From Debra L. Vinnedge, Executive Director
Representing:
Children of God for Life
4613 Barfield Cresent Rd
Murfreesboro, TN 37128

May 4, 2009

Response to Invitation for Public Comment: Draft NIH Human Stem Cell Guidelines

I would like to address the proposed policy and procedures for Executive Order 13505 which provides tax-payer funding for research using embryos that were produced through in vitro fertilization clinics, but will no longer be used for reproductive purposes.

The NIH proposes that the research will be conducted in a manner that is "ethically responsible, scientifically worthy, and conducted in accordance with applicable law."

Ethically Responsible:
Any research that involves the deliberate destruction of human beings in order to obtain stem cells for so called therapeutic purposes is not ethically responsible.

From a biological standpoint, a human embryo is a unique and well defined individual from the beginning of the union of the gametes through the ensuing stages of development. Thus, as a human individual, he/she is entitled to a right to life as guaranteed in the US Constitution. Any intervention that is not of benefit to the embryo itself is not an ethically responsible action and further, it would violate the laws established in US 45 CFR 46, the United Nations Declaration of Human Rights and the Nuremburg Code.

Whether the NIH agrees with such universally known principles or not is of little consequence because by using federal funds to destroy human life, millions of taxpayers would be forced to become complicit with the immoral actions of the government.

Scientifically Worthy
To date, there has not been one single successful cure or treatment using embryonic stem cells to treat patients, whereas over 70 diseases have been successfully treated using adult stem cells. See Science Magazine: http://www.sciencemag.org/cgi/data/315/5810/328b/DC1/1 for a partial listing of adult stem cell therapies.

It is amazing, if not utterly irresponsible, that the Federal Government would invest taxpayer money for embryonic stem cell research when adult stem cells are showing such progress!

The guidelines state that "the most important potential use of human embryonic stem cells is the generation of cells and tissues that could be used for cell-based therapies. Today, donated tissues and organs are often used to replace ailing or destroyed tissue, but the need for transplantable tissues and organs far outweighs the available supply."

In reality, despite numerous attempts and billions of dollars in private funding, embryonic stem cells have failed to produce any cells or tissues for use in human therapies. Further, unlike adult stem cells which are patient specific, embryonic stem cells cause immune rejection in the subject. And precisely because these are undifferentiated cells, they also produce cancerous tumors in addition to undifferentiated, malignant teratomas from the three germ layers.

The NIH further contends that, "stem cells, directed to differentiate into specific cell types, offer the possibility of a renewable source of replacement cells and tissues to treat diseases and conditions, including Parkinson's disease, amyotrophic lateral sclerosis, spinal cord injury, burns, heart disease, diabetes, and arthritis." Yet all of these conditions are already being successfully treated using adult stem cells. There is simply no reason for using taxpayer funds to promote research that is both morally and scientifically unwarranted.

In accord with the law: 45 CFR part 46 Protection of Human Subjects

Interestingly, the guidelines note that the "requirements of the Department's protection of human subjects regulations, 45 CFR part 46, may or may not apply, depending on the nature of the research."

In 45 CFR §46.111 Criteria for IRB approval of research it states:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

As defined in 45 CFR, part 46 (i)
"Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

It is utterly disingenuous at best to state that sections of this law may or may not apply because since human embryos are destroyed while removing the stem cells, they are put at risk of serious harm and thus, 45 CFR 46 would NEVER apply.

In addition, the Nuremburg Code, which was established in 1947 and later became the basis for US 45 CFR 46, states in Article 2:
"The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature."

Clearly, not only are there other procurable methods using adult stem cells, embryonic stem cell research has been proven to yield no fruitful results and is most certainly unnecessary, if not detrimental, toward advancing the good of society.

II. Guidelines for Eligibility of Human Embryonic Stem Cells for Use in Research Specifically

Under Section B. Eligibility of Human Embryonic Stem Cells Derived from Human Embryos, the guidelines state that, " Human embryonic stem cells may be used in research using NIH funds, if the cells were derived from human embryos that were created for reproductive purposes, were no longer needed for this purpose, (and) were donated for research purposes"

Since there are no regulations in place that monitor or limit the production of embryos for in vitro fertilization purposes, there is nothing in the guidelines to prevent IVF clinics from simply over-producing embryos that could later be donated for research purposes and yield financial rewards. In short, the NIH guidelines do not prevent the implementation of full-blown embryo farming.

IV. Other Non-Allowable Research

While the guidelines state under Section B that, "NIH funding for research using human embryonic stem cells derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not allowed", the guidelines do not consider other means of producing embryos that do not involve the IVF process whatsoever and are beyond those listed.

For example, many cells from the zygote through the blastocyst stage and sometimes, beyond are totipotent, meaning they have the ability to form entirely new embryos. Nothing in the guidelines prevent funding for research on embryos that naturally form from these totipotent cells, nor does it prevent scientists from producing new embryos through blastomere splitting.

In summary, embryonic stem cell research using Federal Funding violates the moral and religious rights of millions of US citizens who oppose the destruction of human life for research purposes. It has not yielded any benefits to society; it has not produced treatments or therapies despite years of research using private funds. It violates existing laws governing the use of human subjects for research; it opens the door for reckless abuse of the law and the potential for massive production and destruction of innocent human life. Even if embryonic stem cell research might one day produce some sort of human benefit, millions of people in need will forego such treatments rather than violate their religious beliefs.

To date, over 615,000 Americans have joined the Campaign for Ethical Vaccines because there are several immunizations that are produced using aborted fetal cell lines and families are refusing to use them. Please do not make the same mistake again! Research that uses public funding should be focused on treatments that all Americans and indeed, citizens of the entire world can benefit from without moral compromise.