

NIH Releases Guidelines for Federal Funding of Human Embryonic Stem Cell Research

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According to the National Institutes of Health (“NIH”), “studies of human embryonic stem cells may yield information about the complex events that occur during human development... and could provide information about how diseases arise and suggest new strategies for therapy. Human embryonic stem cells may also be used to test new drugs... [and to] generat[e] cells and tissues that could be used for cell-based therapies.”^[1]

On March 9, 2009, President Obama lifted former President Bush’s restrictions on federal funding for human embryonic stem cell research by signing Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*. In the Executive Order, the President permits the Secretary of Health and Human Services (“HHS”), through the Director of the NIH, to support and conduct “responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.”

Moreover, the President directed the NIH to review and revise its human embryonic stem cell (“HES”) guidelines to be consistent with the Presidential order. On April 23, 2009, the NIH released its new guidelines, available [here](#), which are **open for public comment until May 26, 2009**.

Regulation of Federal Funding for HES Research

Before discussing the NIH guidelines, it is important to understand the long, and controversial, history of federal funding for HES research.

In 1995, as a rider to the annual appropriations bill, Congress enacted an amendment, commonly called the Dickey-Wicker amendment after its sponsors, which prohibited the use of federal funding for any experiment in which a human *embryo* is either created for research purposes or “destroyed, discarded, or knowingly subjected to risk of injury or death...”.^[2] This amendment, which has been enacted every year since 1996 (including fiscal year 2009), effectively prohibited all federal funding for HES research.

However, an opinion from the HHS Office of the General Counsel in 1999 found that the amendment prohibiting the use of federal funds for human *embryo* research would not apply to research using embryonic *stem cells* “because such cells are not a human embryo within the statutory definition.”^[3] After the HHS legal opinion, despite expressions of congressional

opposition, the NIH indicated that it would not fund efforts to derive stem cells from human embryos (because this would destroy the embryo and run afoul of the law), but that it would fund research on the stem cells once they had been derived with private funding, in accordance with the HHS General Counsel's opinion. The NIH published guidelines to implement this policy, which allowed HES research to be conducted using NIH funds only if the cells were derived, without federal funds, from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment.

Nevertheless, before applications under the Clinton Administration guidelines were accepted and funded by the NIH, President Bush took office and issued a new HES research policy. Under that policy, Federal funds could be (and have been) used for research on human embryonic stem cells where: the derivation process was initiated prior to 9 p.m. EDT August 9, 2001; the embryo was created for reproductive purposes; the embryo was no longer needed for these purposes; informed consent was obtained for the donation of the embryo; and no financial inducements were provided for donation of the embryo. The NIH issued new HES research guidelines to carry out this policy, which identified 71 HES cell lines that met these criteria and thus could be used for federally funded research purposes.

New NIH Guidelines

President Bush's policy was in effect until March 9, 2009, when President Obama signed the executive order revoking the restrictions. According to the new NIH guidelines, which were released on April 23, the NIH will fund HES research "using only those human embryonic stem cells that were derived from embryos created by *in vitro* fertilization (IVF) for reproductive purposes and were no longer needed for that purpose." These guidelines preserve President Bush's precedent in permitting funding for certain HES research, but adopt President Clinton's more expansive approach in determining what projects are eligible for funding. The NIH goes on to state that under the new guidelines, it will *not* fund research using human embryonic stem cells derived from other sources, "including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes." Funding will continue to be permitted for adult stem cell research and research on induced pluripotent stem cells.

The new guidelines should provide additional opportunities for federal funding for HES research, and depending upon funding streams, could lead to exciting new scientific advances (which may be patentable). Furthermore, while the Dickey-Wicker amendment is in force for fiscal year 2009, the President's Executive order could be a signal to Congress to reconsider its position in subsequent fiscal years, opening the door for additional federal funding. **Public comments are due on the NIH guidelines by May 26, 2009.**

[1] National Institutes of Health Draft Guidelines for Human Stem Cell Research Notice, 74 Fed. Reg. 18578 (Apr. 23, 2009).

[2] The Balanced Budget Down Payment Act, Pub. L. No. 104-99 § 104 (1996).

[3] Letter from HHS Gen. Counsel Harriet Rabb to Harold Varmus, Director, NIH, January 15, 1999.