

The Context

Among its other purposes, the National Institutes of Health (NIH) dispenses funds for research. One controversial area of research is the use of stem cells from fetal tissue. These cells have great potential for research and health treatments because, unlike adult cells, they are "pluripotent," meaning that they can generate multiple types of cells, such as skin or muscle cells. Research on fetal cells raises legal and ethical questions: Might fetuses be conceived as a source of the cells? NIH policy prohibits the use of federal funds for research on fetal tissue that has been developed for the purpose of research.

The current document is part of the NIH policy statement and guidelines regarding funding of research using fetal stem cells. It needs to be publicized to potential applicants for research funding and also helps the NIH make its decisions. It is an important document because it defines policy and guidelines on a complex and controversial topic.

Instructions

To copyedit this statement, you will need to make decisions about spelling, capitalization, and abbreviations as well as to edit for consistency. Use a style manual and dictionary as you make copyediting decisions.

Make a short **style sheet** indicating choices that involve editorial judgment and that might apply to related documents, even if the judgment is to leave the text as it stands.

You may be tempted to edit for grammar, organization, and sentence structure. However, your supervisor has limited your responsibilities on this task to basic copyediting. You may, however, **query** if you see a confusing point of content.

You will also need to **mark for graphic design** according to these specifications:

- | | |
|---------------|---|
| title | Helvetica 14, boldface, centered, ulc (upper- and lowercase) |
| heading | Helvetica 12, bold, left justified, ulc |
| paragraphs | indent one em; Times 11/12 x 27 flush left, ragged right |
| bulleted list | bullet indented one em; hanging indent on turnover lines of two ems |

The Promise of STEM Cell Research

Human pluripotent stem cells are a unique scientific and medical resource. In 1998, scientists at the University of Wisconsin and at John Hopkins university isolated and successfully cultured human pluripotent stem cells. The pluri-potent stem cells were derived using non-Federal funds from early-stage embryos donated voluntarily by couples undergoing fertility treatment in an in vitro fertilization (IVF) clinic or from non-living fetuses obtained from terminated first trimester pregnancies. Informed consent was obtained from the donors in both cases. Women voluntarily donating fetal tissue for research did so only after making the decision to terminate the pregnancy.

Because pluripotent stem cells give rise to almost all of the cells types of the body, such as muscle, nerve, heart, blood, they hold great promise for both resaerch and health care. This advance in human Biology continues to generate enthusiasm among scientists, patients suffering from a broad range of diseases, including cancer, heart disease and diabetes, and their families. For example, farther research using human pluripotent stem cells may help:

- Generate cells and tissue for trasnplantation. Pluripotent stem cells have the potential to develop into specialized cells that could be used as replacement cells and tissues to treat many diseases and conditions, including Parkinsons Disease, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, and Rheumatoid Arthritis.
- Improve our understanding of the complex events that occur during normal human development and also help us understand what causes birth defects and cancer.

- Change the way we develop drugs and test them for safety. rather than evaluating the safety of candidate drugs in an animal model, drugs might be initially tested on a cells developed from pluripotent stem cells and only the safest candidate drugs would advance to animal and then human testing.

The Need for Guidelines to Govern Research Using pluripotent stem Cells

The NIH is prohibited from using any appropriated funds for "... (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human 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 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))."

Because of the enormous potential of human pluri-potent stem cells to medical research, the NIH asked the General Council of the Department of Health and Human Services to determine whether research utilizing pluripotent stem cells is permissible under existing federal law governing embryo and fetal tissue research. After careful consideration, the DHHS concluded that because human pluripotent cells are not embryos, current Federal law does not prohibit DHHS funds from being used for research utilizing these cells.

Recognizing the ethical and legal issues surrounding human pluripotent stem cell research and the need for stringent oversight of this class of research - oversight that goes beyond the traditional rigorous NIH scientific peer review process - the NIH issued a moratorium on the funding of this research until Guidelines could be developed and an oversight process could be implemented.

In April 1989, the NIH convened a working group of the Advisory Committee to the Director (ACD), NIH, to provide advice to the ACD relevant to guidelines and

oversight for this research. The working group met in public session and included scientists, clinicians, ethicist, lawyers, patients, and patient advocates. During their deliberations, the group considered advice from the National Bioethics Commission, the public, and scientists. Draft guidelines for this research were published for public comment, and, after reviewing and considering all comments received, the *NIH Guidelines for Research Using Human Pluripotent Stem Cells (NIH Guidelines)* were published in the Federal Register and became effective on August 25, 2000.

Specifics of the Guidelines

The purpose of the *NIH Guidelines* is to set forth procedures to help ensure that NIH-funded research in this area is conducted in an ethical and legal manner. By issuing these Guidelines, the NIH aims to enhance both the scientific and ethical oversight of this important arena of research and the pace at which scientists can explore its many promises. These *Guidelines* will encourage openness, provide appropriate federal oversight, help make certain that all researchers can make use of these critical research tools, and help assure full public access to the practical medical benefits of research using these cells.

Style sheet: The Promise of Stem Cell Research

Do not record every change you made. Rather, record choices that should be followed in the rest of the document when a choice (in spelling, capitalization, punctuation, numbers...) had to be made. Do not include the type specs. Use the style manual that your instructor has identified for the course.

A-D	E-H	I-L
M-P	Q-T	U-Z
Numbers	Style-spacing	Miscellaneous

Dictionary consulted:

Style manual consulted: