After almost a year of discussion and debate, Harold Varmus, MD, director of the National Institutes of Health (NIH), has proposed guidelines under which federally funded scientists can pursue research using human pluripotent stem cells.

The issue has been politically charged. Conservative members of Congress have gone on record against the use of the cell cultures because they believe it violates the federal ban on research using human embryos. In response, petitions from well-known US researchers and Nobel laureates arrived, stating that to ignore such an opportunity would delay, and even prevent, the development of treatments for many now-untreatable and incurable diseases.

In December 1998, 2 different research groups reported that they had isolated and cultured human pluripotent stem cells from 2 different sources. Pluripotent stem cells are early progenitors of most of the specialized cells in the human body. The various tissues and organs in the body are composed of these cells. In culture, stem cells can divide for an indefinite period of time.

However, the 2 methods used by the researchers raised ethical issues. One group derived their cells from early-stage human embryos that were created and then not used for the in vitro fertilization of women seeking treatment for infertility problems. The second group derived their cells from fetuses that had been aborted. In each case, the patients involved gave consent to have their embryos or fetal tissue used in the research. Neither of the groups used federal money.

Shortly after the research findings were released, Dr Varmus requested a legal opinion from the general counsel to the US Department of Health and Human Services as to whether federal funds could be used in research using human pluripotent stem cells. The attorney found that federal funds could be used in such research because cells are not embryos. However, the opinion also stated that the human pluripotent stem cells derived from fetal tissue fall within the definition of human fetal tissue and are subject to federal restrictions on the use of such tissue in transplantation.

In a statement released by the NIH, Dr Varmus said, “It is essential that the federal government play a role in funding and overseeing the conduct of this research. Federal funding will make it possible for scientists—both privately and federally funded—to 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 private sources of funding and will also help ensure that the results of research will be accessible to the public.”

In the guidelines, Dr Varmus and the committees that worked with him on the issue proposed the following:

- Studies using pluripotent stem cells derived from early human embryos may be conducted using NIH funds only if the cells were derived from early human embryos that were created for the purposes of infertility treatment and then were not needed in the treatment.
- Donations of the embryos should be voluntary, and consent can be requested only after it is determined that the embryos will not be used in the infertility treatment.
- A clear separation should exist between the decision to create embryos for infertility treatment and the decision to donate unneeded early human embryos for research purposes, including making certain that the attending physician responsible for the fertility treatment and the researcher wanting the material for the purposes of culturing human pluripotent stem cells are not the same person.
- All identifiers associated with the material should be deleted before it is used for the purposes of deriving human pluripotent stem cells.
- No restrictions can be placed on the donation of the tissue, especially those that might specify that the tissue can be used only for specific individuals who might be the recipients of cell transplants derived from the stem cell cultures.
- Informed consent should include a statement in which it is clearly asserted that the human embryos will be used to derive stem cells for research that follows NIH guidelines, that the cells may at some time be used in research involving human transplantation, that all identifiers will be removed from the tissue, and that donors will not receive further information about the embryo or the stem cells derived from it. The consent form must also state that the cells could have future commercial potential and that the donor will not benefit from it. Donors must be told that the embryos will not be transplanted into the uterus of another woman and that they will not survive the process that results in stem cells.

The guidelines for the derivation and use of human pluripotent stem cells from fetal tissue must follow rules similar to those set up for embryos and also follow federal rules for the use of fetal tissue in transplantation research.

Some human pluripotent stem cell research will not be funded, according to the proposed guidelines. Among these are the use of early human embryos that were created for any purpose besides infertility treatment; research in which stem cells are used to create or contribute to the development of a human embryo or in which they are combined with an animal embryo is also ineligible for federal funds. Research in which such cells are derived

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from a process in which a human somatic cell nucleus is transferred into a human or animal egg or work in which cells are derived from embryos created for the sole purposes of research is also in the banned category.

Before the NIH will fund stem cell research, it must have documentation regarding the source of the embryos or fetal tissue. All such applications will be reviewed for scientific merit by a series of different groups and directors. A Human Pluripotent Stem Cell Review Group will be established to review documentation of compliance with the guidelines and to hold public review meetings.

Ruth SoRelle, MPH
Circulation Newswriter
Varmus Proposes Guidelines for Stem Cell Research
Ruth SoRelle

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