

Ethical Challenges in Stem Cell Research and Treatment

Jeremy Sugarman, MD, MPH, MA
Harvey M. Meyerhoff Professor of Bioethics & Medicine
Department of Medicine
Berman Institute of Bioethics
Johns Hopkins University
Baltimore, Maryland USA

No Disclosure

Background Conditions

- Scientific excitement is high
- Desire for access to investigational treatments abounds, especially for devastating disorders
- The financial and moral stakes are high

Stem Cell Research: Excitement

Stem Cell Research: Scrutiny

Embryo-related Questions

- Moral status of the embryo
- Is it morally acceptable to destroy embryos to create hESCs?
- Is there a moral distinction between using discarded embryos versus those created for research?

Ethics and Oocyte Retrieval

- Hormonal treatments used to stimulate oocyte development
- Effects of payments to women

Chimeras

- Bone marrow transplantations create human to human chimeras
- Concern over combining materials from human and non-human animals

Broader Ethical Issues

- **Informed consent**
 - Donors and recipients
 - Immortalized lines
 - Transfer to others for unspecified uses
- **Commercialization and patenting**
 - May limit availability of scientific resources for common good
- **Justice or fairness**
 - Who bears the risk of research?
 - Who will have access to efficacious interventions?
- **Responsible conduct of research**
 - Discussing research fairly and evenly
 - Research integrity

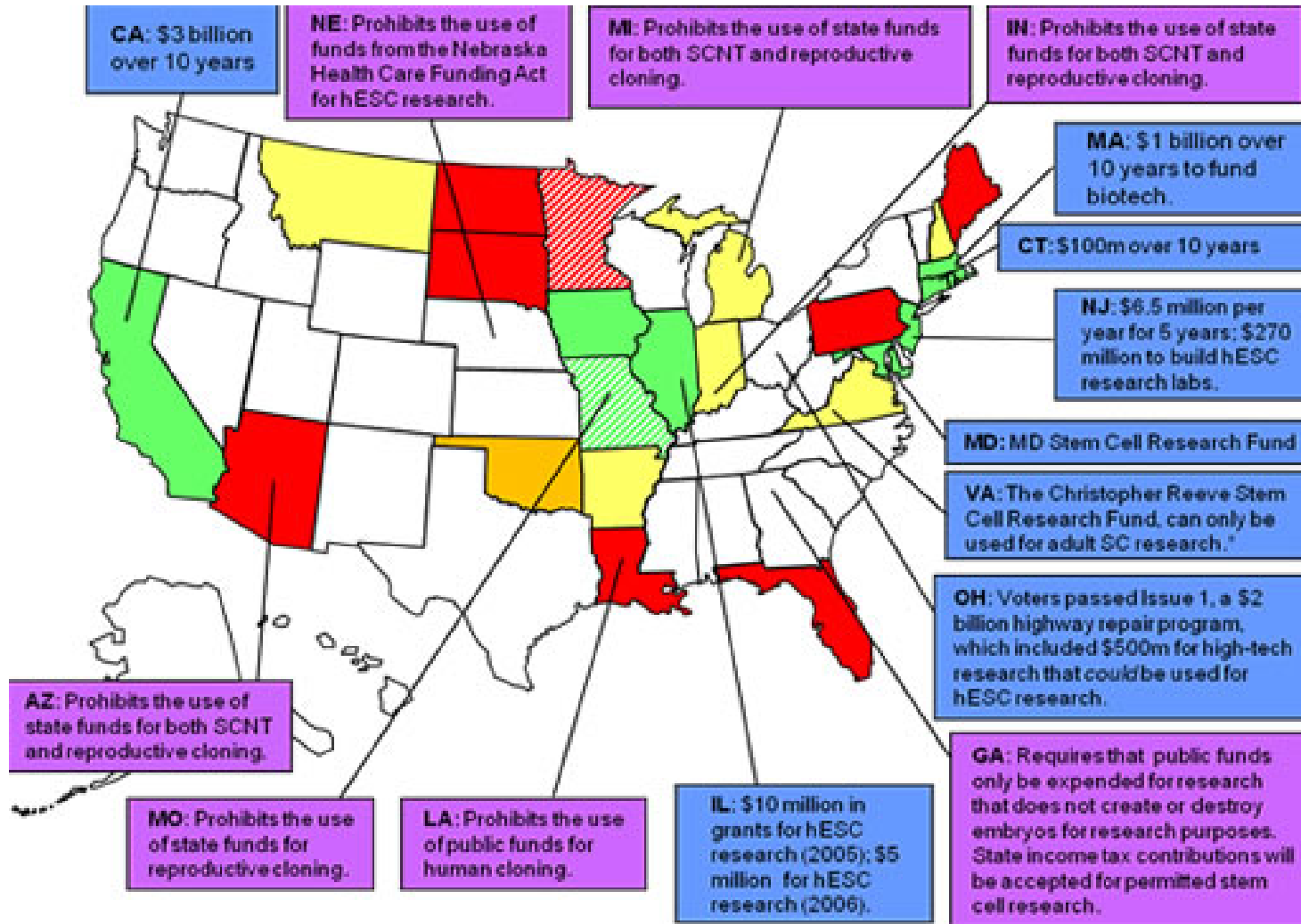
Local and Regional Differences Complicate Collaboration

