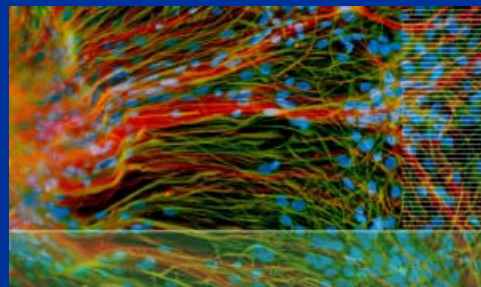


The National Academies' Human Embryonic Stem Cell Research Advisory Committee

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BLS

Board on Life Sciences

The National Academies Issued Its Guidelines in 2005

- Significant public support for hESC research, but unique issues and concerns created uncertainty
 - Research involving human embryos controversial
 - Concerns about protection of donors, especially egg donors
 - Chimeras
- A patchwork of regulations
 - Limited federal support / little federal regulation
 - Disparate state regulations
 - No comprehensive system of oversight for hESC research

Guidelines Committee Statement of Task

- Develop guidelines to encourage responsible practices in hESC research, regardless of source of funding, including the use and derivation of new stem cell lines
 - i) from surplus blastocysts from IVF clinics
 - ii) from IVF blastocysts produced with donated gametes
 - iii) from blastocysts produced using nuclear transfer
- The guidelines should take ethical and legal concerns into account and encompass the basic science and health science policy issues related to the development and use of hES cells for research and eventual therapeutic purposes

GUIDELINES FOR RESEARCH ON HUMAN EMBRYONIC STEM CELLS

- 1.0 Introduction
- 2.0 Establishment of an Institutional Embryonic Stem Cell Research Oversight Committee
- 3.0 Procurement of Gametes, Blastocysts or Cells for hES Generation
- 4.0 Derivation of hES Cell Lines
- 5.0 Banking and Distribution of hES Cell Lines
- 6.0 Research Use of hES Cell Lines
- 7.0 International Collaboration
- 8.0 Conclusion and Need for a National Panel

Oversight of Human Embryonic Stem Cell Research

Local oversight - each institution should establish an Embryonic Stem Cell Research Oversight (ESCRO) committee to

- review and approve the scientific merit of research proposals
- divide research into three categories in setting limits on research and determining the requisite level of oversight

Functions of Embryonic Stem Cell Research Oversight (ESCRO) Committees

- To provide local oversight over all issues related to derivation and research use of hESC lines.
- To ensure adherence to the basic ethical and legal principles of informed consent and protection of donor confidentiality.
- To review compliance of all hESC research with all relevant regulations and guidelines.
- To maintain registries of hESC research conducted at the institution and of all hESC lines.
- To facilitate education of investigators involved in hESC research.
- The ESCRO committee will not substitute for an Institutional Review Board (IRB), but rather will provide an additional level of review and scrutiny warranted for hESC research and review proposals not requiring IRB review.

Research that is Permitted under the Guidelines

- (a) Research that is permissible after notification of the ESCRO committee and completion of all reviews mandated by current requirements; e.g., all purely *in vitro* hESC research with pre-existing coded or anonymous hESC lines.
 - Not covered by Institutional Review Boards
- (b) Research that is permissible only after additional review and approval by the ESCRO committee
 - (i) All derivations of new hESC lines from donated blastocysts, from *in vitro* fertilized oocytes, or by nuclear transfer.
 - (ii) All research involving the introduction of hESCs into nonhuman animals at any stage of embryonic, fetal, or postnatal development.
 - (iii) All research in which identifiable information about donors is readily ascertainable or could become known by the investigator.

(c) Research that should not be permitted at this time:

(i) Research involving *in vitro* culture of any intact human embryo, regardless of derivation method, for longer than 14 days or until formation of the primitive streak begins, whichever occurs first.

(ii) Research in which hESCs are introduced into nonhuman primate blastocysts or in which any ESCs are introduced into human blastocysts.

(iii) No animal into which hESCs have been introduced at any stage of development should be allowed to breed.

