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Embryonic stem cell research stalled despite Obama's try at lifting restrictions

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One year after President Obama announced he was lifting his predecessor's controversial restrictions on federal funding for human embryonic stem cell research, some scientists are complaining that so far the new policy is -- ironically -- more of a burden than a boon to their work.

"The situation at the moment is worse than it was under the Bush administration," said Charles Murry, a professor of pathology and bioengineering at the University of Washington in Seattle. "Because of this, we are going to waste a lot of time."

At issue is the fate of the 21 "lines of cells" that President George W. Bush said could receive federal funding.

Bush limited federal funding to the lines that were already in existence in 2001. He wanted to prevent taxpayer dollars from encouraging the destruction of more embryos to create more lines. Critics of the research praised Bush's move, arguing that destroying embryos to obtain the cell lines is immoral. But the restrictions were condemned by many scientists, who argued they were hindering research that could lead to cures for Alzheimer's disease, diabetes, paralysis and other ailments.

Obama's attempt to loosen restrictions on federal funding was complicated by a thicket of ethical issues. Last summer, the National Institutes of Health issued detailed guidelines aimed at addressing those concerns. The guidelines included stringent requirements that any lines being studied with federal funding meet strict new ethical criteria, including making sure couples who donated the embryos for the lines' creation were fully informed of other options.

The problem is that it remains unclear how many of the original 21 lines, which researchers have spent millions of dollars and nearly a decade studying, were derived at a time when ethical requirements were less specific, leaving in doubt how many would pass muster under the tough new guidelines.

"Some of these lines were derived more than a decade ago, and some of the researchers who derived them aren't around anymore," said Timothy J. Kamp, director of the stem cell and regenerative medicine center at the University of Wisconsin. "Some of those records may not be available. Some providers of those original lines might not be motivated to provide those records in a timely fashion."

So far, the NIH has approved 43 lines. But that includes only one of the original 21 "Bush" lines. An additional 115 lines are awaiting review. But that includes only two more of the original lines.

"We're losing access to those lines in this approval process for some period of time -- maybe indefinitely," Kamp said. "They are the main workhorses for many of our projects."

Kamp wants the NIH to revise its guidelines to grandfather in the existing lines or give researchers a two-year grace period to continue to work with them until they get formal approval.

NIH officials said the new guidelines were designed to try to make the transition as smooth as possible while applying responsible ethical guideposts.

"We are completely sympathetic and understand where the research community is coming from," said Lana Skirboll, NIH's director of science policy. "Our responsibility is to make sure we're conducting research with lines that were responsibly derived. . . . We have a process and are moving as fast as we can."

Researchers with existing federal grants can continue to work on the old lines regardless of whether they have been approved under the new policy. But any research involving new grants, including those awarded using the flood of new funding the NIH received as part of the stimulus package, can only use lines approved under the new policy. That has left researchers scrambling to decide how to proceed: They can wait in the hopes that the lines they've been using will be approved. Or they can switch to a new line.

"We're in this funky limbo state," said Michael Kyba, an assistant professor of pediatrics at the University of Minnesota, who has been using the most popular of the original lines, known as H9, to study how stem cells morph into specific tissues. H9 has not yet been approved under the new guidelines.

Kyba's is one of several laboratories in the third year of a five-year $2.5 million grant. That work will be able to continue, but Kyba and others are uncertain whether they will have to switch lines when the grant comes up for renewal if H9 has not been approved by then.

"We're in the dark. That's the really frustrating thing," Kyba said.

Kyba also was awarded a $500,000 grant that he intended to use to study the H9 line, but switched to one of the newly approved lines because of the uncertainty. That will require him to do additional work to replicate advances he had already made with the H9 line.

"The error they made is assuming that it's easy to switch lines. Some can be switched quickly, but most of it's wasted time," he said.

Some researchers have spent years studying the lines, including sometimes painstakingly making genetic alterations needed to tease out key information.

"Now we have to start over and invest the time and energy to create a whole new tool set when in a year or two these lines could be approved again," Kamp said. "No one wants anyone spinning their wheels and wasting resources."