

# US issues new rules for university germ research

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The Obama administration is tightening oversight of high-stakes scientific research involving dangerous germs that could raise biosecurity concerns, imposing new safety rules on universities and other institutions where such work is done.

Wednesday's move follows controversy over creation of a more easily transmitted form of bird flu, research aimed at learning how the virus could mutate to threaten people but that sparked fierce debate over whether it also might aid would-be bioterrorists.

The new rules require many scientists and their employers do more to alert the [government](#) about research that may raise those concerns .But it doesn't settle the bigger question of whether certain kinds of studies should be done at all.

"This is an active area of consideration right now within the U.S. government. We ask that you stay tuned," said Amy Patterson, associate director of [biosecurity](#) policy at the National Institutes of Health.

At issue is how to handle rare instances involving research that could bring a big medical payoff but which also could cause harm if it ever is misused. NIH Director Francis Collins calls it the "dual-use dilemma."

The U.S. has long had strict rules on how scientists can handle certain germs that pose security threats—such as bird flu, Ebola, smallpox, anthrax and plague—to prevent accidental spread of the bugs and assure

extra research oversight.

But the issue made headlines in late 2011 with the [bird-flu](#) experiments. Researchers in the U.S. and the Netherlands were studying how the H5N1 virus that today only occasionally sickens people might worsen, when they created strains that some mammals—ferrets—could spread by coughing and sneezing. The NIH paid for the experiments and has called them very important, but the U.S. government temporarily kept details of the research secret for fear the results would be misused.

That research eventually was published, and the U.S. in 2012 laid out new steps for the NIH and other [government agencies](#) to determine what projects pose biosecurity concerns—such as those that enhance transmission or treatment resistance—and manage the risks.

On Wednesday, the government issued Part 2 of that policy: Scientists at universities and other federally funded research organizations must notify their employers if their projects raise red flags. The institution must evaluate the project and tell the government if it agrees, or risk losing federal money.

Scientists know their research best, and new biosecurity concerns may arise as studies progress after the government's review, said Andrew Hebbeler of the White House Office of Science and Technology Policy.

Patterson called it "a check and balance" of federal oversight. It goes into effect in a year.

The government recently checked a few hundred projects involving the 15 pathogens of concern and found a handful of those met the criteria for special attention, Patterson said.

Universities have been expecting the rules since last year, and depending

on how much research they do, evaluating what meets the criteria "can be a lot more work," said Rebecca Moritz, manager of select-agent research at the University of Wisconsin-Madison.

A bigger question, she said, is whether the policy expands beyond the current 15 targeted agents. For example, worrisome new viruses such as SARS and MERS aren't on the list.

"My personal guess is that this will eventually be expanded," Moritz said, saying her campus already is considering the dual-use question more broadly.

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