

The first academic year since 11 September brings with it much greater oversight of research—along with huge opportunities for bioterrorism funding

One Year



Regulatory heft. Complying with new bioterror research rules is keeping Cheri Hildreth Watts of the University of Louisville busy this fall.

Tighter Security Reshapes Research

When the University of Louisville in Kentucky drew up floor plans for a \$48 million science building to house its chemistry, biology, and engineering departments, officials gave serious thought to placing faculty members' offices next to their labs. The layout promised greater convenience and efficiency over the traditional separation into administrative and research spaces. After 11 September, however, convenience and efficiency gave way to security: Offices and labs would be put in separate wings, so that students who might not have clearance to work in a lab could still meet with their professors.

Across the country, in hundreds of ways both large and small, U.S. academic researchers are feeling the effects of that catastrophic day on their ability to carry out science. The airplane hijackings, and subsequent anthrax mail attacks, have triggered sweeping changes in the regulatory environment on campus. Next week, for instance, universities and other research facilities must notify the federal government if their researchers possess any potential bioweapons—the first step in registering users of such so-called select agents (*Science*, 31 May, p. 1585).

In the meantime, the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, has already announced proposed changes to its list. In the weeks ahead, that will be joined by a similar compilation of potentially lethal agricultural materials to be issued by the U.S. Department of Agriculture. Then there are pending rules for securing the labs where these agents are kept and for restricting the pool of scientists allowed to work with them, for example, by excluding felons and researchers from so-called terrorist states.

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Hunt for NIH Funds Fosters Collaboration

Picking the right name was important when infectious-diseases researchers at the University of California (UC), Davis, decided to join forces in an ambitious new center earlier this year. After several false starts, one name stuck: The Western National Center for Biodefense and Emerging Diseases (WNCBED). It might be a mouthful, but Frederick Murphy, who masterminded the nascent center, says that it's perfect for the post-11 September funding environment. "Western" locates it on the U.S. map, he says, and "national" proclaims its coast-to-coast ambitions. "Biodefense" demonstrates concern for protecting the country, and "emerging diseases" conveys the message that most disease outbreaks still have natural causes.

Such attention to detail is essential when the stakes are so high. Congress is now debating President George W. Bush's request for \$1.75 billion for the National Institute of Allergy and Infectious Diseases (NIAID) to fight bioterrorism. The 2003 request, a 2000% increase from the institute's pre-11 September budget for bioterrorism, is a direct result of the terrorist attacks on New York City and Washington, D.C., and the subsequent anthrax mailings in several states. It's also an unprecedented commitment to increase understanding of organisms that can be fashioned into terrorist weapons. The budget dwarfs the \$133 million requested by the Defense Advanced Research Projects Agency for its biological warfare defense program; another key agency, the Centers for Disease Control and Prevention, wants \$1.6 billion next year primarily to beef up public health infrastructure and buy drugs and vaccines. That leaves NIAID as researchers' favorite funding agency, and getting a slice of the pie has become almost a full-time job for some.

With advice from several expert panels, NIAID has begun to



Grand plans. The University of California, Davis, hopes the new NIH program will help fund a \$190 million bioterrorism research center, including a biosafety level-4 lab.

CREDITS: (TOP TO BOTTOM) TOM FOUGEROUSSE/UNIVERSITY OF LOUISVILLE; UC DAVIS

PROFILE:

Janet Shoemaker, Shaping the Politics of Bioterrorism

It was a classic Washington moment: After a long and sometimes contentious congressional hearing on bioterrorism earlier this year, a harried staffer clutching a sheaf of papers sought out a crisply dressed woman chatting with reporters. "Here's the latest; let us know what you think," he said.

The invitation—to review a confidential draft of a bill to regulate research on potential bioweapons—is the kind typically extended to only a select group of the most influential lobbyists. And on the issue of regulating biological research in a post-11 September world, that group includes Janet Shoemaker, head of public affairs for the American Society for Microbiology (ASM).

