Higher status for 'research risks' office?

[WASHINGTON] The future of the office that protects human subjects in much US biomedical research is likely to be decided by a report soon to be delivered to Harold Varmus, the director of the National Institutes of Health (NIH).

Whether the Office for Protection from Research Risks (OPRR) should remain in the NIH, or be elevated to the office of the secretary of the Department of Health and Human Services (DHHS), is being considered by a six-member panel put together by Varmus last autumn.

The two co-chairs of the panel declined to comment on the report's contents, pointing out that these are not final. But there is belief in Washington that the group is likely to recommend the office's elevation to the DHHS.

The group is also charged with deciding whether the office needs more authority to ensure that thousands of institutions and government workers conducting DHHS-funded research worldwide comply with regulations protecting animal and human subjects.

The panel was planning to debate its draft report in a conference call scheduled for yesterday (17 February). It will then go "as soon as humanly possible" to Varmus, says Nancy Neveloff Dubler, one of the panel's co-chairs, a professor of bioethics at the Albert Einstein College of Medicine in New York.

According to Dubler, although the issue of research with human subjects has attracted relatively little attention for a long time, it is now under increasing scrutiny. "This comes at an important moment," she says.

For instance, the ethics of psychiatric research in which subjects receive drugs that induce symptoms, or are withdrawn from medications and become symptomatic, have received widespread media attention. As a result, the National Institute of Mental Health has set up a panel to provide an additional layer of scrutiny for such experiments.

The OPRR's effectiveness was questioned at a Congressional hearing last year (*Nature* **393,** 610; 1998), where Congressman Christopher Shays (Republican, Connecticut) called it "pathetic" that the office had only one full-time investigator into human subjects on its staff of 29 (three employees also work as investigators part-time), the rest primarily being administrators.

The weaknesses of the office were also documented in a separate report last year by the DHHS inspector-general, and a report two years earlier by the General Accounting Office (GAO). Among other problems, critics point out that the office's budget, at $2.1 million in 1998, has declined as the amount of research it is required to monitor has grown.

But perhaps the chief concern of critics, including the GAO, is what they call an inherent conflict of interest in the office operating within the NIH, where it is in the Office of Extramural Research. "It is very difficult to monitor human subjects' protection from within an agency that has as its primary mission the advancement of research," says Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania.

The GAO report, for instance, stated that in one case it took five years for intramural scientists at the NIH to implement corrective actions that had been required by the OPRR.

At a Congressional hearing in 1997, Varmus denied to Shays that a conflict existed, arguing that the OPRR had no vested interest in research progress. That Varmus set up the committee — which will officially report to his advisory committee — appears to signal his readiness for the office to be moved.

Some argue that placing the OPRR directly under Donna Shalala, the secretary of health and human services, would still not guarantee the office the independence it needs in the face of the rapid expansion of US biomedical research.

John Fletcher, for example, emeritus professor of bioethics at the University of Virginia, has proposed that the office be an independent entity within the government, like the Nuclear Regulatory Commission. "This is a national issue," he says. "The NIH is a major research institution, but it is one among many. The agency would have more respect and influence if it were independent."

Others argue that, wherever it is located, the OPRR needs a significantly larger budget. "A 'mom and pop' store is no longer adequate when a supermarket is required," says Caplan.

Meredith Wadman

Congressman aims to punish cloning research

[WASHINGTON] In a warning shot in the battle on human cloning, a conservative Republican has introduced a bill banning federal payments to any business, institution or organization that "engages in human cloning or human cloning techniques".

Congressman Ron Paul (Republican, Texas), a former obstetrician and gynaecologist, says his bill has been crafted to avoid inhibiting research: "It just means that universities and medical centres that set out to clone people get their funds cut off." But biomedical researchers have described the proposal as "massively punishing".

The bill, which was introduced two weeks ago, has so far won no co-sponsors, and Paul, a junior member of Congress, has little power to move it without patronage from more senior Republicans. However, it is symbolic of conservative opinion on cloning.

David Korn, senior vice-president for biomedical and health sciences research at the Association of American Medical Colleges, says the bill goes further than the existing ban on human embryo research, as it would cut all federal funding to institutions where researchers use somatic-cell nuclear transfer, even if they do so with private funds. (The present ban allows privately funded embryo research.)

Paul: wants funding ban.

Furthermore, says Larry Goldstein, a professor of cellular and molecular medicine at the University of California, San Diego, the definition of 'human cloning' in the bill is so ambiguous as to potentially prohibit stem-cell research.

The bill defines human cloning as "making an identical ... copy of the genetic material of an individual ... so as to cultivate one or more new human cells which could, if not otherwise engineered, develop into a new individual human being".

While it is believed that stem cells isolated from unused embryos left over from fertility treatments could not grow into a human if they were implanted in a uterus (*Nature* **396**, 104; 1998), this is not known for certain and cannot be proved without experiments that are themselves considered unethical. As a result, says Goldstein, the bill would at the least allow legal challenges to stem-cell work.

Paul disputes that interpretation, saying that stem-cell research would be protected. But he makes no apologies for seeking to ban any cloning that would produce a human embryo not destined for life, even though this technique could aid the development of cell and tissue therapies.

Meanwhile, the American Society for Cell Biology met around 30 representatives of scientific and patient groups last week to discuss their approach to the stem-cell research issue on Capitol Hill. Forty-five groups have signed a letter to Congress applauding a recent legal opinion by the Department of Health and Human Services that federal funding of stem-cell research is allowed under the current law (*Nature* **397**, 185; 1999).

M. W.