

Alternative Sources of Human Embryonic Stem Cells

**Ethics
Matters**

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Introduction: The Issue

For those who believe that the embryo is a human person from the moment of conception, destruction of the embryo is equivalent to murder.

But the stem cells obtained from human embryos offer great hope for curing diseases.

Question: Is there any way of obtaining human embryonic stem cell without destroying or harming human embryos?

Stem Cells



Stem cell research offers the promise of important cures, but so far these seem to be at the price of the destruction of embryos.

The Dickey Amendment

The Dickey Amendment, named for its author, former Representative Jay Dickey of Arkansas, has been attached to the Health and Human Services authorization bill each year since 1995.

SEC. 510.

(a) None of the funds made available in this Act may be used for—

(1) the creation of a human embryo or embryos for research purposes;

or

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term ‘human embryo or embryos’ includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.



The Bush Policy



For Immediate Release: August 9, 2001

Fact Sheet: Embryonic Stem Cell Research

"As a result of private research, more than 60 genetically diverse stem cell lines already exist" I have concluded that we should allow federal funds to be used for research on these existing stem cell lines " where the life and death decision has already been made", This allows us to explore the promise and potential of stem cell research" without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life."

-- George W. Bush

No federal funds will be used for:

1. the derivation or use of stem cell lines derived from newly destroyed embryos;
2. the creation of any human embryos for research purposes; or
3. the cloning of human embryos for any purpose.

Another Perspective

“The simple proposals that are now widely accepted by the majority of ethicists and scientists alike are as follows:

Allow the use of spare IVF embryos to develop more human stem cell lines. These are entities that do not possess a single neuron and are ready to go and can create tens of thousands of cell lines. Put another way, a piece of DNA is not a human being. A human being is an entity with a functioning brain consisting of billions of neurons with trillions of synapses that develops over time and with crucial interactions with the environment.”

Allow biomedical cloning (SCNT) to go forward. This laboratory procedure has been tested and it works. SCNT can only be carried out in a laboratory and the 14-day-old entity that results from the procedure also has not a single neuron. After the specific stem cells are harvested by 14 days, the remaining tissue is disposed of.”

Michael S. Gazzaniga, Ph.D.

The Obama Policy

Draft National Institutes of Health Guidelines for Human Stem Cell Research

SUMMARY: The National Institutes of Health (NIH) is requesting public comment on draft guidelines entitled "National Institutes of Health Guidelines for Human Stem Cell Research" (Guidelines).

The purpose of these draft Guidelines is to implement Executive Order 13505, issued on March 9, 2009, as it pertains to extramural NIH-funded research, to establish policy and procedures under which NIH will fund research in this area, and to help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Internal NIH procedures, consistent with Executive Order 13505 and these Guidelines, will govern the conduct of intramural NIH research involving human stem cells.

These draft Guidelines would allow funding for research using human embryonic stem cells that were derived from embryos created by in vitro fertilization (IVF) for reproductive purposes and were no longer needed for that purpose. Funding will continue to be allowed for human stem cell research using adult stem cells and induced pluripotent stem cells. Specifically, these Guidelines describe the conditions and informed consent procedures that would have been required during the derivation of human embryonic stem cells for research using these cells to be funded by the NIH. NIH funding for research

- “...allow funding for research using only those human embryonic stem cells that were derived from embryos created by in vitro fertilization (IVF) for reproductive purposes and were no longer needed for that purpose.”
- “...NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research...otherwise known as the Dickey-Wicker Amendment. “

Obama, 2

Eligibility of Human Embryonic Stem Cells Derived from Human

Embryos: 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, were donated for research purposes, and for which documentation for all of the following can be assured:

1. All options pertaining to use of embryos no longer needed for reproductive purposes were explained to the potential donor(s).
2. No inducements were offered for the donation.
3. A policy was in place at the health care facility where the embryos were donated that neither consenting nor refusing to donate embryos for research would affect the quality of care provided to potential donor(s).
4. There was a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes.
5. At the time of donation, consent for that donation was obtained from the individual(s) who had sought reproductive services. That is, even if potential donor(s) had given prior indication of their intent to donate to research any embryos that remained after reproductive treatment, consent for the donation should have been given at the time of the donation. Donor(s) were informed that they retained the right to withdraw consent until the embryos were actually used for research.
6. Decisions related to the creation of human embryos for reproductive purposes were made free from the influence of researchers proposing to derive or utilize human embryonic stem cells in research. Whenever it was practicable, the attending physician responsible for reproductive clinical care and the researcher deriving and/or proposing to utilize human embryonic stem cells should not have been the same person.

