Ethical Challenges in Stem Cell Research and Treatment

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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

CA: $3 billion over 10 years

NE: Prohibits the use of funds from the Nebraska Health Care Funding Act for hESC research.

MI: Prohibits the use of state funds for both SCNT and reproductive cloning.

IN: Prohibits the use of state funds for both SCNT and reproductive cloning.

MA: $1 billion over 10 years to fund biotech.

CT: $100m over 10 years

NJ: $6.5 million per year for 5 years; $270 million to build hESC research labs.

MD: MD Stem Cell Research Fund

VA: The Christopher Reeve Stem Cell Research Fund, can only be used for adult SC research.

OH: Voters passed Issue 1, a $2 billion highway repair program, which included $500m for high-tech research that could be used for hESC research.

GA: Requires that public funds only be expended for research that does not create or destroy embryos for research purposes. State income tax contributions will be accepted for permitted stem cell research.

AZ: Prohibits the use of state funds for both SCNT and reproductive cloning.

MO: Prohibits the use of state funds for reproductive cloning.

LA: Prohibits the use of public funds for human cloning.

IL: $10 million in grants for hESC research (2005); $5 million for hESC research (2006).
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 Gametetes, 2008

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.
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 (ISCR) 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.
Purpose of the ISCRRO 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

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**Stem Cell Treatment** - Accepting Patients Now, | CellMedicine.com
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.stemcell-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/octoday/ - 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
Emerging Data

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.
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/