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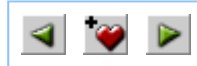
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Bio-Warfare Research in the USA Threatens Public Health & Safety

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Major US universities involved in recombinant-DNA research into diseases like anthrax and plague are failing to comply with the National Institutes of Health biosafety guidelines.

Elisa D. Harris, a senior research scholar at the Center for International and Security Studies at the University of Maryland, says it is time to replace the guidelines with a comprehensive laboratory-safety law that would cover all research institutions.

Philip Chandler, of the biosafety committee at the Medical College of Georgia, agrees saying the guidelines have given colleges too much "poetic license".

Biosafety Committees Come Under Scrutiny As the panels are about to take on a wider role, investigations find flaws in their work

By KELLY FIELD

Tulane University, in New Orleans, is a biomedical-research powerhouse. A partner in two federally financed biodefense-research consortiums, the university operates one highly secure Biosafety Level 3 laboratory and is building three more. The university's scientists are developing vaccines against anthrax, plague, and other diseases.

Yet when Edward Hammond, director of the Sunshine Project, a private, international group that seeks controls on biological weapons, asked the university for copies of the minutes from the last two meetings of its

Institutional Biosafety Committee, Tulane could not provide any. The chairman of the committee, which is responsible for ensuring the safety of recombinant-DNA research, said that members had conducted their business by telephone and e-mail until 2004.

Mr. Hammond says that practice was a violation of federal guidelines that require institutions that receive grants from the National Institutes of Health to hold meetings to review detailed, formal plans for research, known as protocols, and to record their votes in minutes. He is asking the NIH to cut off funds to more than a dozen universities like Tulane that failed to comply with his request. The agency says it is investigating every complaint but has not yet taken action against any university.

The investigations come at a time when the nation's roughly 400 biosafety committees are preparing to take on new oversight responsibilities. Historically charged with protecting human health and the environment, the committees have been tapped to review dual-use research -- experiments that could be misused for terrorist or offensive military purposes. Mr. Hammond, who evaluated 218 college and university biosafety committees based on their response to his request for minutes, says that institutions are ill prepared for this new role. He argues that it would be "unsound, and potentially dangerous" to broaden their mandate.

But the biosafety committees and the NIH's Office of Biotechnology Activities, which is conducting the investigations of the Sunshine Project's complaints, say that many universities have simply misunderstood the guidelines, which are broadly written and allow for multiple interpretations. To clarify its expectations, the biotechnology office issued two memoranda to institutional biosafety committees, or IBC's, last year, and plans to begin site visits to institutions soon.

"We want to bring the quality of IBC's up to a common level," said Allan C. Shipp, director of outreach for the Office of Biotechnology Activities.

A New Role

Created in 1976 to monitor the then-nascent field of recombinant-DNA research, which studies alterations of genetic material, institutional biosafety committees are governed by a 130-page NIH document that details safe practices and containment procedures for experiments. The guidelines require universities that receive grants from the NIH to register their committee with the agency, and to file an annual report updating their committee's roster. They also direct institutions to make committee minutes available to the public upon request, and to open meetings to the public when possible.

While the guidelines do not carry the force of law, universities risk losing their NIH money, or having to obtain prior approval from the NIH for any recombinant-DNA projects, if they do not comply.

To date, the biosafety committees have been primarily concerned with safety and physical containment. However, in 2003 a National Academy of Sciences panel recommended making the IBC system "the first review tier for experiments of concern." Such experiments would include studies designed to create vaccine-resistant microbes, enhance the virulence of a pathogen, or "weaponize" a biological agent or toxin. It also proposed a new national advisory board to provide general guidance and case-specific advice to the biosafety committees.

