



## Do we still need embryos and cloning?

*Answering Common Claims about induced pluripotent stem cells (iPSCs), an ethically unproblematic alternative to human embryonic stem cells (hESCs).*

### **Claim 1: Good science demands that we investigate all avenues of inquiry.**

Response: “Good” research respects both scientific and ethical standards. iPSC research meets every mark of good science and has the following ethical advantages: it does not destroy human embryos; it does not use human oocytes; and it does not alienate a large part of the country’s citizens by engaging in research that they find deeply immoral.

### **Claim 2: Politicians should continue to pursue federal funding for the use of so-called “left over” IVF embryos despite the recent advance of iPSCs.**

Response: Direct reprogramming to create iPSCs provides a scientifically feasible and promising alternative to research that requires destroying human embryos. Even President Clinton’s bioethics commission concluded that embryo destruction posed a moral problem and was “justifiable” only if there were no alternatives.

**“In our judgment, the derivation of stem cells from embryos remaining following infertility treatments is justifiable only if no less morally problematic alternatives are available for advancing the research** But as we have noted, ES cells from embryos appear to be different in scientifically important ways from AS cells and also appear to offer greater promise of therapeutic breakthroughs. The claim that there are alternatives to using stem cells derived from embryos is not, at the present time, supported scientifically. **We recognize, however, that this is a matter that must be revisited continually as science advances.”**

- National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research* (Sept. 1999), Volume I, p. 53 (boldface added).

### **Claim 3: Scientists still need to compare iPSCs to hESCs.**

Response: Yes, but this does not require cloning or destroying human embryos to make more hESC lines. At least 21 viable lines of human embryonic stem cells are available for federally funded research to make these comparisons. The currently eligible and available cell lines are listed here:

<http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp>

Furthermore, the primate system permits the best in-depth platform for comparative studies. From rhesus macaque monkeys, primate pluripotent stem cells are available from

all conceivable sources: IVF embryos, naturally conceived embryos (removed from the Fallopian tube after fertilization), SCNT-cloned embryos, parthenoids and soon iPS cells.

**Claim 4: We don't know if iPSCs are really equivalent to ESCs.**

Response: Dr. James Thomson, the first scientist ever to isolate, culture and characterize human embryonic stem cells in 1998, and author of one of the two iPSC studies, found that iPS cells “meet the defining criteria” for embryonic stem cells “with the significant exception that the iPS cells are not derived from embryos.”

Mouse iPSCs have passed the strictest possible scientific tests for being functional equivalents of mouse ESCs. Tests for human cells are more limited, but human iPSCs have met all the available criteria for being the functional equivalent of hESCs. This can be established with greater certainty through comparisons with the existing hESC lines eligible for federal funding, which have been used in the vast majority of human ESC studies throughout the world.

**Claim 5: We don't know whether iPSCs or hESCs will be better for research.**

Response: There are at least three significant reasons why iPSCs are better for RESEARCH:

- First, patient-specific iPSCs are available “here and now,” compared to the merely theoretical prospects of stem cells from human embryo cloning. Direct reprogramming is the ONLY way to derive pluripotent cells from specific adult patients (i.e. patient-specific stem cells) for research on human genetic diseases at this time.
- Second, direct reprogramming makes multiple iPSC lines from an individual patient’s skin cells without any additional cost or effort – an enormous scientific advantage. Obtaining iPSCs does not require access to a fertility clinic, simplifying the requirements for research, and these cells are easier to produce than hESCs, so more scientists will work with them and research will advance much more quickly.
- Third, because iPSCs do not involve human embryos or human eggs, they will be subject to significantly simpler regulatory requirements. iPSCs are fully eligible now for funding by the NIH, and in fact the Wisconsin iPSC study was partly funded by the NIH.

**Claim 6: We don't know whether iPSCs or hESCs will be better for therapies.**

Response: Currently, there are no clinical trials for either hESCs or iPSCs, because several problems remain to be overcome in terms of safety (cancer risk) and efficacy (ability to differentiate into useful cell types). However, if these obstacles can be overcome, there are at least two significant reasons why iPSCs may be better for THERAPIES:

- iPSCs are patient specific, a huge advantage for therapeutic use, compared to hESCs “left over” from fertility clinics that are not patient-specific and would require immune suppression.
- iPSCs do not use human eggs, making it possible to develop therapies without imposing significant medical risks on women (who must be given hormones to produce numerous eggs per cycle for egg donation).

**Claim 7: iPSCs can make tumors and convert to cancer cells.**

Response: Multiple scientific studies show that *all* pluripotent cells, including hESCs, form tumors (teratomas) and can convert to cancer cells. The risk of tumor formation may, at this time, be higher in iPSCs than in embryo-derived stem cells because the genes used for reprogramming remain inserted in the cell. However, leading stem cell biologists are optimistic that they can modify the iPS technique to eliminate any added risk of tumor formation. Dr. Douglas Melton, co-director of the Harvard Stem Cell Institute, predicts this problem will be “solved quickly, maybe within a year or so” ([AP, 22 November 2007](#)), also noting: “Anyone who is going to suggest...that it won’t work is wrong” ([New York Times, 21 November, 2007](#)). Rudolf Jaenisch, a leading stem cell researcher at the Whitehead Institute for Biomedical Research in Cambridge, Massachusetts concurs, stating: “I don’t think it is a big hurdle” ([Washington Post, 21 November 2007](#))

The risk of tumor formation that is NOT due to the reprogramming procedure but common to all pluripotent stem cells can theoretically be addressed by converting pluripotent stem cells into mature cells that do not form tumors and can be transplanted safely to patients. It is important to understand that the efficient conversion of pluripotent stem cells to transplantable cells useful in the clinic is not yet possible for any human cell type, although much progress has been made. Thus, no immediate therapies should be expected from human pluripotent stem cells, either embryo derived or iPSC.

**For more information:**

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