



## University of Wisconsin Stem Cell & Regenerative Medicine Center

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[Site Home](#)

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[Membership](#)

[Research Oversight](#)

[Affiliated Centers and Programs](#)

[The Wisconsin Idea](#)

[National Stem Cell Bank](#)

[Make a Gift](#)

[Job Opportunities](#)

[Contact](#)

[SCRMC > Newsroom > Bac\\_report](#)

### **FINAL REPORT OF THE BIOETHICS ADVISORY COMMITTEE ON HUMAN STEM CELL RESEARCH AT THE UNIVERSITY OF WISCONSIN-MADISON**

The Bioethics Advisory Committee was appointed by Virginia Hinshaw, Dean of the Graduate School, to review ethical, legal and social issues regarding specified research projects being conducted at UW-Madison and to advise on the development of University policy, when appropriate. The Committee convened on October 6, 1998 and held eight meetings. Discussion during these meetings centered on research conducted by Dr. James Thomson that developed pluripotent immortal cell lines derived from human embryonic stem cells.

The Committee reviewed a variety of issues in this research including the following:

- The scientific goals and methods of the research, including possible alternative methods of achieving the same information;
- Potential and probable clinical and commercial applications of the research;
- Other related research projects at UW-Madison and laboratories in other institutions;
- The relative importance of academic freedom in the context of ethics, law, and public opinion;
- The procedures by which the embryonic stem cells were obtained, including the process and content of informed consent;
- Relevant law and regulations regarding research involving human embryos;
- Federal law regarding funding of research involving human embryos;
- The review of the research by the UW-Madison Health Sciences Human Subjects Committee;
- Diverse opinion in our society on the ethics of research in this area;
- Reports and recommendations of other committees and commissions who have considered ethical issues in research involving human embryos, including those from the United States, Canada, and Great Britain;
- Selected scholarly papers on ethical issues from leading writers in this field.

The Committee also considered patent issues and other aspects of applications of

this research.

Based on this review, the Committee unanimously finds that Dr. Thomson's research is scientifically important; has potential clinical benefits; is consistent with existing law, regulations and guidelines; is consistent with the University's mission and its commitment to academic freedom; and is supported by the mainstream of ethical opinion. In light of all these considerations, the Committee unanimously concludes that this research is ethically appropriate.

Regarding future use of such cells, the Committee concludes that human embryonic stem cell lines developed by this research are not themselves embryos.

Finally, the Committee recommends that cells from these cell lines NOT be used for introduction into a uterus without further University of Wisconsin review and approval.

Any other introduction of cells or derivatives from these cell lines into human beings will require the prior review and approval of an appropriate review board.

**Committee Members:**

Patricia T. Becker  
Robin Alta Charo  
Norman Fost (Chair)  
Hector DeLuca  
R. Timothy Mulcahy  
John D. Pirsch  
Elliott R. Sober  
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[Contact](#)

SCRMC > Newsroom > Bac\_report2

### **SECOND REPORT OF THE BIOETHICS ADVISORY COMMITTEE ON HUMAN EMBRYONIC STEM CELL RESEARCH AT THE UNIVERSITY OF WISCONSIN-MADISON**

#### **Introduction**

The Bioethics Advisory Committee was appointed in 1998 by the Dean of the Graduate School, to review ethical, legal and social issues regarding specified research at UW-Madison and to advise on the development of University policy. The Committee convened on October 6, 1998 and held eight meetings resulting in the January 1999 publication of a report on human stem cell research at UWMadison.

Since that report was issued, the committee met nine times between April-October 2001 to discuss further developments in human stem cell research. This second report summarizes the Committee's discussions and sets out a revised set of recommendations.

The Committee paid close attention to concerns about academic freedom; to the scientific goals and methods of the research, including possible alternative methods; the risks and benefits; potential and probable clinical and commercial applications; and other related research projects at UW-Madison and other institutions.

In its consideration of the ethics of research using human embryos, the Committee also paid close attention to public debate and diverse religious views about the moral status of the embryo; the procedures by which embryonic stem cells are obtained, including the process and content of informed consent; animal welfare and ecological issues; and relevant state and federal law or regulations regarding research using human embryos.

The committee also took into consideration the review of the research by the UW-Madison Health Sciences Human Subjects Committee; reports and recommendations of other committees and commissions that have considered ethical issues in research involving human embryos, including those from the United States, Canada, and Great Britain; and scholarly papers on ethical issues from leading writers in this field.

