



Overview of Federal Stem Cell Research Law

Prepared by: Kelly McGraw, Staff Attorney, and Margit Kelley, Principal Attorney

The use of stem cells in research and therapeutic treatments is an advancing field that carries questions on the ethical use of human embryonic stem cells. Although other organisms have stem cells, this issue brief addresses only human stem cells. Various reports have recommended limits relating to stem cell research since the 1980s. This issue brief provides a brief overview of the federal funding regulations and guidance that limit stem cell research.

WHAT ARE STEM CELLS?

Very broadly, a stem cell is a cell from which other types of cells develop. A stem cell may have the capacity to develop into a specific type of cell, or it may have the capacity to develop into many different types of cells or tissues, and the stem cell is categorized based on that capacity. For example, a blood stem cell, or “hematopoietic stem cell,” is an immature “multipotent” stem cell that can develop into a blood cell, including white or red blood cells or platelets. A “pluripotent” stem cell is able to develop into most different types of adult, or “mature,” cells or tissues. A “totipotent” stem cell, i.e., a zygote, is able to develop into all different types of both adult and embryonic cells or tissues.¹

Stem cells are found in different types of body tissue and are sometimes referred to by their location. Such location-based references include, for example, bone marrow stem cells, umbilical cord blood stem cells, and embryonic stem cells.

Stem cells with pluripotent capacity are a common area of research. Two types of pluripotent stem cells are embryonic stem cells and induced pluripotent stem cells. An embryonic stem cell is separated from an embryo, cultured, and stabilized into a “stem cell line” in a process referred to as “derivation.” An induced pluripotent stem cell is reprogrammed from an adult skin or blood cell. Once reprogrammed, an induced pluripotent stem cell can become most types of cells in the body. An induced pluripotent stem cell can exhibit essential characteristics of an embryonic stem cell. Some argue that induced pluripotent stem cells make embryonic stem cell research obsolete.²

FEDERAL LAW

Federal law addresses funding for embryonic stem cell research and imposes certain limitations on that research. Because the federal law operates as a condition of federal funding, the law applies only to research that receives federal funds. Currently, a federal budget provision, executive order, and restrictions on human subject research impact federally funded embryonic stem cell research.

First, the federal Further Consolidated Appropriations Act of 2024 prohibits funding for stem cell research that would destroy an embryo.³ In particular, the act prohibits the use of funds for: (1) the creation of an embryo or embryos for research purposes; or (2) research in which an embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under certain federal laws. Federal budgets have included similar language since 1996.⁴

Second, an executive order signed by President Obama in 2009 permits the federal government to support stem cell research, with some limitations, through the NIH. The NIH is the federal medical research agency charged with seeking fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The NIH states that it is the largest public funding source for biomedical research in the world.⁵

Under the 2009 presidential executive order, the federal government, through the NIH, may support and conduct responsible, scientifically worthy stem cell research, including embryonic stem cell research, to the extent permitted by law. The order requires the NIH to issue guidance consistent with the order.⁶

Under the NIH guidance, to research with embryonic stem cells, an applicant institution may either use embryonic stem cells on the NIH Registry or cells that the applicant derives, or obtains, by a method that complies with the guideline requirements on embryo derivation. Under the first option, the NIH Registry provides a list of embryonic stem cell lines that have been reviewed for ethical derivation. Stem cell lines identified in the registry are eligible for use in NIH-supported research. Under the second option, the guidelines require that if the embryo was created for reproductive purposes, but no longer needed for those purposes, the embryo was donated without payment, and the embryo donor's consent met certain requirements.⁷

Lastly, under general federal research law, some embryonic stem cell research is considered human subject research when a cell is derived from a human embryo that is individually identifiable and is linked to a specific living individual. Human subject research must comply with the U.S. Department of Health and Human Services regulations for the protection of human research subjects.⁸

STATE LAW

In addition to federal law and guidelines, some states either support or restrict stem cell research.⁹ Wisconsin is one of approximately 21 states that do not have laws addressing stem cell research. However, any stem cell research in Wisconsin that uses federal funding must comply with the federal laws and guidelines noted above.

AN ORGANIZATION'S OWN RESEARCH POLICY

Separate from federal and state law, some organizations have policies that impact stem cell research. For example, a UW-Madison Stem Cell Research Oversight Committee oversees all research on campus, or involving campus employees, that involves the use of human embryonic stem cells or their derivatives, regardless of the source of funding. University policy requires a researcher to document that the Stem Cell Research Oversight Committee has approved the provenance of human embryonic stem cells before the researcher may use human embryonic stem cells.¹⁰

¹ For background resources on stem cells, see, for example: National Institutes of Health (NIH), [Stem Cell Basics](#) (2016); Mayo Clinic Staff, [Stem cells: What they are and what they do](#), Mayo Clinic (March 23, 2024); Inna Tabansky and Joel N.H. Stern, [Basics of Stem Cell Biology as Applied to the Brain](#), Stem Cells in Neuroendocrinology (July 27, 2016); and Antonio Romito and Gilda Cobellis, [Pluripotent Stem Cells: Current Understanding and Future Directions](#), Stem Cells International (December 20, 2015).

² Qiang Bai, et al., [Embryonic stem cells or induced pluripotent stem cells? A DNA integrity perspective](#), Current Gene Therapy (April 2013); Waisman Center, [iPSC – Induced Pluripotent Stem Cells](#), University of Wisconsin (UW)-Madison; Junying Yu, et al., [Induced pluripotent stem cell lines derived from human somatic cells](#), Science (December 21, 2007); Bernadine Healy, [Why Embryonic Stem Cells Are Obsolete](#), U.S. News (March 4, 2009); and Salomon Poliwooda, et al., [Stem Cells: a comprehensive review of origins and emerging clinical roles in medical practice](#), Orthopedic Reviews, Vol. 14, Issue 3 (August 25, 2022).

³ For the purpose of this provision, a human embryo is any organism, not protected under federal research law, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

⁴ [Further Consolidated Appropriations Act, 2024](#), P.L. 118-47; and Kirstin RW Matthews and Daniel Morali, [Can we do that here? An Analysis of US federal and state policies guiding human embryo and embryoid research](#), Journal of Law and the Biosciences, Vol. 9, Issue 1 (January-June 2022).

⁵ NIH, [WHAT WE DO](#) (October 24, 2024).

⁶ [Executive Order 13505](#), Removing Barriers to Responsible Scientific Research Involving Human Stem Cells (March 9, 2009).

⁷ NIH, [Guidelines for Human Stem Cell Research](#) (July 7, 2009).

⁸ U.S. Department of Health and Human Services, Office for Human Research Protections, [45 C.F.R. Part 46](#).

⁹ See, for example, Nefi D. Acosta and Sidney H. Golub, [The New Federalism: State Policies Regarding Embryonic Stem Cell Research](#), Journal of Law, Medicine & Ethics, Vol. 44, Issue 3 (2016). In 2005, former Governor Jim Doyle issued [Executive Order #147](#), directing the then-Department of Commerce to invest in and market the stem cell industry. Some bills related to the topic have been introduced, but not enacted. See, for example, 2005 Assembly Bills [499](#) and [1130](#) and the respective companion bills 2005 Senate Bills [243](#) and [603](#).

¹⁰ UW-Madison, [Human Embryo and Human Pluripotent Stem Cell Research](#), Policy No. UW-4025 (May 15, 2007; revised February 18, 2025).