In Addition: Research on Reproductive Uses of Nuclear Transfer Should Not Be Conducted

The guidelines do not apply to reproductive uses of nuclear transfer. These are addressed in the 2002 report *Scientific and Medical Aspects of Human Reproductive Cloning*, in which the National Academies recommended that “Human reproductive cloning should not now be practiced. It is dangerous and likely to fail.”

Although the guidelines do not specifically address human reproductive cloning, it continues to be the view of the National Academies that research aimed at the reproductive cloning of a human being should not be conducted at this time.

Donations of blastocysts, oocytes, sperm and somatic cells

- Should always be reviewed by an Institutional Review Board
- Should be governed by informed consent of all donors
- Separation of decision to donate from all clinical decisions
- No payments to donors beyond reimbursement of direct expenses
- No purchase or sale of donated materials
- Protection of donor privacy

Oversight of Human Embryonic Stem Cell Research

A national panel should be established to assess periodically the adequacy of the guidelines and to provide a forum for a continuing discussion of issues involved in hES cell research.

- politically independent and without conflicts of interest
- respected in the lay and scientific communities
- able to call on suitable expertise to support this effort

The membership of the new Human Embryonic Stem Cell Research Advisory Committee is as follows:

Co-chairs: Richard O. Hynes, Massachusetts Institute of Technology

R. Alta Charo, Boalt Hall, UC Berkeley and University of Wisconsin

- **Eli Y. Adashi**, Brown University
- **Brigid L.M. Hogan**, Duke University
- **Marcia Imbrescia**, Arthritis Foundation
- **Terry Magnuson**, University of North Carolina at Chapel Hill
- **Linda B. Miller**, Volunteer Trustees Foundation
- **Jonathan D. Moreno**, University of Virginia
- **Pilar N. Ossorio**, University of Wisconsin
- **E. Albert Reece**, University of Maryland
- **Joshua R. Sanes**, Harvard University
- **Harold T. Shapiro**, Princeton University
- **John E. Wagner, Jr.**, University of Minnesota

Statement of Task

The Advisory Committee will meet 2 to 3 times per year over a period of 36 months to (1) monitor and review scientific developments and changing ethical, legal, and policy issues related to human embryonic stem cell research, (2) discuss the need for revisions to the Guidelines for Human Embryonic Stem Cell Research, and (3) prepare periodic reports to update the Guidelines as needed.

Minimal but necessary changes to the Guidelines may be issued as letter reports, but more extensive modifications may necessitate the preparation of traditional reports to fully provide the rationale for the changes.

Sources of information that will be considered by the Advisory Committee will include public symposia organized by the Committee to review developments in stem cell science and how these impact the ethical and policy issues surrounding hESC research.

The NAS Guidelines Were Amended in 2007 and 2008

- “Grandfathered” Bush lines
- Added an “acceptably derived” provision
- Expanded egg donor reimbursement to explicitly include lost wages
- Incorporated guidelines on uses of hPS cell lines
- Clarified other points

In July 2009, NIH Issued Its Own Rules

- Expanded number of lines eligible for research with federal funds
- Provisions of the NIH rules on informed consent quite similar to the NAS and other Guidelines
- Some areas will still be uncovered by NIH
 - Derivation by any means
 - Lines made for research rather than reproduction, by SCNT, parthenogenesis, etc.

In August 2009, the Committee Solicited Input from a Group of Long Time Supporters

- Members of the group unanimously called for continued Academies participation
- Stated that there is a need for a “forum” to discuss gaps and contentious issues dealing with the “new, weird, and gnarly” things
- The NAS was said to provide a “safe, informed place” for discussions to help guide institutions that approve studies on chimeras, gametes from IPS cells, etc.

Future of the Committee

- Short Term: Issue a final brief report stating how the NAS guidelines continue to apply in areas not covered by NIH and recommending how ESCRO Committees can continue to be useful
- Long Term: Morph the NAS body into a forum or roundtable for open discussions of controversial or difficult issues.

The Guidelines and amendments will continue to be available for download free of charge

- <http://www.nap.edu/catalog/11278.html>

or

- Follow link to “Related reports” at <http://www.nationalacademies.org/stemcells>

or

- National Academies Press, search on stem cell guidelines

