

NIH Guidelines for Human Stem Cell Research

**Lana R. Skirboll, Ph.D.
NIH**

**Advisory Committee to the Director
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Overview of Presentation

- NIH Guidelines for Human Stem Cell Research
- ACD Working Group for Human Embryonic Stem Cell Eligibility Review

Executive Order 13505

Removing Barriers to Responsible Research Involving Human Stem Cells

March 9, 2009



Executive Order 13505

- The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct **responsible, scientifically worthy** human stem cell research, including human embryonic stem cell research, to the extent permitted by law.
- Within 120 days from the date of this order, the Secretary, through the Director of NIH, shall **review existing NIH guidance and other widely recognized guidelines on human stem cell research**, including provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with this order.
- The Secretary, through NIH, shall review and update such guidance periodically, as appropriate.

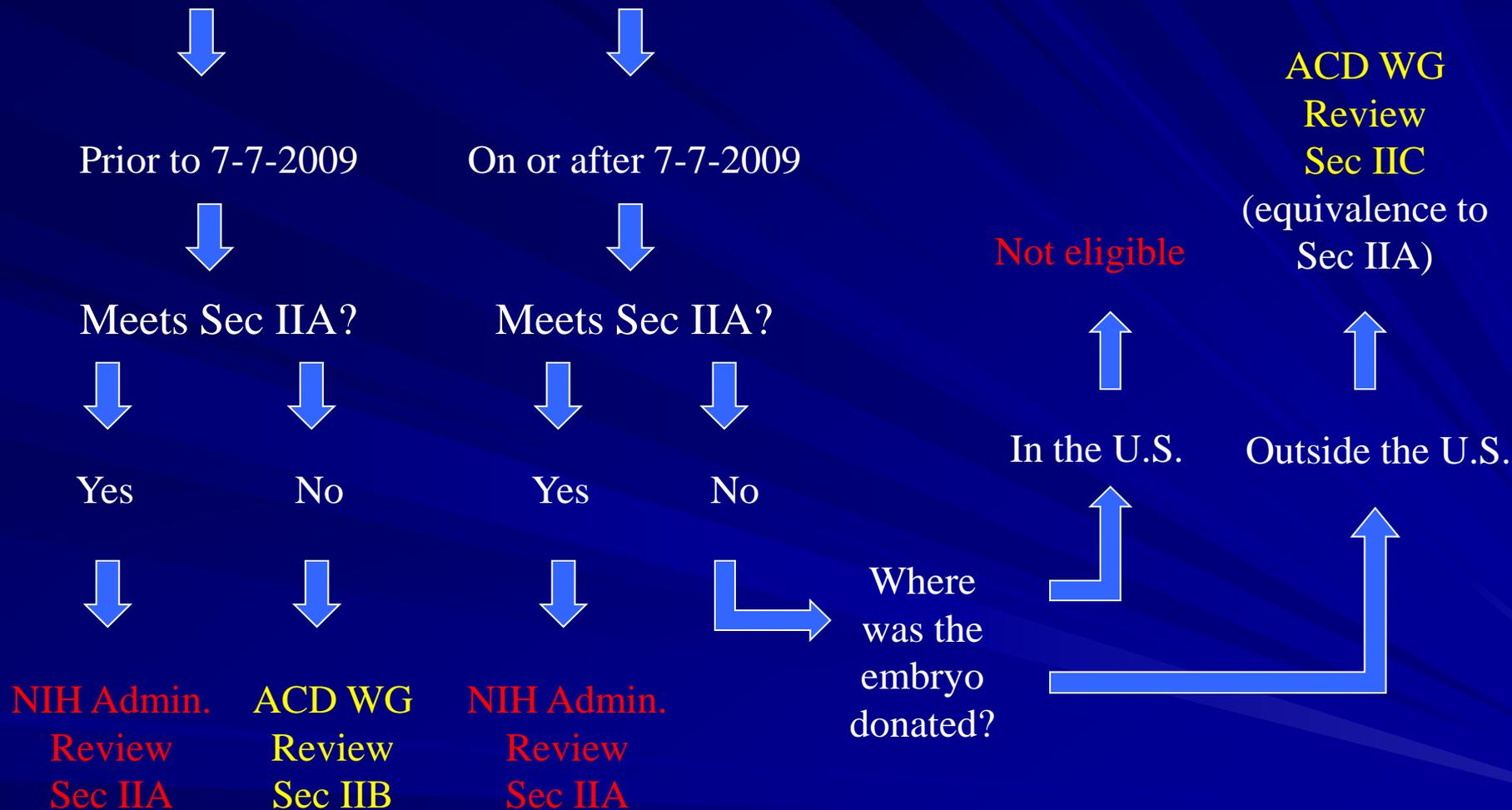
Development of NIH Guidelines for Human Stem Cell Research

- Draft Guidelines released April 23, 2009
- Over 49,000 comments received
- Final Guidelines published July 7, 2009
 - No changes to basic eligibility criteria
 - Do not provide exact wording for consent forms but require robust informed consent process and written consent

NIH Guidelines for Human Stem Cell Research

- Effective July 7, 2009
- All hESCs **must** be:
 - Derived from embryos created by IVF for reproductive purposes and no longer needed for that purpose
 - Donated by individual(s) who sought reproductive treatment and who gave voluntary written consent for human embryos to be used for research purposes

When was the embryo donated?