W. Emmett Barkley, the director of laboratory safety at the Howard Hughes Medical Institute and a member of the academy panel, said that biosafety committees were chosen because they assess research at its earliest stages, when "thinking regarding dual-use concerns should begin." He said the value of IBC's is evident in the "safe blossoming of the field of recombinant-DNA technology." The Bush administration has embraced this plan, and in March 2004 enthusiastically announced the creation of a 25-member National Science Advisory Board for Biosecurity. Its first task was to develop guidelines for the oversight of dual-use research.

More than a year later, however, the board's members have not been named, and some scientists are questioning the president's commitment to biosecurity. One member of the academy panel, Ronald M. Atlas, co-director of the Center for Deterrence of Biowarfare and Bioterrorism, at the University of Louisville, said the delay has "left the community in limbo," and "sent mixed messages as to whether the government sees this as a critical issue." A spokesman for the NIH said that the board is being formed and will hold its first meeting June 30 and July 1. Thomas V. Holohan, a physician who has served in the U.S. Public Health Service and in the Veterans Health Administration, was appointed as the board's executive director in January.

Other scientists say that the IBC system is too dysfunctional to take on such an ambitious new role. Mark Wheelis, a senior lecturer in microbiology at the University of California at Davis and an expert on biological weapons, said that biosafety committees have to "start taking their responsibilities seriously" if they are going to assume a role in biosecurity.

"They are going to have to start acting as a critical, authoritative review board rather than a rubber stamp," Mr. Wheelis said.

The Survey

Mr. Hammond's investigation of IBC's began in January 2004, when he sent faxes to nearly 400 universities, nonprofit institutes, government laboratories, and private agencies asking for copies of the minutes from their last two biosafety committee meetings. He also asked the recipients whether they were registered to handle any of the more than 60 dangerous microbes and toxins that the federal government classifies as "select agents." The request generated a buzz on electronic mailing lists for biosafety officers and college attorneys, as recipients of the faxes debated whether, and how, to reply. One biosafety officer volunteered to compile a list of who had, and who had not, responded. Another vowed to respond "when and only when directed by the NIH to do so."

By late March, when 70 percent of the recipients had responded, Mr. Hammond sent follow-up faxes to dozens of universities reiterating his request. On May 3, he filed his first complaint with the NIH, asking the agency to suspend payments to nine institutions that had not replied.

Ultimately, 82 percent of public universities and 79 percent of private universities replied to the request -- a far better response rate than among biotechnology companies, 45 percent of which replied. However, only two-thirds of public universities and 57 percent of private universities polled produced minutes containing protocol review, and a number of universities refused to answer the select-agents question. While the federal government does not bar institutions from disclosing that information,

universities are not legally obligated to do so.

Several of the universities that failed to provide minutes told The Chronicle their meetings were via e-mail at the time of the survey. The Medical College of Wisconsin said its biosafety committee reviewed 222 research protocols between January 2001 and June 2004, but could not provide documentation beyond a pile of approval letters. Rockefeller University said its committee reviewed 161 protocols between January 2000 and July 2004, but provided only one set of minutes from that period. It said that the electronic record -- including member polls -- is not subject to public-disclosure requirements.

While the NIH guidelines do not specify how the committees should meet, Mr. Shipp of the Office of Biotechnology Activities said that committees must be convened to meet the guidelines' records-keeping and open-meeting requirements. Both Tulane University and Rockefeller University say their IBC's began meeting in person after Mr. Shipp's office issued new guidance on minute-taking last spring. The Medical College of Wisconsin says it will hold its first face-to-face meeting in May.

Other universities provided minutes that focused mainly on administrative matters, not on protocol reviews. One of them, the Medical College of Georgia, said it had omitted the information on protocols to preserve the anonymity of its researchers. It now uses numbers to obscure researchers' identities. Emory University said that protocols were reviewed, but not by the full committee, and not in a formal meeting. The full committee began voting last fall.

