Message: 3
Date: Wed, 13 Sep 2000 13:02:49 -0500
From: "Sally Eckert-Tilotta" <sally_eckert-tilotta@mail.und.nodak.edu>
To: <mcwirb@mcwirb.org>
Subject: Chronicle of Higher Education article - Dr. Koski's views

The following article is in the Chronicle of Higher Education's Today's News.

New Director of U.S. Human-Research Office Says System Is in Need of Repair

By JEFFREY BRAINARD

Washington

The United States' system for protecting human research subjects is "dysfunctional" and needs some significant changes, said the new director of the main federal agency responsible for protecting them. E. Greg Koski said on Tuesday that he was considering a variety of reforms, including increased public participation in the review process and a new role for university review boards.

In his first public remarks since becoming director of the Office of Human Research Protections on Monday, Dr. Koski offered a preliminary, general road map for change at a meeting of the National Bioethics Advisory Commission. The panel advises the president about federal policies and rules, and its members are crafting a report, due later this year, that will offer recommendations for improving protections for research subjects.

Dr. Koski outlined a dual approach. He wants to encourage scientists, universities, and institutional review boards, or I.R.B.'s -- the university review boards that approve and monitor research involving human volunteers -- to improve protections voluntarily. At the same time, oversight of research should improve, and scientists who do not protect volunteers adequately should be barred from research, he said.

Instead, he said, I.R.B.'s have focused too heavily on paperwork and procedure and have little contact with research subjects or scientists.

Many scientists and I.R.B.'s want to ensure adequate protections, Dr. Koski said. He told the bioethics commission that he would focus on encouraging all scientists, institutions, and I.R.B.'s to collaborate more closely to achieve that goal. This closer cooperation, he said, is critically important for establishing a system that better promotes the quality of protections, and better monitors that quality.

"I realize that this is certainly idealistic in one dimension, and we cannot lose sight that oversight is critically important," he said. He added, "We can simply no longer have a system where research is approved and continues on an ongoing basis with no oversight of the conduct of the research."

He told the bioethics commission that he was not yet ready to propose specific changes, but instead offered some general ideas.

Dr. Koski -- a former associate professor of anesthesiology at Harvard Medical School who directed the office of research oversight for three of the university's teaching hospitals -- supported the development of more-uniform national standards to guide the decision-making of I.R.B.'s. Some I.R.B. members have expressed difficulty interpreting federal regulations.

I.R.B.'s should probably include more nonscientists and members of the public, he added. Currently, the review boards are generally required to have no more than one representative from outside the institution to represent the public. Critics of the current system have said that that tends to bias I.R.B.'s in favor of approving research projects. But some scientists have worried that including more lay representatives on I.R.B.'s could bog down their work.

In addition, Dr. Koski said, regulations may evolve to allow several universities to establish a single, joint I.R.B. to review all of their research projects.

Currently, institutions that receive federal research funds generally are required to have their own, in-house I.R.B.'s.

Dr. Koski said that having one I.R.B. serve several institutions might help to distance the I.R.B. from any one institution, thus reducing the inherent conflict of interest that some critics see in the current system.

Universities also need to find ways to reward investigators for exemplary work at protecting research subjects, he added.

After his presentation, Dr. Koski said that he expected to receive a "significant" increase in the budget and staffing for his office in next year's federal budget. The Office of Human Research Protection has succeeded the Office for Protection from Research Risks, a unit of the National Institutes of Health that had an annual budget of $3-million and a staff of 26.

The N.I.H. unit had been variously criticized as ineffective and overaggressive, and Dr. Koski indicated a desire for a fresh start for his office. The Office of Human Research Protections has been moved out of the N.I.H. and will report to the assistant secretary for health in the Department of Health and Human Services.

"This is a new office with a new mandate," he told the bioethics commission. "This will, I believe, for the first time enable us to take the important steps that are required to meet these goals" of improving protections for research subjects. "I take this responsibility very seriously, and we expect others to do the same."