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Human Embryonic Stem Cell Research Frequently Asked Questions and Fact Sheet

Stem Cell Science Basics

What are stem cells?

Stem cells are naturally occurring cells that are not yet fully differentiated. In contrast, once an "ordinary" cell has become specialized into a particular tissue type, such as skin or blood, it can only divide into more cells of that type. (However, see "*How do the new methods to derive stem cells change the field?*," below.) Another key characteristic of stem cells is that they can be maintained and grown in a laboratory for quite some time. Thus, a stem cell "line" can be established, characterized, and shared much like bakers or brewers maintain and share a line of yeast.

Why are scientists interested in stem cells?

Scientists are developing ways to use stem cells to better test drugs before trying them in humans. Others are creating stem cell lines that have all the genes that contribute to a particular disease, allowing them to study a "disease in a dish."

Scientists also believe they can learn to use stem cells to regenerate damaged body tissues. Many conditions which result from damaged tissues, such as diabetes, spinal cord injury, and some types of blindness, may be able to be treated through such cell therapies.

Are all stem cells the same?

No. Stem cells derived from different sources have different characteristics. Some stem cells are *pluripotent*: they can turn into any cell type. Others are *multipotent*: they can turn into some, but not all, cell types.

"Adult stem cells," which can be isolated from various organs or from placentas or umbilical cords, are generally multipotent, although new "cell reprogramming" techniques have created pluripotent stem cells from adult body tissue. (See "*How do the new methods to derive stem cells change the field?*," below.) Stem cells derived from embryos are generally pluripotent. Most embryonic stem cell research uses "leftover" embryos that were created but not used in assisted reproduction clinics, which generally create more embryos than are needed. A few researchers are trying to create human embryos via cloning from which they

wish to derive stem cells. (See "*How does cloning fit into stem cell research?*," below.)

How far along is stem cell research towards therapies?

Several adult stem cell therapies are already part of medical practice, and more are being tested in clinical trials. Procedures using human embryonic stem cells are not yet being tested on people, although clinical trials are likely to begin soon. The routine availability of any therapies based on embryonic stem cells is many years away. Stem cells from clonal embryos have not been successfully isolated. (See "*How does cloning fit into stem cell research?,*" below.)

Stem Cell Policy Basics

Why is human embryonic stem cell research controversial?

Deriving stem cells from human embryos requires the destruction of embryos, which some view as morally equivalent to taking the life of a child or adult. Supporters of the research point out that the embryos scientists use consist of about 100 undifferentiated cells, and that these embryos are being stored by fertility clinics and will eventually be destroyed anyway.

Controversy about the moral status of human embryos led to a hotly contested partisan divide over embryonic stem cell research, with both sides prone to exaggeration and distortion. As a result, little attention has been given to social and ethical issues unrelated to the embryo. These include the need for responsible representations about the potential of the research, consistent and enforceable regulation and oversight, the risks to women entailed by the requirement for large numbers of human eggs in cloning-based stem cell research, and the need for federal policy to prevent reproductive cloning and other objectionable forms of human genetic manipulation that embryonic stem cell research may help enable.

What did President Bush's policy do?

On August 9, 2001, President Bush declared that federal funds could be used to work with human embryonic stem cell lines that had already been established, but not with stem cell lines created after that date. In a televised speech, he said that this would allow important scientific work to proceed, but would rule out federal funding for any future destruction of embryos.

Some religious conservatives objected to any federal funds at all being spent on embryonic stem cell research; others were glad that at least some limits had been applied. Some stem cell scientists were initially pleased that federal funding was at last available for this research. But it turned out that only 22 lines that were at all suitable were actually eligible for federal support, and many of these were later found to be contaminated with animal material. Research with these lines has received about $40 million annually from the federal government.

Congress twice passed bills that would have undone these funding restrictions, but Bush vetoed them both.

What was the impact of the Bush policy?

As time went on, and newer and better stem cell lines were established through efforts receiving private and state funding, the federal funding restriction created logistical difficulties for scientists. Some researchers established two sets of laboratory facilities, one of which would be free of federal funding support and could be used for a wider range of research. In addition, the number of useful stem cell lines available for federal funding turned out to be fewer than initially estimated, leading to more requests that the federal constraints be lifted.

Dissatisfaction with the Bush policy contributed to efforts to fund embryonic stem cell research in several states. The most visible example is in California, where a ballot initiative passed in 2004 provided $300 million annually for stem cell work. Other states have taken similar steps. Additionally, hundreds of millions of dollars have been provided in private donations. One result is an absence of enforceable federal regulation and oversight of embryonic stem cell research. (See "*Is stem cell research subject to other federal oversight?,"* below.)

What is President Obama expected to do?

