



Center for Genetics and Society Comments on NIH draft guidelines on stem cell research

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As a public affairs organization working for responsible uses and governance of human biotechnologies, we are encouraged by the draft guidelines for the federal funding of human embryonic stem cell research. We believe they represent an informed and thoughtful approach that will foster embryonic stem cell research, while ensuring that it proceeds in a manner consistent with social and ethical values shared by the great majority of Americans.

We support the expansion of federal funding for research involving stem cells derived from embryos created but not needed for assisted reproduction. We likewise support the provisions for fully informed consent on the part of potential donors of embryos for stem cell research, and the prohibition of inducements for donating embryos.

We also concur that federal funding for stem cell research involving somatic cell nuclear transfer, parthenogenesis, and human/animal chimeric embryos should be forgone at this time. These procedures raise many serious social and ethical questions that have not been resolved.

We urge speedy approval of these draft guidelines as the stated policies of the U.S. government. They will allow needed medical research to proceed in a responsible manner, and will set a precedent for careful public oversight of additional new human biotechnologies.

Below we summarize the reasons for our support of the major provisions of the draft guidelines, and offer several suggestions.

Support for provisions on sources of embryonic stem cell lines

The decision to allow federal funding for research on stem cell lines derived from embryos that were created but not needed for assisted reproduction will support useful medical research and will remove the logistical obstacles that the previous funding policy imposed.

It is appropriate to disallow federal funding of research using stem cell lines derived from embryos created through the use of somatic cell nuclear transfer and parthenogenesis for these reasons:

1. *Cloning-based stem cell research requires large numbers of women's eggs.* Both SCNT and parthenogenesis require large numbers of human eggs to create clonal embryos. The extraction of eggs poses significant health risks to the young women who would provide them.

2. *Effective procedures and regulations to prevent the misappropriation of clonal efforts for efforts to produce human children are not in place.* There is currently no federal prohibition of reproductive cloning, although it is opposed by a large majority of Americans and by most scientists. In his March 9 remarks on stem cell research, President Obama said that reproductive cloning is "dangerous, profoundly wrong, and has

no place in our society, or any society.” We urge NIH to work with the White House and Congress in support of federal legislation prohibiting human reproductive cloning.

3. *Cloning-based stem cell research has been largely unsuccessful, and now appears technically unnecessary for the production of genetically matched stem cell lines.* Several research groups claim to have created human clonal embryos, but there have been no reports of successful efforts to derive stem cell lines from clonal embryos. Meanwhile, rapid progress has been made using cellular reprogramming techniques to create genetically matched (disease-specific and patient-specific) stem cell lines, which was the goal of cloning-based stem cell research.

4. *There is wide support for embryonic stem cell research, but not for the use of cloning techniques.* Surveys indicate that Americans support research that uses embryos slated for destruction, but balk at creating embryos specifically for research purposes, either by fertilization or cloning. Excluding federal funding for cloning-based stem cell research, as well as research involving the creation of human-animal chimeras, is consistent with the values held by most Americans. It is also consistent with President Obama’s campaign pledge that embryonic stem cell research “must be conducted using the highest ethical standards, including only the use of embryos that would otherwise be discarded, and the written consent of donors.”

Support for provisions on informed consent and related protections

The draft guidelines provide a full set of important protections for people who choose to donate embryos that were created when they sought reproductive services, but that are no longer needed for reproductive purposes.

We support the guidelines’ provisions for fully informed and written consent from these donors, the prohibition on inducements to donation, and the requirement that the physician providing reproductive services and the researcher deriving or using the stem cells derived from the donated embryos not be the same person.

We suggest three changes to these provisions, all of which, we believe, are consistent with the principles that inform the guidelines:

- The draft guidelines require that “the attending physician responsible for reproductive clinical care and the researcher deriving and/or proposing to utilize human embryonic stem cells” not be the same person “whenever ...practicable.” We suggest strengthening this important protection by requiring that the physician and researcher not be the same person unless exceptional circumstances exist and an IRB has approved an exemption from this requirement. Further, we suggest that the guidelines require that the physician not have a financial interest in the outcome of the research.
- Extend the informed consent requirements to people who provided eggs or sperm used in the creation of embryos that are being considered for donation for stem cell research. These parties provided their gametes with the understanding that the embryos created from them would be used for assisted reproduction.
- Create an exception to the informed consent requirements for stem cell lines that have already been derived. If the lines were derived using informed consent procedures considered ethically responsible at the time and approved by an IRB, federal funding for research on them should be permitted.