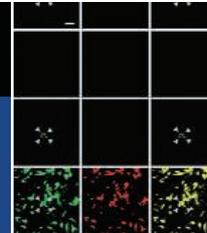




Are genomic studies off track?

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Behind a retracted paper

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## BIOMEDICAL POLICY

## Draft Stem Cell Guidelines Please Many, Disappoint Some

They are not perfect, but they're a big improvement over what scientists have been living with since 2001. That's how most feel about the draft guidelines on human stem cell research released last week by the U.S. National Institutes of Health (NIH).

The proposed rules, to be finalized this summer, will expand the number of human embryonic stem (hES) cell lines available to researchers by eliminating the cutoff date for cell lines that qualify for federal funding. Acting NIH Director Raynard Kington predicted that "in a matter of months, we are likely to increase greatly the number of human embryonic stem cell lines eligible for federal funding." He said that NIH estimates up to 700 lines exist based on literature reviews and registries.

But some restrictions remain. The cell lines must be derived from surplus embryos donated by couples receiving fertility treatment. Stem cells lines derived through research cloning, or somatic cell nuclear transfer (SCNT), which many researchers are eager to try, will not be eligible.

Some researchers are also concerned about just how many of the existing hES cell lines will be eligible, given NIH's newly detailed requirements on informed consent. But most share the sentiments of stem cell researcher Sean Morrison of the University of Michigan Medical School in Ann Arbor, who says the proposed policy is "a huge advance" over the Bush policy and "a reasonable compromise based on where the science stands."

On 9 August 2001, then-President George W. Bush decreed that federal funding be restricted to research on stem cell lines derived before that date. To the delight of many scientists, President Barack Obama's 9 March executive order lifted those restrictions. But the order did not spell out the source of the embryos, leaving that to NIH to decide (*Science*, 20 March, p. 1552). Now researchers have the answer: The stem cells must be "derived from embryos created by in vitro fertilization (IVF) for reproductive purposes and were no longer needed for that purpose," NIH's draft states. The use of cells from "other



**Cells galore.** Federally funded researchers will soon have access to hundreds more lines.

sources, including [SCNT], parthenogenesis, and/or IVF embryos created for research purposes, is not allowed." It also notes that Congress has barred NIH from funding the derivation of stem cells from human embryos under the so-called Dickey-Wicker amendment.

Kington explained to reporters last week that in drafting its guidelines, NIH heeded both legal restrictions and professional guidelines, including a 2005 report on stem cell research from the National Academies. "There's strong, broad support" for allowing research on surplus embryos from fertility clinics, he said, as shown by legislation that passed Congress twice (and was twice vetoed by Bush). "There's not similar broad support for using the other sources." Moreover, Kington pointed out, cell lines created solely for research either by IVF or SCNT don't yet exist as far as NIH is aware. NIH will review its policy as the science advances, he added. Funding continues to be allowed for research with induced pluripotent stem (iPS) cells—cultivated from adult cells—which many think will offer the same promise as cells from SCNT.

Many researchers would like to be able to

work on hES cell lines derived in other ways—in particular, through SCNT. That technique might be used, for example, to make an embryo by inserting DNA from a skin cell of a patient with a disease into an enucleated egg. Researchers could then derive stem cells for studying that disease in test tube experiments.

Stanford University School of Medicine stem cell researcher Irving Weissman says the proposed ban on SCNT goes against the policy implied by Obama's earlier comments. "The NIH has not served its president well," Weissman said in a statement. He said there is no prohibition on SCNT in guidelines established by the International Society for Stem Cell Research (ISSCR) or by the National Academies.

It's unclear how many more lines will qualify under the new rules. A limiting factor could be the informed consent procedures. NIH hewed closely to those recommended by the National Academies and ISSCR. But Harvard University stem cell researcher George Daley points out that some of the 21 lines eligible for federal funding under the Bush policy would not qualify under the "exhaustive informed consent language" that was "not widely practiced before 2006." Therefore, there is some talk both at NIH and in Congress about the potential need to "grandfather" in some Bush-approved lines currently in use. (Grant applications already submitted to NIH will also need to pass muster.)

The draft policy includes a few other restrictions. NIH will not fund work that involves the possible introduction of pluripotent human cells (either iPS cells or ES cells) into the germ lines of any animals, a restriction recommended by the academies' report. Parthenotes, which are short-lived embryos created from an unfertilized egg, are also forbidden, as they qualify as human embryos under the Dickey-Wicker amendment.

The public has until 30 days after the policy is published this week in the *Federal Register* to submit comments, and NIH must issue final rules by 7 July. Some lawmakers have already weighed in. Representatives Michael Castle (R-DE) and Diana DeGette (D-CO), co-authors of the legislation that Bush vetoed, say they favor "more expansive guidelines"—a hint that an effort may be afoot to overthrow Dickey-Wicker. But Tom Harkin (D-IA), a Senate sponsor of the vetoed legislation, said he is "very pleased" with the NIH draft.

—CONSTANCE HOLDEN AND JOCELYN KAISER

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