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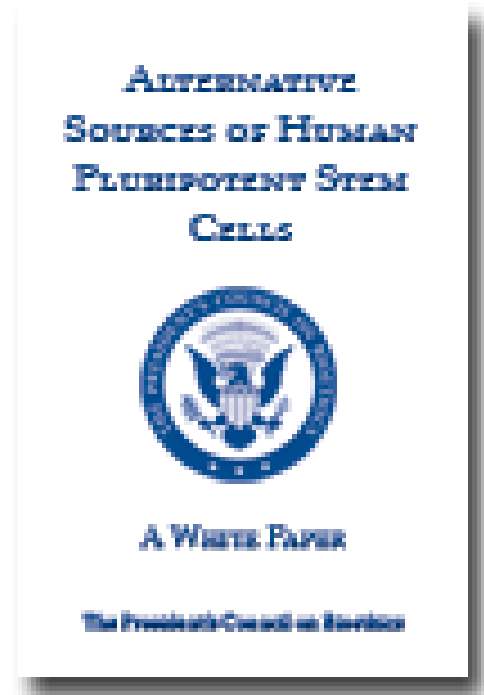
7. Written informed consent was obtained from individual(s) who sought reproductive services and who elected to donate human embryos for research purposes. The following information, which is pertinent to making the decision of whether or not to donate human embryos for research purposes, was in the written consent form for donation and discussed with potential donor(s) in the informed consent process:

- a. A statement that donation of the embryos for research was voluntary;
- b. A statement that donor(s) understood alternative options pertaining to use of the embryos;
- c. A statement that the embryos would be used to derive human embryonic stem cells for research;
- d. Information about what would happen to the embryos in the derivation of human embryonic stem cells for research;
- e. A statement that human embryonic stem cells derived from the embryos might be maintained for many years;
- f. A statement that the donation was made without any restriction or direction regarding the individual(s) who may receive medical benefit from the use of the stem cells;
- g. A statement that the research was not intended to provide direct medical benefit to the donor(s);
- h. A statement as to whether or not information that could identify the donor(s) would be retained prior to the derivation or the use of the human embryonic stem cells (relevant guidance from the DHHS Office for Human Research Protections (OHRP) should be followed, as applicable; see OHRP's [Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles \(37.8 KB PDF; get Adobe Reader\)](#) and [Guidance on Research Involving Coded Private Information or Biological Specimens, or successor guidances](#)); and
- i. A statement that the results of research using the human embryonic stem cells may have commercial potential, and a statement that the donor(s) would not receive financial or any other benefits from any such commercial development.

The Report of the President's Council on Bioethics

The President's Council on Bioethics
White Paper: Alternative Sources of
Pluripotent Stem Cells

The President's Council on Bioethics
Washington, D.C., May 2005



- **Available on-line at:**
- http://www.bioethics.gov/reports/white_paper/index.html

The Challenge

Given the Dickey amendment and President Bush's statement of August 8, 2001, the question was whether there were any ways of obtaining hESC without destroying human embryos.

The situation became worse as it became clear that perhaps only a dozen of the sixty existing and federally-sanctioned stem cell lines could in fact be used.

Even those lines were less than optimal, since they were derived through techniques that resulted in contamination from animal cells.

This came to be known as the quest for "alternative sources of human pluripotent stem cells." Could science, in other words, provide ways of obtaining these cells without destroying human embryos?



Six Possible Sources

- I. Pluripotent Stem Cells Derived from Organismically Dead Embryos (Landry-Zucker Proposal)
- II. Pluripotent Stem Cells via Blastomere Extraction from Living Embryos
- III. Pluripotent Stem Cells Derived from Biological Artifacts
- IV. Pluripotent Stem Cells via “Parthenogenesis.”
- V. Amniotic Fluid that contains embryonic stem cells
- VI. Induced Pluripotent Stem Cells (iPSC)

Dead Embryos



Howard Zucker

Proposed by Landry and Zucker

Landry, D. W. and H. A. Zucker, “Embryonic death and the creation of human embryonic stem cells,” *The Journal of Clinical Investigation* 114, 1184-1186 (2004).

