

Panel told no guarantee against unethical research

March 1 2011, By MIKE STOBBE , AP Medical Writer

(AP) -- The nation has a "leaky system" for protecting patients in medical research, and it's possible - though unlikely - that the kind of unethical studies done in the past could occur again, bioethics experts told a presidential panel Tuesday in Washington.

The meeting was triggered by the government's apology last fall for federal doctors infecting prisoners and mental patients in Guatemala with [syphilis](#) 65 years ago.

The Presidential Commission for the Study of Bioethical Issues was told to explore the question of whether such a study could ever happen again. On Tuesday, the commission held its first public meeting on the topic and heard testimony from bioethicists, researchers and a historian.

Speakers noted that over the last several decades, as many as 1,000 ethical rules, regulations and guidelines have been enacted globally to ensure the ethical conduct of medical research. In the United States, there are rules to protect people in every study done by federal scientists, funded by federal agencies or those testing a product requiring federal approval to be sold.

But that oversight is inconsistent - ethical rules can vary among federal agencies. What's more, if federal funding or review is not involved, an unethical study could be done and no one in authority would ever know about it.

"We have a leaky system," said Eric Meslin, director of the Indiana University Center for Bioethics.

Dr. Robert Califf, Duke University's vice chancellor for clinical research, agreed there are weaknesses.

"It's night and day and what you could do in the 'good old days' with no one knowing about it. But there's no 100 percent guarantee. There still will be bad things that will happen," he said.

The commission, ordered to report to President [Barack Obama](#) by September, was given two tasks:

- Examine federally funded international studies to make sure research is being done ethically. The commission named a 14-member international panel of experts to study the question.

- Take a more intensive look at the Guatemala study. More than a dozen commission investigators have already started poring through hundreds of boxes of old government documents.

What they will turn up is unknown, but there are doubtless more unethical studies from the past that have never been publicly reported, said Susan Lederer, a medical historian at the University of Wisconsin.

On Sunday, The Associated Press reported on dozens of studies from the past - most of them between 40 and 80 years ago - involving researchers deliberately infecting people to study the effects of diseases or to see if an experimental treatment might work.

The AP investigation itself was triggered by the Guatemala study.

At Tuesday's commission meeting, Lederer was the most pessimistic of

five guest speakers about whether that kind of research could happen again.

"I don't think you should look to historians for optimism," she said.

More information: The Commission Web site:
<http://www.bioethics.gov/>

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