One of the Barack Obama's first acts as president is expected to be the removal of President Bush's restrictions on the federal funding of human embryonic stem cell research. After that, research with stem cell lines derived from "leftover" embryos in assisted reproduction clinics will be eligible for federal funding. President Obama is also expected to call for the establishment of regulations and oversight of stem cell research.

After that, will federal funds be used to derive stem cells from human embryos?

Because stem cell lines can be maintained and shared, research with most human embryonic stem cell lines, once established, will be eligible for federal support. The actual derivation of new human embryonic stem cell lines will remain ineligible for federal funding, as it was during the Clinton administration and before President Bush announced his funding policy. This is due to the "Dickey Wicker Amendment," an annually renewed clause in a federal appropriations bill that prohibits federal dollars from going towards the destruction of embryos. In addition, work with stem cell lines that are derived without proper consent or that are derived from embryos other than those leftover in assisted reproduction clinics will not be eligible for federal dollars.

Is stem cell research subject to other federal oversight?

Stem cell research is not subject to any federal regulations beyond those that apply to other biomedical research. During the Bush administration, the federal government did not develop any such regulations. Although non-governmental

bodies such as the National Academies and the International Society for Stem Cell Research have established stem cell research guidelines, these are non-binding. Congressional bills subsequent to President Obama's new policy are likely to request that the National Institutes of Health write regulations for federally funded stem cell research.

How do the new methods to derive stem cells change the field?

In 2007, two teams of researchers developed methods to reprogram normal body cells into a state of pluripotency, raising the prospect that embryo destruction may not be needed for stem cell research and therapies. However, these initial experiments creating "induced pluripotent stem cells," or iPS cells, used viral vectors to genetically modify the cells, methods which will need to be refined or replaced before the cells are put into humans. Since then, significant steps have been made towards using better methods of cellular reprogramming. Some scientists are shifting from using embryonic sources to these reprogrammed cells, and high-profile cloning researchers including Sir Ian Wilmut, who created Dolly the cloned sheep, have abandoned cloning-based stem cell research. However, most believe that investigations using embryonic stem cells are still needed.

How does cloning fit into stem cell research?

The use of cloning techniques to create stem cells was conceived as a way to address the immune rejection issue that some scientists believe will complicate therapies based on stem cells from "leftover" embryos. However, the method – known as somatic cell nuclear transfer (SCNT) or research cloning – has been largely unsuccessful. The first human clonal embryo was created just last year, and no stem cells have been derived with this method.

Moreover, the cloning process is socially and ethically problematic. It requires large numbers of women's eggs, and obtaining them poses non-trivial risks. It involves the creation of cloned embryos, raising the risk of their unauthorized in attempts at reproductive cloning. (The United States is the only major industrial country that has not prohibited reproductive cloning; many believe that such a law is urgently needed.) In contrast, the new method of cellular reprogramming (see above) creates pluripotent stem cell lines with the known genetic characteristics of a specific disease or an existing person, which was the goal of cloning-based stem cell research.

For more information, see *The Basics: Stem Cells and Public Policy* [PDF], a 2006 briefing booklet published by The Century Foundation and authored by CGS's Richard Hayes, available at http://www.tcf.org/Publications/HealthCare/Stemcellbasics.pdf.

Human Embryonic Stem Cell Research
Reference Table

Source of cells	Federal funding policy	Federal legality	Potency	State of science	Ethical concerns*
Adult stem cells Various organs and tissues including placentas and umbilical cords	Funds available	No restrictions	Multipotent	Therapies available and in clinical trials; research ongoing	None
Embryonic stem cells Early-stage embryos (blastocysts)	• Under Bush, funds available only to work with lines established by 8/9/01 • Under expected Obama policy, funds available to work with all lines from leftover embryos, but not available for actual derivation of lines	No restrictions	Pluripotent	Lines established; clinical trials expected soon; research ongoing	Destroys early embryos
Clonal stem cells Embryos produced using by cloning (somatic cell nuclear transfer, or SCNT)	Funds not available	No restrictions	Pluripotent	No lines established; some cloning researchers switching to iPS cells	• Requires women's eggs • Could facilitate unauthorized reproductive cloning • Destroys early embryos
Induced pluripotent stem (iPS) cells Ordinary body cells "reprogrammed" in laboratories	Funds available	No restrictions	Pluripotent	Lines established; research ongoing	Could facilitate efforts to use artificial sperm and eggs to create embryos and establish pregnancies

* The ethical concerns listed here are based on divergent perspectives, not necessarily those of the Center for Genetics and Society. In addition, stem cell research entails concerns that also apply to other biomedical research, including informed consent, human research subjects protection, and conflicts of interest.