In reviewing developments since our first report, the Committee paid particular

attention to the following issues:

#### **The Acceptability of Human Embryo Research**

The Committee continues to endorse its earlier conclusion that research using human embryos is ethically defensible. Considerable attention was paid to the role of public opinion concerning stem cell research, particularly in the context of a publicly funded institution. This included consideration of the arguments of those with objections to some aspects of such research, as well as consideration of the public interest in advancing knowledge and enhancing medical treatment of common serious disorders. The Committee concluded that research on human embryos should be conducted with an attitude of respect. This respect suggests that research using human embryos should not be done without clear justification, and that human embryos should be used in the smallest numbers and at the earliest stages of development consistent with good science.

#### **Sources of Human Embryos for Research**

Human embryos used for derivation of stem cells are most commonly obtained from in vitro fertilization (IVF) clinics following donation of excess blastocysts (embryos) by couples who consent to their use for research purposes. As these embryos would otherwise be discarded, IVF clinics represent the preferred source of embryos for stem cell research. It may ultimately be necessary to create embryos for the purpose of deriving stem cell lines should available IVF embryos prove inappropriate for scientific reasons, or if it were necessary as a component in clinical applications (e.g., to provide cell lines that are genetically compatible with the patient). Although arguments for and against creation of embryos specifically for research purposes were identified, the Committee concluded that there were no compelling moral arguments for outright prohibitions on the creation of embryos for research under such circumstances. However, the Committee agreed that this approach should be reserved for situations when important research or treatments cannot be accomplished in any other way.

#### **Mixing Human Embryonic Stem Cells with Experimental Animals**

Mixing of human stem cell lines with experimental animals (i.e., creating chimeras) is essential to developing knowledge about stem cells and their potential clinical applications. If appropriate attention is paid to considerations of animal welfare and potential ecological hazards, these studies are not likely to be problematic when human cell lines are introduced in laboratory animals late in fetal development, after organ development has occurred and particularly after reproductive germ cells have differentiated.

Mixing human stem cell lines with experimental animals late in the animal's fetal development may result in the development of non-neural human structures (such as liver, heart or kidney) in the experimental animal. This raises some concerns about animal welfare and possible environmental hazards such as propagation of viruses. These concerns should be addressed by the relevant campus committees before such research is under-taken.

Mixing human stem cell lines with experimental animals early in the animal's fetal development may also result in the development of human neural tissue in the experimental animal, which raises at least the theoretical possibility that such tissue could become integrated in a way that human experiences become possible. After consulting with biologists, the Committee concluded, based on current knowledge of developmental biology, that this risk is extremely remote unless such mixing occurred very early in embryonic life. It is for this reason that introducing human stem cells into developing animals very early in embryonic life

raises greater concerns about the creation of chimeras with human-like characteristics, and such experiments should receive careful ethical and scientific scrutiny.

#### **Recommendations**

Based on these discussions, the Committee unanimously finds that human embryonic stem cell research is scientifically important; has potential scientific and clinical benefits that are not expected to be equally achievable by other means; is consistent with existing law, regulations and guidelines; and is consistent with the University's mission and its commitment to academic freedom. In light of these considerations, the Committee concludes that such research is ethically appropriate, subject to the following guidelines:

First, such research should be done only with the fully informed and voluntary consent of the donors. Donors should be told of their other options concerning the care and disposition of their embryos, including freezing for later use, donation to others for reproductive uses, or discard without research use. To the extent possible, donors should be informed of the range of future research uses before giving consent to donate embryos for research. In addition, donors who are undergoing fertility treatments or other medical interventions should not have their care altered specifically to make embryos available for research.

Second, researchers should use embryos that would otherwise be discarded unless the relevant scientific or medical research cannot best be done in this fashion. These embryos can be either fresh or frozen, provided that they are donated by couples who have given voluntary, informed consent.

Third, human embryonic stem cells and cell lines should not be used for introduction into a woman's uterus without further University of Wisconsin review and approval, because the extent of biologic risks of such procedures are uncertain at the present time.

Fourth, human embryonic stem cells and cell lines should not be introduced into any non-human species without review by appropriate animal care committees. Attention should be paid to ensuring full consideration of any ecological or developmental consequences of such research

Fifth, studies involving introduction of human embryonic stem cells or their derivatives into developing animals should have strong scientific justification and receive special review when human cells are introduced prior to development of organs or germ cells.

#### **Committee Members:**

Jan Brahms

R. Alta Charo

Norman Fost (Chair)

R. Timothy Mulcahy

John D. Pirsch

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