- Cultural and religious practices
- Laws
- Funding

Stem Cell Research Policy

<http://hinxtongroup.org/>

September 2011



Truth and Consequences in International Collaboration

- Some countries facilitate hESC – others prohibit it
- Which rules should be followed when collaborating?
- Debates about appropriate practices, provenance, consent
- Difficulties at maintaining scientific integrity at a distance

Professional Guidelines

- National Research Council and Institute of Medicine (of the National Academies), 2005
- International Society for Stem Cell Research (ISSCR), 2006



- Transnational Cooperation in Stem Cell Research, 2006
- Science, Ethics and Policy Challenges of Pluripotent Stem Cell-Derived Gametes, 2008
- Policies and Practices Governing Data and Materials Sharing and Intellectual Property in Stem Cell Science, 2010

<http://www.hinxtongroup.org/au.html>

Recommendations for Oversight of hESC Research

- **Local oversight:** Each institution should establish an oversight committee to review and monitor all proposals to conduct hESC research
- ESCRO/SCRO committees should include representatives of the public and persons with expertise in developmental biology, stem cell research, molecular biology, assisted reproduction, and ethical and legal issues in hESC research


SEARCH

Research

[For Our Researchers](#) [Research Topics](#) [Departments](#) [Research Centers & Core Facilities](#) [Events Calendar](#)

JHU Institutional Stem Cell Research Oversight Committee

Information:

[Notices & Updates](#)

[Policies & Procedures](#)

[ISCRO Applications](#)

[ISCRO Approved hESC Lines](#)

[ISCRO Training Module](#)

[FAQs](#)

[Contact Us](#)

[Other Resources](#)

FONT SIZE

PRINT THIS PAGE

Share this page: [Email](#) [Twitter](#) [Facebook](#) [More](#)

[Home](#) > [Johns Hopkins Research](#) > [Institutional Stem Cell Research Oversight](#)

Institutional Stem Cell Research Oversight Committee

It is the policy of the Johns Hopkins University School of Medicine (JHU) that some types of research involving human pluripotent stem cells (hPSCs) being conducted by JHU faculty, staff or students or involving the use of JHU facilities or resources shall be subject to oversight by the JHU Institutional Stem Cell Research Oversight (ISCRO) Committee. Covered research includes:

- A. All research using human embryonic stem cells (hESCs);
- B. All research involving somatic cell nuclear transfer (SCNT) involving human cells;
- C. Other hPSCs (e.g., human induced pluripotent stem cells [iPSCs], human embryonic germ cells [hEGCs] where the research involves:
 - 1. Introduction of the cells into humans;
 - 2. Introduction of the cells into the central nervous system of non-human primates;
 - 3. Introduction of the cells into non-human animals *and* there is a reasonable possibility of the cells giving rise to gametes; or
 - 4. Creation of gametes or embryos.

Important Updates:

[Revised Policies & Procedures March 2010](#)

[Ethical Oversight of hESC Research Educational Module](#)

[Research Ethics Consulting Service](#)

[Search Clinical Trials](#)

[Find a Faculty Director](#)

[View Calendar](#)

[Stimulus Response Resources](#)

About Johns Hopkins
[Find Out More](#)

Out of State and International Patients
[Find Out More](#)

Purpose of the ISCRO Committee

- Ethical oversight and review of all hESC research and/or SCNT involving human cells
- Ethical oversight and review of all other hPSC research that involves:
 - Introduction of hPSCs into humans
 - Introduction of hPSCs into the central nervous system of non-human primates
 - Introduction of hPSCs into non-human animals where a significant possibility of the cells giving rise to gametes exists
 - Creation of gametes or embryos
- Consultative body for related research
- Works in collaboration with other bodies charged with research oversight

Structure of Oversight

- Similar to IRB and IACUC oversight with initial approval and periodic review
- Multidisciplinary committee appointed by Vice-Dean for Research
 - Scientists
 - Ethicists
 - Public member
- Monthly meetings

ISCRO Review

- Ethically and scientifically sound
- Considers compliance with applicable government regulations and institutional policies related to stem cells and research

Moving Forward

- Approval and consent for collecting biological materials anticipating they will be used for the production of pluripotent stem cells
- Approval (and perhaps re-consent) for using previously banked biological materials for the production of pluripotent stem cells where such uses were not anticipated at the time of collection
- Clinical translation

Anticipated Derivation of hPSCs

- Review process
- Consent template

Using Banked Materials to Derive hPSCs

- Appropriate review?
- Potential barriers?
- Re-consent?

