National Institutes of Health
Department of Health and Human Services
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FACT SHEET ON STEM CELL RESEARCH

The Department of Health and Human Services (DHHS) has concluded that current law permits federal funds to be used for research utilizing human pluripotent stem cells. The National Institutes of Health (NIH) plans to move forward in a careful and deliberate fashion to develop rigorous guidelines that address the special ethical, legal, and social issues relevant to this research. The NIH will not fund research using human pluripotent stem cells until guidelines are developed and widely disseminated to the research community and an oversight process is in place.

The Promise of Stem Cell Research

Scientists have recently isolated and successfully cultured human pluripotent stem cells[1]. These human pluripotent stem cells have an unlimited capacity to divide, and the ability to develop into most of the specialized cells or tissues in the body.

This advance represents a major step forward in human biology and has generated much enthusiasm and interest among scientists and the public, particularly patients and their families. Because these cells can give rise to many different types of cells, such as muscle cells, nerve cells, heart cells, blood cells, and others, they are enormously important to science and hold great promise for advances in health care. For example, further research using pluripotent stem cells may help us:

- Generate cells and tissue that could be used for transplantation. Pluripotent stem cells may be stimulated to develop into many different specialized cells of the body, which may someday be used as replacement cells and tissue to treat many diseases and conditions including Parkinson's disease, spinal cord injury, stroke, burns, heart disease, diabetes, and arthritis.

- Improve our understanding of the complex events that occur during normal human development and also help us understand what goes wrong to cause diseases and conditions such as birth defects and cancer.

- Change the way we develop drugs and test them for safety and potential efficacy. New medications could be tested using human pluripotent stem cells, such as liver cells or skin cells; only the drugs which are both safe and appear to have a beneficial effect would graduate to human testing.

Legal Issues

These human pluripotent stem cells were isolated using two different methods. One group of

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[1]Michael Shamblott, et al, Derivation of pluripotent stem cells from cultured human primordial germ cells. PNAS, 95: 13726-13731, Nov. 1998.

James Thomson, et al, Embryonic stem cell lines derived from human blastocysts. Science, 282: 1145-1147, Nov. 6, 1998.

scientists derived the pluripotent stem cells from early-stage embryos donated by people who were undergoing fertility treatment in an *in vitro* fertilization (IVF) clinic. Another group of scientists isolated the pluripotent stem cells from non-living fetuses obtained from pregnancies that had been terminated. In both cases, all of the individuals gave full informed consent for the embryos or fetal tissue to be used in research. Neither research project utilized federal funds. Because of the regenerative capacity of pluripotent stem cells, a single culture of human pluripotent stem cells could supply numerous other researchers.

Federal law currently prohibits the DHHS from funding human embryo research. In light of this legislative ban, the Director of the NIH sought a legal opinion from the DHHS Office of the General Counsel on whether DHHS funds may be used for research utilizing human pluripotent stem cells.

After a thorough analysis of the law, DHHS concluded that the congressional prohibition on the use of DHHS funds for certain types of human embryo research does not apply to research utilizing human pluripotent stem cells because such cells are not embryos. The legal opinion also clarified that human pluripotent stem cells derived from non-living fetuses would fall within the legal definition of human fetal tissue and are, therefore, subject to certain Federal restrictions on the use of such tissue.

Thus, research using pluripotent stem cells derived from human embryos can be funded by DHHS. Research that generates and uses pluripotent stem cells from non-living fetuses can also be supported by DHHS, subject to existing law and regulation.

NIH Support

In view of the scientific and medical benefits that may result from research using pluripotent stem cells, the NIH plans to fund research using these cells. It is essential that the Federal government play a role in funding and overseeing the conduct of this research, so that all scientists--both privately and federally funded--have the opportunity to pursue this important line of research. Federal funding will provide oversight and direction that would be lacking if this research were the sole province of industry and academe.

The NIH understands and respects the compelling ethical, legal, and social issues relevant to pluripotent stem cell research and is sensitive to the need for stringent oversight of this research that goes beyond the traditional NIH scientific peer review process. In light of these issues, the NIH plans to move forward in a careful and deliberate way, prior to funding any research utilizing pluripotent stem cells.

In an effort to ensure that any research utilizing human pluripotent stem cells is appropriately and carefully conducted, the NIH will convene a Working Group of the Advisory Committee to the Director (ACD), NIH to advise the ACD on guidelines and oversight for research involving human pluripotent stem cells, at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland 20814, on April 8, 1999. The meeting will begin at approximately 9:00 a.m. and end at approximately 5:30 p.m. The goal of the Working Group is to provide advice to the ACD about the scientific, ethical, legal, and social issues relevant to guidelines for the conduct of research utilizing human pluripotent stem cells. The working group will meet in public session and will be composed of scientists, patients and/or their families, ethicists, clinicians and

lawyers. They will be asked to consider advice from the National Bioethics Advisory Commission (NBAC), the public, and the Congress. Once developed, guidelines for research utilizing human pluripotent stem cells will be published in the Federal Register for public comment. Until both the guidelines and the oversight process are in place, interested investigators have been notified, via the NIH web site, NIH program staff, and the Deputy Director for Intramural Research that they cannot use DHHS funds to conduct research using human pluripotent stem cells.