"[Shoemaker] is incredibly knowledgeable; we all turn to her for expertise," says Anthony Mazzaschi, a lobbyist with the Association of American Medical Colleges in Washington, D.C. She's also politically savvy. Shoemaker "knows when to let an issue drop and where and when to stand and fight," says Representative Billy Tauzin (R-LA), chair of the House Government Affairs committee, which crafted the bioterrorism bill that Congress approved in June. He credits her with having "a positive impact" on the legislation.

A Minnesota native with degrees in history and public policy and a "longtime interest" in science, Shoemaker joined ASM 25 years ago and has headed its office of public affairs since 1989. In that job, she has become an expert on bioterrorism policy's impact on research and ASM's unofficial liaison to a government increasingly worried about potential bioweapons.

Since the 11 September and subsequent anthrax attacks, Shoemaker and ASM scientists have had to shift into high gear. They persuaded lawmakers drafting the antiterrorism Patriot Act, which passed last October, to exempt "bona fide" researchers from its harsh criminal penalties for possessing select agents. And they altered language barring all foreign scientists from working with the

agents, limiting it to a ban on scientists from nations tagged as sponsors of terrorism.

The Patriot Act wasn't the only instance of Shoemaker's ability to modify extreme proposals. When some lawmakers drafting the bioterror bill suggested banning all research on select agents, Shoemaker arranged for ASM scientists to explain why that idea would doom efforts to develop new treatments and vaccines. "[Shoemaker] had a major impact on the bill," says George Leventhal, an ally and lobbyist at the Association of American Universities in Washington, D.C.

That impact is unusual in the small world of science policy, notes Edith Holleman, a Democratic staffer on Tauzin's committee. "It's not as if members of Congress get up and say: 'I have to respond to the microbiologists today,'" she says. Shoemaker has earned their respect, Holleman adds, by "always being responsive. When we ask for a position, we get a position." —D.M.



Microclout. Janet Shoemaker has helped make the American Society for Microbiology a major player in the bioterrorism debate.

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"We're all getting used to a new landscape for research," says molecular biologist Nancy Martin, vice president for research at Louisville, one of many schools scrambling to adapt. "It will take some doing."

Eager to plug security gaps, Congress and

agency officials have set tight deadlines for complying with the new regulations. On most campuses, a disproportionate share of the burden has fallen on the university's environment, safety, and health (ESH) officers. At Louisville, that means Cheri Hildreth Watts, whose office is piled high with new, security-related paperwork.

For 15 years, Watts has led the university's efforts to comply with a growing list of federal ESH requirements. A nationally recognized expert on the subject, she helped found a 50-university group that develops and shares best practices. But even she is having a hard time keeping pace with the government's rush to regulate potential bioweapons.

The first step requires every life sci-

ences researcher to disclose to university officials and the government by 10 September whether they are working with any of about 40 agents that could be potential bioweapons, such as plague or anthrax. At Louisville, that meant getting hundreds of scientists and graduate students to interrupt work and vacations and crack open storage freezers, then fill out the necessary forms. The next step, to be completed early next year, will be for researchers to formally register their collections with CDC.

"It's been a deluge, a whirlwind, and it's not going to stop," says Watts, noting that government agencies have issued six regulatory notices on the subject in recent months. The welter of paper has left university officials to ponder questions such as whether live poisonous snakes and lizards have to be reported because they manufacture regulated toxins (they don't). "The incentive to get it right is very high," she adds, because universities and researchers who don't comply face stiff, potentially criminal, penalties—as a graduate student at the University of Connecticut recently discovered (*Science*, 2 August, p. 751).



Timely rules? University of Louisville biochemist Russell Prough (left) says complying with new bioterror rules was a snap but that the growing number of federal regulations is eating into research and teaching time.

CREDITS: (TOP TO BOTTOM) RICK KOZAK; TOM FOUGEROUSSE/UNIVERSITY OF LOUISVILLE

Support from senior Louisville administrators—including Martin and graduate dean Ronald Atlas, a nationally known bioterrorism expert who helped shape the new law as president of the American Society for Microbiology—has helped the process go “pretty smoothly” on her campus, Watts says. Louisville biochemist Russell Prough says it took him “just a few minutes” to confirm that he didn’t deal with any of the agents in his four-person lab. But some scientists chose to avoid greater paperwork by disposing of potentially problematic research materials. “They decided they didn’t want to have to fill out the forms,” she says.