Richard H. Ebright, a professor of chemistry and chemical biology at Rutgers University at New Brunswick, said such lapses show that IBC's are not fulfilling their current responsibilities and are "most definitely not well positioned to assume additional oversight of dual-use research." Mr. Atlas, the National Academy of Sciences panel member, acknowledged that some IBC's have been "lax," and that some researchers do not take biosafety review seriously enough. But he said that the system can be fixed, and IBC's can take on new responsibilities if universities, and researchers, start viewing the committees as important.

"Rather than saying that things are broken, we need to say, 'If they aren't working, let's fix them,'" Mr. Atlas said. "If this is the impetus to fix the whole system, well and good."

More Regulation Needed?

The Office of Biotechnology Activities will not say whether it plans to penalize any universities, but says that it is systematically investigating every complaint filed by Mr. Hammond. Several institutions said the office has contacted them, and Utah State University provided a copy of its response to a letter from the NIH seeking evidence that the committee was fulfilling its role.

But Mr. Hammond says that the biotechnology office has been too easy on IBC's, preferring guidance over punishment. Over the last 30 years, the Office of Biotechnology Activities has cut off NIH funds only once, when a professor took a gene-therapy study abroad to circumvent review.

"They like to think of themselves as being the nice-guy enforcer," Mr. Hammond said. "Now is the time to use the stick instead of the carrot. It

was time to use the stick years ago." The NIH's Mr. Shipp acknowledges that the relationship between the NIH and institutional biosafety committees is largely based on trust. The agency does not collect IBC minutes to confirm that they are reviewing research, and it does not require biosafety committees to certify that they are in compliance, as it does with institutional review boards.

Institutional review boards, which are responsible for ensuring human subjects protection in research, are governed by federal law.

Elisa D. Harris, a senior research scholar at the Center for International and Security Studies at the University of Maryland at College Park, said it is time to replace the guidelines with a comprehensive laboratory-safety law that would cover all research institutions.

At least one IBC chairman agrees. Philip Chandler, of the biosafety committee at the Medical College of Georgia, said the guidelines have given colleges too much "poetic license," and replacing them with a law would "remove the inconsistencies."

"People who like to flout guidelines can't flout rules," he said.

But Mr. Barkley, of the Howard Hughes Medical Institute, said it would be a mistake to regulate biosafety committees.

"What we have is an approach where the scientific community really joins in assessing issues of importance" in biosafety, he said. "A regulation might constrain that openness."

BREACHES IN BIOSAFETY APPROVALS AT MAJOR RESEARCH UNIVERSITIES

Early last year, Edward Hammond of the Sunshine Project, a watchdog group, sent a flurry of faxes to institutional biosafety committees at nearly 400 universities asking for copies of the minutes from their two most recent meetings. The biosafety committees review research involving recombinant DNA-- alterations to genetic material -- at institutions that receive funds from the National Institutes of Health.

The responses to Mr. Hammond's request revealed that many of the committees were not complying with NIH guidelines governing public access and recordkeeping. The NIH is investigating several of those committees, and could withhold money from any universities it finds at fault. Here are some major universities that were found to be falling short.

* Emory University Response to the Sunshine Project survey: The university provided copies of minutes from three meetings held between 2001 and 2003, but none of these included reviews of proposed research.

* Tulane University Response to the Sunshine Project survey: The university did not provide minutes, and sent a letter saying it had "no documents that are responsive to your request."

* University of Hawaii-Manoa Response to the Sunshine Project survey: The biosafety officer provided copies of minutes from two meetings, but later acknowledged that he created those from memory for the benefit of the Sunshine Project.

* Utah State University Response to the Sunshine Project survey: The university provided a copy of minutes from February 2004, along with a list of research projects approved by the committee between 1998 and 2003. When subsequently asked for minutes dating back to January 2000, the university did not reply.

* Washington University in St. Louis Response to the Sunshine Project survey The university told the Sunshine Project it could review the minutes on site, but would not provide copies.

[See the rest of this Table including 'University's explanation to The Chronicle' and 'NIH Office of Biotechnology Activities' response.](#)

SOURCE: [Chronicle reporting](#)

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