“*organismic death* for the early-stage human embryo: the irreversible loss of the capacity for ‘continued and integrated cellular division, growth and differentiation’.”

Extracting stem cells from an embryo that is organismically dead would not harm the embryo, since it would already be dead.

Problems with Organismic Death

Can we know that the IVF embryos are really dead?
Will the screening to find dead embryos itself harm some embryos?

- Will this be an incentive to produce even more embryos than necessary for IVF?
- Will this in fact yield stem cells of sufficient quality?



Removing a Single Cell

Currently, to perform preimplantation genetic diagnosis (PGD), doctors extract a single cell from the early embryo.

Can we do the same in order to then use the cell to develop hESCs?

Issues:

- Will this harm the embryo?
- Are the removed cells not themselves equivalent to embryos?
- Can one research this issue without harming embryos?

Biological Artifacts

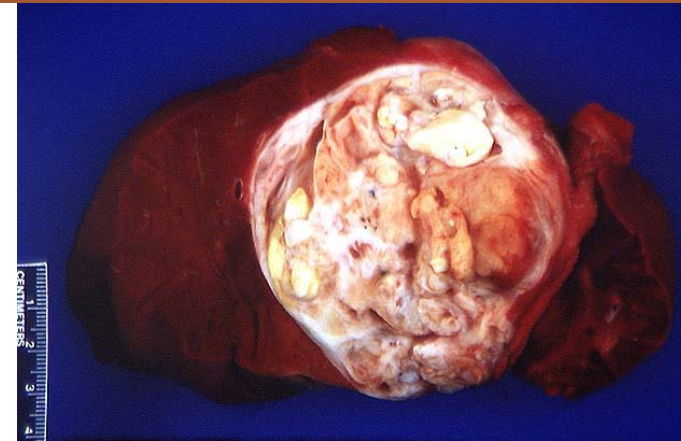


William Hurlbut, M.D. Stanford University

- Hurlbut's suggestion was to knock out a specific gene through Altered Nuclear Transfer (ANT) in such a way that the resulting entity does not qualify as a human being. "The scientific challenge of ANT is to find the right genetic or epigenetic alteration to ensure that pluripotent cells can be produced while not creating an embryonic human being." (White Paper)
- The resulting entity, Hurlbut argues, "...would, by intention, lack the active potential and inviolable moral nature of a living human being."

Teratomas

- Such entities in fact sometimes occur in nature—they are known as teratomas—and they can never develop into full human beings even though the teratomas may show evidence of certain human characteristics such as fingernails.
- Typically these are viewed as freakish and some critics have maintained that this solution is morally and aesthetically repulsive.



Parthenogenesis

Essentially involves tricking a human egg into thinking it had been fertilized when it had not.

The egg would then develop to the 50-100 cell stage, at which point hESCs could be extracted.

Are these really embryos? Could they actually develop as human beings? There is no way to answer that question without implanting the embryo, and this is itself a morally dangerous step.

