



Renewals of two diabetes grants held by Megan Sykes (right) of Columbia University could be held up by a new federal policy scrutinizing fetal tissue research.

Michael DiVito

In wake of Trump's fetal tissue clampdown, scientists strain to adjust

By [Meredith Wadman](#), [Jocelyn Kaiser](#) Jun. 11, 2019 , 3:00 PM

Megan Sykes, an immunologist at Columbia University, has spent years using human fetal tissue to develop a mouse with a humanlike immune system, which mimics how type 1 diabetes develops in humans. The tissue is donated after elective abortions, and the mice are testbeds for potential diabetes treatments. But last week, she learned that President Donald Trump, acting on a priority of advocacy groups opposed to abortion, had issued a new policy that is likely to cause lengthy delays the next time she seeks U.S. government grants for her work—and could even choke off federal funding for all studies that use fetal tissue. The policy “is incredibly disappointing,” Sykes says, because it is a “politically motivated decree” that could derail numerous disease research efforts.

The new Trump policy, issued 5 June after a 9-month review led by officials at the Department of Health and Human Services (HHS), has three major components. One kills a long-standing contract between the National Institutes of Health (NIH) in Bethesda, Maryland, and the University of California (UC), San Francisco, under which the university used fetal tissue to develop humanized mice for HIV drug testing. Another ends research using fetal tissue conducted by any scientist directly employed by NIH. The third and widest-reaching provision adds a lengthy and uncertain step to NIH's

process for awarding new or renewal grants to university scientists, such as Sykes, for studies that use human fetal tissue. It requires HHS to appoint a separate 14- to 20-member ethics advisory board to review each proposal that NIH reviewers have found worthy of funding. The review of up to 6 months will result in a funding recommendation to the HHS secretary, who can accept or reject the advice.

Enacting the new policy “was the president’s decision . . . to protect the dignity of human life,” Judd Deere, deputy White House press secretary, told *Science*. It was applauded by antiabortion activists, whose lobbying prompted HHS to launch its review of U.S.-funded fetal tissue research in September 2018. “This is a major pro-life victory,” said Marjorie Dannenfelser, president of the Susan B. Anthony List in Washington, D.C.

Many biomedical researchers were stunned, noting that the tissue, which would otherwise be discarded, has properties that make it valuable for research. It is less specialized than adult tissue, for instance, and readily adapts to new environments. “These new restrictions have no scientific or ethical basis and will roll back decades of consensus in the U.S., delaying the development of new treatments,” said Doug Melton, president of the International Society for Stem Cell Research in Skokie, Illinois, and co-director of the Harvard Stem Cell Institute.

“The whole point here is to so wrap the research in red tape that it’s impossible or at least unlikely to be feasible for many researchers,” says bioethicist Alta Charo of the University of Wisconsin in Madison.

A 1993 law formalized rules for using fetal tissue donated after elective abortions in U.S.-funded research. Last year, NIH spent \$115 million on roughly 173 projects that rely on the tissue; about 160 were run by university scientists. One-third of the 173 grants focus on HIV/AIDS, many using humanized mice to probe, for example, how HIV hides out and evades the immune system, and what drugs might defeat it. Others tackle other infectious diseases, eye disease, and fetal development as well as toxic exposures during pregnancy.

NIH says its scientists are conducting just three projects affected by the new rules; all will stop. “This decision is devastating. It effectively ends our studies looking into new approaches for an HIV cure,” says Warner Greene, director of the Gladstone Institutes Center for HIV Cure Research in San Francisco. Greene is a partner in one of the projects, run by retrovirologist Kim Hasenkrug of NIH’s Rocky Mountain Laboratories in Hamilton, Montana.

At universities, the policy allows existing projects to continue until their current NIH funding expires. Nearly half of these extramural grants will expire within the next 18 months, and scientists will need to apply for a renewal if they want to keep the work going. Grantees are now grappling with what the new review process might mean.

It has already caused at least one researcher to change course. HIV scientist Jerome Zack last week told colleagues at UC Los Angeles (UCLA) that he had decided to remove his work using fetal tissue to develop humanized mice from a renewal application, due at NIH in August, for a large grant supporting the university’s long-

standing Center for AIDS Research. “The grant covers way more than mouse work, it covers all HIV research on campus,” he says. “I don’t want to jeopardize that.”

Scott Kitchen, a Zack collaborator who directs mouse production at UCLA, says that in the past year his group provided humanized mice for more than 70 scientists on campus and nine at other institutions, as well as performing multiple large projects for several companies. “All of this has been critical in scientific and therapeutic development,” Kitchen says. “And all of it may now be derailed.”

At Columbia, Sykes is worried about the one-third of her 15 staff who are funded through two NIH grants. She recently submitted a renewal proposal for one grant and planned to submit the other in July. HHS hasn’t said when the policy will kick in. But when Sykes asked NIH officials how it might affect her proposals, the response “wasn’t reassuring,” she says.

Much could depend on whom the HHS secretary appoints to the ethics review boards. Under existing law governing HHS ethics boards, one-third to one-half of a board’s members must be scientists, and each must include at least one theologian, one ethicist, one physician, and one attorney. The law “absolutely” would allow HHS to pack the boards with members who oppose abortion, Charo says.

Critics of the new policy also say it will undermine a goal of opponents of fetal tissue research: to find and encourage the use of alternatives. In December 2018, NIH Director Francis Collins noted that his agency was putting up to \$20 million over 2 years into research on such alternatives. But scientists say that those alternatives need to be tested for validity against human fetal tissue itself. For the time being, Collins said in December 2018, fetal tissue would “continue to be the mainstay” for certain kinds of research.

The new rules could remove that mainstay. But Charo notes a new president could reverse the policy, which is not codified in law.