

White House Releases Final Stem Cell Guidelines

BY JOYCE FRIEDEN

Federally funded human embryonic stem cell research may only use stem cells from embryos created by in vitro fertilization for reproductive purposes and that are no longer needed, according to final guidelines issued by the Obama administration.

The human embryonic stem cells (hESCs) must be donated by individuals

“who gave voluntary written consent for the human embryos to be used for research purposes,” according to the guidelines. Researchers must obtain written documentation that hESCs meet requirements, including:

- ▶ All options for disposition of embryos no longer needed for treatment were explained to the donors;
- ▶ No payments of any kind were offered for the embryos;

▶ Policies were in place ensuring that neither consenting nor refusing to donate embryos would affect the treatment given to any patient;

▶ Decisions about whether to donate embryos were made free of influence from stem cell researchers.

▶ Donors were informed that they retained the right to withdraw their donation up until the embryo was actually used.

“The guidelines will ensure that [National Institutes of Health]-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law,” according to a statement from the NIH, which will oversee all federally funded hESC research.

“Internal NIH policies and procedures, consistent with [President Obama’s March 9 executive order] and these guidelines, will govern the conduct of intramural NIH stem cell research.”

Under the Bush administration, federal funding for human embryonic stem cell research was limited to studies using only the few stem cell lines that were in existence when the policy was created in August 2001. President Obama’s executive order lifted those restrictions and allowed funded research to include embryonic stem cell lines created after that date. It also called for the NIH to develop new stem cell research guidelines. However, the order did not lift a current ban on using federal funds to create stem cell lines if the creation involved destruction of human embryos. Federal policy does not affect privately funded stem cell research.

One question raised by the executive order was how the guidelines would treat stem cell lines already in existence when the guidelines were issued.

In a document accompanying the guidelines, NIH officials note that “many lines were derived consistent with ethical standard and/or guidelines developed by various states, countries, and other entities such as ... the National Academy of Sciences. These various policies have many common features, rely on a consistent ethical base, and require an informed consent process, but they differ in details of implementation.”

The guidelines authorize use of such stem cell lines if they are either compliant with the new guidelines or if they undergo a review by an NIH working group. “Working group review will enable pre-existing hESCs derived in a responsible manner to be eligible for use in NIH-funded research,” the document states.

The draft hESC guidelines, which were released in April, generated 49,000 comments.

When the draft guidelines were announced, Dr. David Stevens, CEO of the Christian Medical Association, in Bristol, Tenn., cited both moral and scientific problems with embryonic stem cell research. “We understand that embryos are human beings. Every one of us was an embryo,” he said. “When you destroy an embryo, you destroy a distinct human being.” On the scientific side, the prospects for embryonic stem cell research have been overblown, he said.

Several groups reacted positively to the release of the final guidelines. The Association of American Medical Colleges, for example, said it was “pleased that the NIH has issued clear guidelines on stem cell research, and established a pathway for existing lines to be considered for federal funding.”

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