New Frontiers: Alternative Sources of Pluripotent Stem Cells from Amniotic Fluid

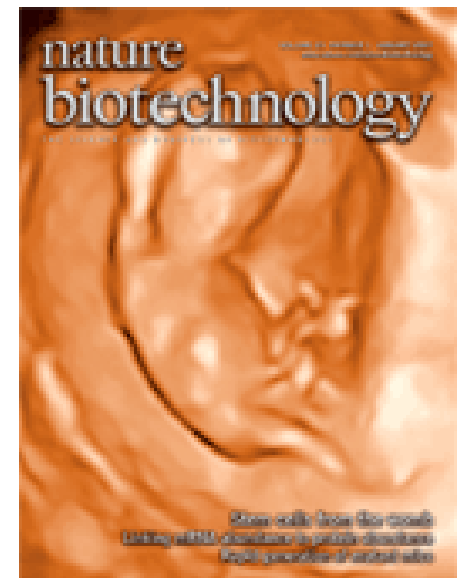
washingtonpost.com

Scientists See Potential In Amniotic Stem Cells

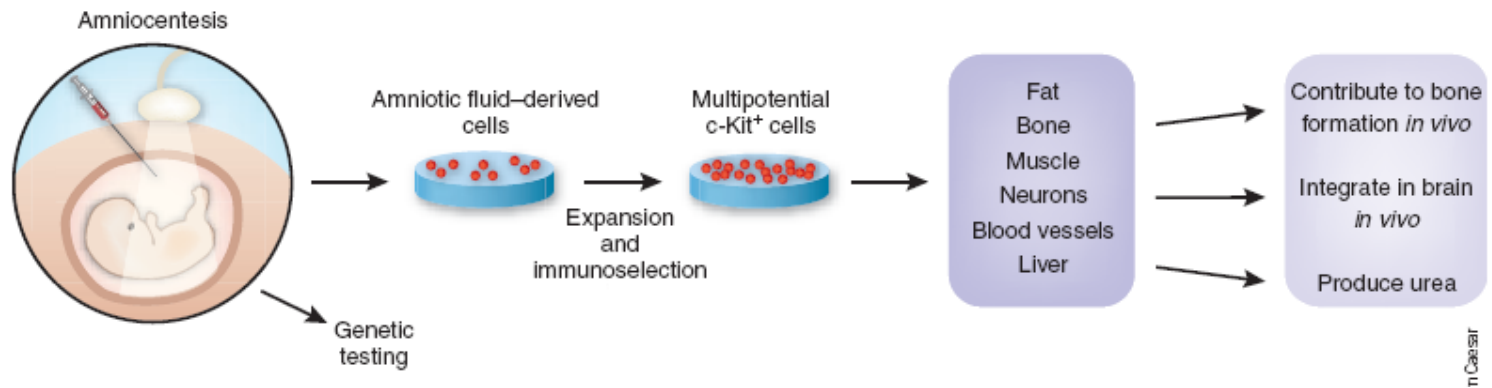
They Are Highly Versatile And Readily Available

By Rick Weiss
Washington Post Staff Writer
Monday, January 8, 2007; A01

A type of cell that floats freely in the amniotic fluid of pregnant women has been found to have many of the same traits as embryonic stem cells, including an ability to grow into brain, muscle and other tissues that could be used to treat a variety of diseases, scientists reported yeste

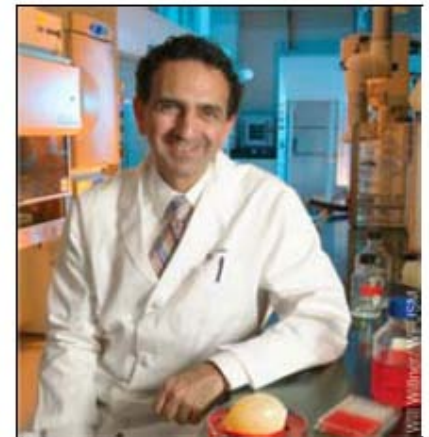


Developing Stem Cell Lines



The process of deriving stem cell lines from amniotic fluid

Anthony Atala

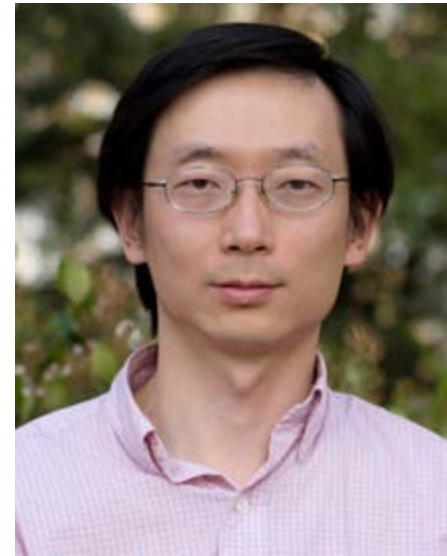


Induced Pluripotent Stem Cells (iPSC)

First developed in 2006 with mice and then a year later with human cells, this technique allows researchers to take an adult somatic cell and step it back to the point where it was pluripotent, that is, could become almost any type of cell in the human body.

