



March 25, 2010

National Institutes of Health
ATTN: Proposed Revision to NIH Guidelines for Human Stem Cell Research
MSC 7997
9000 Rockville Pike
Washington, DC 20892-7997

Re: “Proposed Revision to NIH Guidelines for Human Stem Cell Research”
[75 Fed. Reg. 8085 \(February 23, 2010\)](#)

Dear Director Collins, National Institutes of Health:

On behalf of the Family Research Council (FRC), this document responds to the above-captioned public notice in which the National Institutes of Health (NIH) has requested comment on the “Proposed Revision to NIH Guidelines for Human Stem Cell Research”; in particular, replacing the current definition of hESCs in Section II of the [NIH Guidelines for Human Stem Cell Research](#):

For the purpose of these Guidelines, “human embryonic stem cells (hESCs)” are cells that are ~~derived from the inner cell mass of blastocyst stage human embryos~~ **pluripotent cells that are derived from early stage human embryos, up to and including the blastocyst stage**, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers.

The following demarcated text is our submission via NIH electronic form, which limited comments to 6,000 characters (including spaces.)

The proposed redefinition of human embryonic stem cells (hESCs) contravenes Section V.B. of the NIH Guidelines on Human Stem Cell Research, expands the unethical use of human embryos for experiments, and creates additional incentives for embryo experimentation.

One primary reason for the proposed redefinition is to benefit a company, Advanced Cell Technology, which claims they can isolate one blastomere from an embryo and create hESC lines without harming the embryo ([Nature 444:481](#); [Cell Stem Cell 2:113](#)). The claim of no harm is dubious at best, as their own data show not all embryos in the experiments survived or developed further. Data from various groups concur that this is not a harmless technique ([NEJM 357:9](#); [Hum Rep 23:2813](#); [Hum Rep 23:2818](#); [Biennial Review of Infertility 2009:289](#); [Mol Cell Proteom 8:1490](#)). Funding the technique itself would contravene the [Dickey-Wicker amendment](#) because of the embryos being subjected to risk of injury or death.

The blastomere biopsy technique may in fact create a new embryo during the process. It has been shown that a 4-cell human embryo can be disaggregated and each of the 4 cells can individually form a complete new embryo ([Hum Rep 23:1742](#)). This would constitute a form of embryo-splitting or cloning. The newly-created human embryos from this technique have been shown to

develop (indicating their totipotency, i.e., ability to form a complete new embryo) and used for derivation of embryonic stem cells ([Hum Rep 24:2709](#)). It is unknown whether the cells of an 8-cell human embryo or later stages also retain totipotency, but experiments with mice suggest that at the 8-cell stage and even perhaps the 16-cell stage, each blastomere cell may retain totipotent ability ([Int J Dev Biol 49:825](#); [Dev Biol 322:133](#)). If that is the case for human embryos, any removal of 1 or 2 blastomeres from such an early human embryo, even with the intent to use the blastomeres for derivation of hESC, would constitute creation first of a new embryo, i.e., embryos created for research purposes. Funding hESC lines based on this technique would contravene Section V.B. of the NIH Guidelines. If funds were to be used for the blastomere isolation technique as well, this would contravene the Dickey-Wicker amendment, both in terms of the prohibition against creating embryos for research and the prohibition against embryo destruction.

Further, the proposed redefinition risks improper assignment of embryos as abnormal or failing to develop. [NIH already mistakenly approved 3 such lines](#) and others are likely to be submitted. But determination that an embryo is abnormal or even not viable is usually subjective, based on visual observation or sometimes PGD. Yet there is ample evidence that even such “lower grade” embryos can develop normally (e.g., [Fert Ster 84:1328](#); [Repro Biomed Online 13:255](#); [Repro Biomed Online 8:460](#)). The redefinition would provide an incentive to create more embryos for couples, then pre-emptively cull embryos for hESC research funding based on subjective criteria; this is all the more possible due to the flaw in the Guidelines allowing the fertility doctor and the hESC scientist to be the same person, creating a conflict of interest.

The proposed redefinition is not based on definitive biological evidence regarding the characteristics of cells from different stage embryos. The assumption is that cell lines created from embryos up to and including blastocyst are functionally equivalent. However, this has not been demonstrated, and moreover may indeed be incorrect, given that various changes in gene expression occur during the time frame from single-cell embryo to blastocyst.

In regards to practical applications, [adult stem cells](#) have already [demonstrated successful patient therapies](#), [documented](#) by [peer-reviewed publications](#), of the type only hoped for with hESC. Given that hESC are an artifact of cell culture, they are neither necessary nor sufficient to study diseases.

The proposed redefinition is not a minor technical change—it illustrates the willingness of NIH to change guidelines to fit desires (for more embryos and for taxpayer funds), not scientific data. It is neither ethically responsible nor scientifically worthy.

Thank you for your consideration of these comments.

Respectfully submitted on behalf of the Family Research Council,

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