Overall, Watts estimates that fewer than two dozen Louisville researchers currently work with the regulated agents. Still, the university might develop new policies and rules that govern their conduct in the lab and go beyond current federal rules. There is already talk of a policy that would require a witness to certify that a researcher has properly destroyed regulated materials, for instance. More thorough and frequent laboratory inventories could also become routine, and some labs might have to be remodeled to meet security requirements. “We’re not done; this will be a moving target,” Watts predicts.

Other universities report similar discussions. Although a half-dozen institutions contacted by *Science* say that the notification process is going relatively smoothly, others report some bumps in the road. At Stanford University in Palo Alto, California, for instance, biophysicist Steven Block thinks that ESH officials have gone way too far in asking researchers to inventory “any and all biological agents and biological toxins that are used or stored” on campus. The request exceeds legal requirements, doesn’t inform researchers about potential legal ramifications, and is maddeningly vague, he complains. “Does this mean [I have to report] even house plants or home-brewed beer? How about grad students?” he asks, only partly in jest.

Lawrence Gibbs, Stanford’s associate provost for ESH, says the inventory is a “prudent measure” to create a baseline for future biosafety planning. “We don’t want to have to poll the faculty every 2 months because of inconsistencies,” he explains. Other faculty members applaud his strategy. “The [broader] survey was absolutely the right thing to do,” says John Boothroyd, chair of Stanford’s microbiology department. “The fewer requests, the better.”

Universities are also pondering how to collect and store the information securely. Some have established supposedly hacker-proof Web sites and e-mail accounts. But

other schools, including Louisville, are insisting that researchers deliver their signed notification forms in person. “We are not allowing anything to go through mail or e-mail,” notes ESH director Karen VanDusen of the University of Washington, Seattle.

Virtually every university official *Science* contacted also voiced concern about unrealistic deadlines. “It is putting the squeeze on everyone,” says L. Todd Leasia, director of the office of research safety at Northwestern University in Evanston, Illinois. And Gibbs worries about the uncertainties over how to handle certain classes of agents such as genetically engineered proteins. “The CDC needs to clarify its guidelines,” he says.

That’s expected to happen in the next few months as government agencies issue policies on a variety of research-related security issues. In the meantime, Watts and her colleagues are preparing to ride out the continuing aftershocks from last year’s attacks. “It’s certainly given us a lot to think about and a lot to do,” she says.

It’s also changed the nature of her professional interactions. “I get invited to some pretty high-level meetings now,” she says. “Health and safety issues have always been important to universities, but now they are really in the limelight.”

—DAVID MALAKOFF

With reporting by Erica Goldman.

UNDERGRADUATE EDUCATION

New Lure for Young Talent: Extreme Research

Science funding agencies are letting students experience weightlessness in hopes of keeping them grounded in science

HOUSTON, TEXAS—Eleven thousand meters over the Gulf of Mexico, Graylan Vincent and Karen Kennell are floating—or diving to Earth in a 3-kilometer free fall, depending on how you look at it. The University of Washington (UW), Seattle, undergraduates are inside a KC-135 micro-gravity research airplane, running a self-designed experiment in a lab that flies in a sinusoidal wave pattern to mimic the weightlessness of space. The plane belongs to NASA, which doles out a fraction of its flying time to undergraduates looking to experience science on the edge.

Trying to hold himself steady, Vincent, a senior in aeronautical engineering and geology, hits a button on a laptop that’s wired to a motor-controlled milling machine inside a Plexiglas cage. A half-inch (1.27-centimeter) drill bit whirs to life and slices through a slab of aluminum. For a few seconds, thousands of silvery shards hover aloft. They move as if in slow motion until Vincent flips another switch that turns on a converted Toro leaf blower, which blows the flecks into a mesh screen and out of the way.

At 8000 meters, NASA pilot Stephanie Wells gently pulls back on the yoke. The



On the fly. UW undergraduates Graylan Vincent (left) and Karen Kennell (front right) spend 25 seconds in free fall while running an engineering experiment aboard NASA’s “Vomit Comet.”