Initially, this technique has several scientific drawbacks, including the possibility of creating cancer. Dr. Rudolph Jaenisch (MIT and the Whitehead Institute for Biomedical Research) solved this problem in a paper published in 2008 in *Cell*.

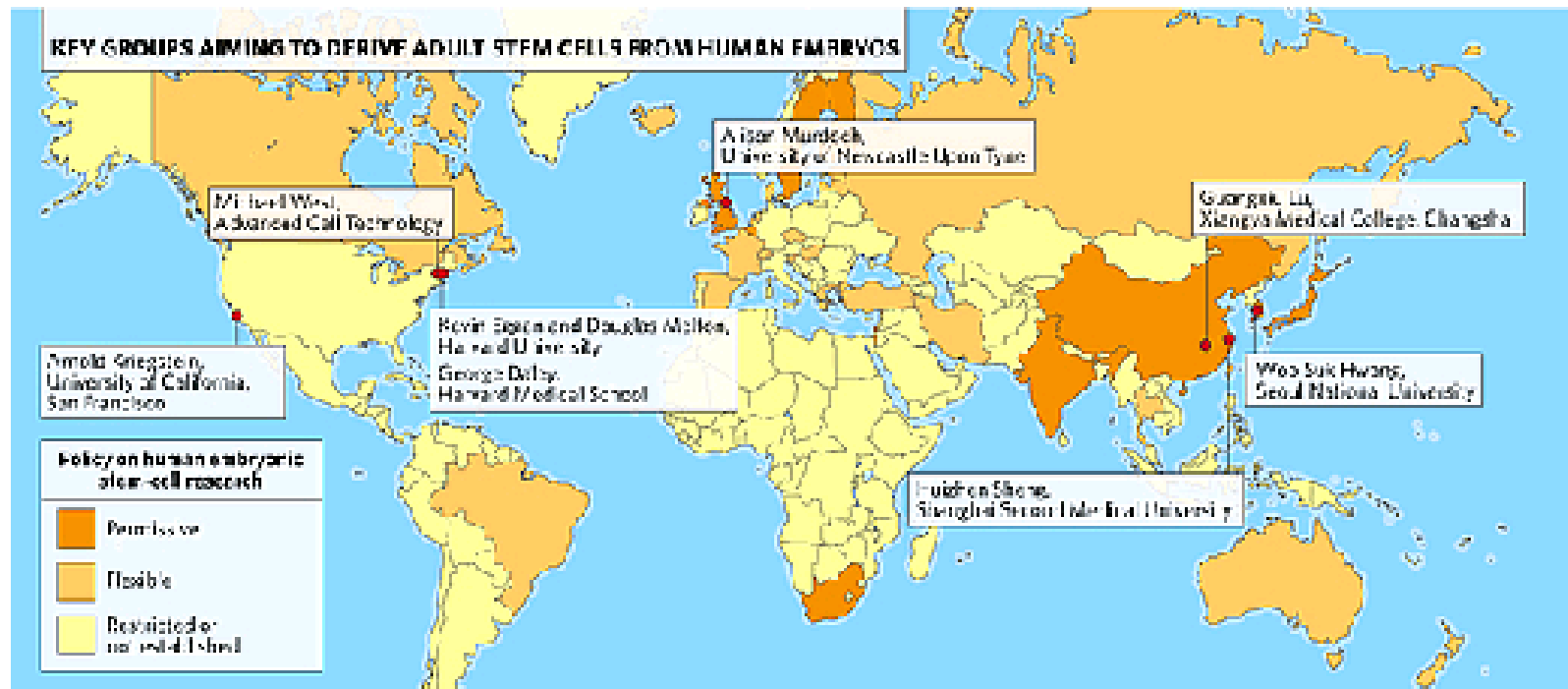
Sheng Ding (Scripps Research Institute, La Jolla) has developed a protein-based technique for inducing such cells that has far fewer liabilities than previous techniques. (*Cell Stem Cell*, April 2009).



A Global Perspective

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Research that is forbidden in the United States may be carried out in a number of other countries throughout the world.