difficult decisions. "The new authority will rule on a case-by-case basis, meaning that decisions will be postponed until four or five years down the line," says one official. ■