Section IIA Requirements

■ Institution must assure

- All options available in facility pertaining to embryos no longer needed for reproductive purposes were explained
- No payments were offered for embryos
- Policies/procedures were in place that neither consenting nor refusing to donate embryos would affect quality of care for donor(s)

Section IIA Requirements (cont.)

- Institution must assure clear separation between decision by donor(s) to create embryos for reproduction and decision to donate embryos for research
 - Decision to create embryos for reproduction free from influence of researchers
 - Physician and researcher should not have been same person (unless not practicable)
 - Consent for donation obtained at time of donation
 - Donor(s) informed they have right to withdraw consent until derivation occurs or until identifiable information removed

Section IIA Requirements (cont.)

Institution must assure that during consent process, donor(s) informed:

- Embryos would be used to derive hESCs for research
- What would happen to embryos in derivation
- hESCs may be kept many years
- No restriction or direction regarding individuals who may receive medical benefit (ex. transplant recipients)
- Research not intended to provide direct medical benefit to donor(s)
- Research results may have commercial potential; donor(s) would not receive benefits
- Whether information identifying donor(s) would be available to researchers

Section IIB: Guidance for ACD Working Group

- For embryos donated anywhere before July 7, 2009 (if Section IIA is not met), Working Group will take into account
 - Principles in Section IIA
 - 45 CFR 46 Subpart A (Common Rule)
 - Points to Consider: During informed consent process, whether donor(s) were
 - Informed of other available options pertaining to use of embryos
 - Offered any inducements for the donation
 - Informed about what would happen to the embryos

Preamble to Guidelines

“...the NIH is also cognizant that in the more than a decade between the discovery of hESCs and today, many lines were derived consistent with ethical standards and/or guidelines developed by various states, countries, and other entities ... These various policies have many common features, rely on a consistent ethical base, and require an informed consent process, but they differ in details of implementation. ... **It is important to recognize that the principles of ethical research, e.g., voluntary informed consent to participation, have not varied in this time period, but the requirements for implementation and procedural safeguards employed to demonstrate compliance have evolved.** “

Preamble to Guidelines

“The ACD...will advise NIH on whether the core ethical principles and procedures used in the process for obtaining informed consent for the donation of the embryo were such that the cell line should be eligible for NIH funding. This Working Group will not undertake a *de novo evaluation* of ethical standards, but will consider the materials submitted in light of the principles and points to consider in the Guidelines, as well as 45 CFR Part 46 Subpart A. Rather than “grandfathering,” ACD Working Group review will enable pre-existing hESCs derived in a responsible manner to be eligible for use in NIH funded research.”

Section IIC: Guidance for ACD Working Group

- For embryos donated abroad on/after July 7, 2009 (if Section IIA is not met), Working Group will consider whether alternative procedural standards of a foreign country where embryos were donated provide protections at least equivalent to those provided by Section IIA of Guidelines.

Ineligible Research using hESCs or iPSCs

Research using hESCs and/or induced pluripotent stem cells (iPSCs) that is ineligible for NIH funding :

- Research in which hESCs (even if lines are eligible) or iPSCs are introduced into non-human primate blastocysts.
- Research involving the breeding of animals where the introduction of hESCs (even if lines are eligible) or iPSCs may have contributed to the germ line.

Other Research Not Eligible for NIH Funding

- NIH funding of the derivation of stem cells from human embryos
- Research using hESCs derived from other sources, including:
 - somatic cell nuclear transfer
 - parthenogenesis
 - embryos created by IVF for research purposes

Review Process

- NIH staff conduct administrative reviews for Section IIA compliance
- ACD Working Group reviews other submissions under Section IIB and Section IIC
 - Working Group findings presented to ACD
 - ACD makes recommendations to NIH Director
- NIH Director makes final decisions on eligibility of all hESCs
- Eligible hESCs listed on NIH Human Embryonic Stem Cell Registry

Working Group for hESC Eligibility Review

- Jeffrey Botkin, M.D., M.P.H., University of Utah School of Medicine
- Dena Davis, J.D., Ph.D., Cleveland-Marshall College of Law
- Pamela Davis, M.D., Ph.D., Case Western Reserve University
- David Grainger, M.D., M.P.H., University of Kansas School of Medicine-Wichita; Center for Reproductive Medicine
- Richard Lifton, M.D., Ph.D., Yale School of Medicine
- Bernard Lo, M.D., University of California, San Francisco
- Terry Magnuson, Ph.D., University of North Carolina (Chapel Hill)
- Jeffrey Murray, M.D., University of Iowa Children's Hospital
- Carlos Pavão, M.P.A., Education Development Center

Status of Submissions and Review

- Over 100 hESC lines submitted for review (includes both for ACD and administrative review): review ongoing
- NIH Director approved 13 lines on 12/2/09 submitted for administrative review
 - Children's Hospital Boston (11 lines)
 - Rockefeller University (2 lines)
- Working Group findings for 28 lines presented to ACD today for consideration

Your turn!

Goal: Recommendation to NIH
Director regarding eligibility of hESC
lines for use in NIH-funded research