Threats to Meeting Fiduciary Obligations to Patients

- Some cell-based interventions are being delivered to patients without sufficient published data regarding safety or efficacy
- Anecdotal reports suggest this is occurring outside the research setting



stem cell therapy

Search

About 15,400,000 results (0.13 seconds)

Advanced search

Everything

Images

Videos

News

Shopping

Realtime

More

Durham, NC

Change location

Any time

Latest

Past 24 hours

Past 2 days

Past week

Past month

Past year

Custom range...

All results

Wonder wheel

Related searches

Stem Cell Treatment - Accepting Patients Now. | CellMedicine.com

Ads

Medical Information: (800) 980-STEM

Autism - Multiple Sclerosis - Osteoarthritis - Rheumatoid Arthritis

www.cellmedicine.com

Stem Cell Therapy in USA - Treatment Center - Fraction of Cost

Same Day Harvesting and Treatment!

www.stem-cell-center.com

Stem Cell and Platelet | stemcellorthopedic.com

Cutting Edge Regenerative Stem Cell Platelet Rich Plasma, or PRP, is BL

www.stemcellorthopedic.com

Stem cell treatments - Wikipedia, the free encyclopedia

Stem cell treatments are a type of intervention strategy that introduces new cells into damaged tissue in order to treat disease or injury. ...

Current treatments - Potential treatments - Clinical Trials - Stem cell use in animals

en.wikipedia.org/wiki/Stem_cell_treatments - Cached - Similar

Stem Cells In Use

Somatic **Stem Cell Therapy**: Using a Bone Marrow Transplant to Cure Leukemia ... Like other blood cells, leukocytes develop from somatic stem cells. ...

learn.genetics.utah.edu/content/tech/stemcells/sctoday/ - Cached - Similar

Stem Cell Treatments

We have all heard about the extraordinary promise that **stem cell** research holds for the **treatment** of human diseases. Clinics all over the world claim to ...

www.closerlookatstemcells.org/ - Cached - Similar

Ads

Stem Cell Treatment

Call Today To Learn More About Our BMT Expertise & Program!

www.uofmmedicalcenter.net/Blood&Marrow

B18R Recombinant Protein

Get iPS Cells on Demand

Control Cell Reprogramming

www.ebioscience.com

Stem Cell Transplants

Learn More About Treatment Options At CTCA. There May Be Hope.

www.cancercenter.com

Swiss Cellular Therapy

Be 20 yrs younger & healthier with the original Swiss cellular therapy

www.celltherapyprogram.com

Stem Cell Therapy

Your Stem Cells available now.

We can help you

www.stemaid.com

Stem Cell Philippines

Expanded & Manipulated Adipose-Cell Disease-Specific: 2 Treatments Incl

Emerging Data

- Lau, et al. *Cell Stem Cell*, 2008
- Zarzeczny, et al. *Nature Biotechnology*, 2010

Stem Cell Treatments - Windows Internet Explorer

http://www.closerlookatstemcells.org//AM/Template.cfm?Section=Home

Google Search

Stem Cell Treatments

English

ISSCR
International Society for Stem Cell Research

Search GO

Home What to Ask Frequent Questions Other Resources From the Experts About ISSCR

considering
STEM CELL
treatment?

**Find out what's possible.
Know what to ask.**

We have all heard about the extraordinary promise that stem cell research holds for the treatment of human diseases. Clinics all over the world claim to offer stem cell treatments for a wide variety of conditions. But are all of these treatments likely to be safe and effective?

The ISSCR provides information to help you evaluate these claims.

[Learn more about what this site can provide.](#)

TOP 10 Things to Know About Stem Cell Treatments

ISSCR Patient Handbook

How Science Becomes Medicine

start ISSCR | About Stem ... Stem Cell Treatments... Help and Support Ce... Document1 - Microsof...

Internet 100% 5:46 PM

Guidelines for the Clinical Translation of Stem Cells

- Multidisciplinary task force representing 13 countries convened by the ISSCR
- Released 12/2008
- Available at www.isscr.org

Intent

- The Guidelines for the Clinical Translation of Stem Cells highlight the scientific, clinical, regulatory, ethical, and social issues that should be addressed *so that basic stem cell research is responsibly translated into appropriate clinical applications for treating patients.*
- The Guidelines offer recommendations founded on general principles for scientific, clinical, and ethical conduct that should be followed by all translational stem cell researchers, clinician-scientists, and regulators in the international community.

Scope of the Guidelines

- Cell processing and manufacturing
- Pre-clinical studies
- Clinical research
- Medical innovation
- Social justice

Closing Comments

- Scientific and commercial interests along with the hopes of patients and politicians need to be considered in light of scientific realities and not merely aspirations
- There are a clear set of ethical considerations involved with the derivation of stem cells, in moving to clinical trials, and in their therapeutic use
- Explicit deliberation and attention to these ethical issues is essential

Thanks!

<http://www.hopkinsmedicine.org/Research/iscro/>