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Rule Changes Proposed for Research on Humans

By ANDREW POLLACK

The government is proposing sweeping changes in the rules covering research involving human subjects, an effort officials say would strengthen protections while reducing red tape that can impede studies.

The officials said the changes were needed to deal with a vastly altered research climate, whose new features include genomics studies using patients' DNA samples, the use of the Internet and a growing reliance on studies that take place at many sites at once.

"These are the first substantial changes that have been made to the rules governing human subjects in decades, so this is really quite a historic moment," Kathy Hudson, a deputy director of the National Institutes of Health, said in a telephone news conference on Friday.

The changes would be in the rules that cover topics like the informed consent that research participants must provide and the institutional review boards that oversee research at universities and hospitals. Initially drawn up by the Department of Health and Human Services in the 1970s and '80s, the system was adopted by 14 other federal agencies and departments in 1991 and became known as the Common Rule.

But some experts said it had become too cumbersome.

"It's a terrible drag on getting good research done," said Dr. Robert J. Levine, a professor of medicine and a bioethicist at Yale who headed the university's institutional review board for 31 years. He said Sunday that while he had not thoroughly reviewed the government's lengthy proposal, he was encouraged by what he had seen.

The process is still at an early stage. The government has described possible changes and asked for public comment over the next 60 days; after that, specific rules will be formulated and again sent out for comment.

The government said its proposal was consistent with President Obama's executive order in January calling on agencies to weed out unnecessary regulations. But some of the proposed changes would add regulation.

One change would expand the rules' coverage to all studies conducted at institutions that receive money from any of the 15 federal agencies that have adopted the Common Rule. For example, if a university gets financing from the National Institutes of Health, then even a study at that university paid for by a drug company would be covered by the rules.

While that would encompass more medical research, it was not clear whether trials financed by drug companies and conducted at individual physicians' offices would be covered.

Another proposed change would allow a single institutional review board to oversee studies that take place at multiple sites.

Right now, the institutional review board at each location generally must endorse a trial, which can lead to long delays. Federal officials said that besides eliminating redundancy and delays, having a single reviewer that is truly accountable for its decisions might actually strengthen oversight.

Other proposed changes would be aimed at making it less cumbersome to do surveys or other social science research in which the risks to participants are usually less than for medical studies.

Carl Wieman, associate director for science at the White House Office of Science and Technology Policy, said it was now difficult to observe teachers and students in classrooms to help determine what makes a good teacher, given all the consent required. "You're not doing anything here except watching people," he said.

Another possible change would be that donors of blood, DNA or tissue samples would be asked to give consent before those samples could be used in subsequent research. Now, if the identity of the donor cannot be determined, samples can often be used for further research without permission. But Dr. Hudson, of the health institutes, said that with modern DNA sequencing, biological specimens are "inherently identifiable." So the proposal would make consent required.