Standards Working Group Meeting

Stem Cell-Based Human Embryo Model Research Policy Review

Geoffrey Lomax, Dr.PH.

Associate Director Medical Affairs and Policy

2.9.24

CIRM
CALIFORNIA'S STEM CELL AGENCY

Awards related to Stem Cell-Derived Embryo Models

Proposition **71**
2004

$3B Bond Funding

Basic research awards
- *4 trophoblast*

Proposition **14**
2020

$5.5B Bond Funding

Basic research awards
- 1 embryo model
- *2 trophoblast*

Current applications and consultations

2000 **2005** **2010** **2015** **2020**

1998
human embryonic stem cells (hESC)

2007
human induced pluripotent stem cells (hiPSC)

- *Human biology models*
- *Human disease models*
- *Stem Cell-Based Embryo Models*

Overview CIRM Medical and Ethical Standards

OPEN ACCESS Freely available online

PLoS MEDICINE

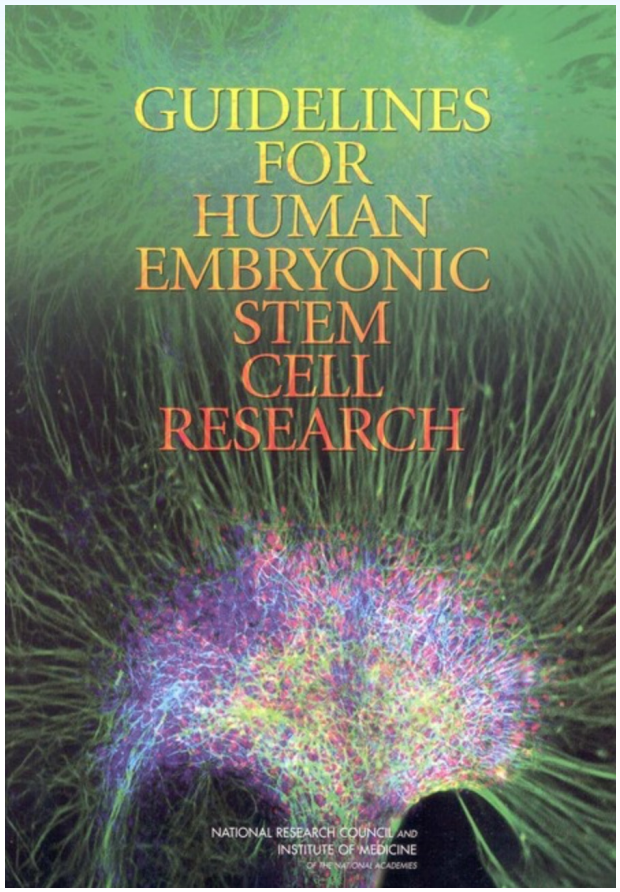
Policy Forum

Responsible Oversight of Human Stem Cell Research: The California Institute for Regenerative Medicine's Medical and Ethical Standards

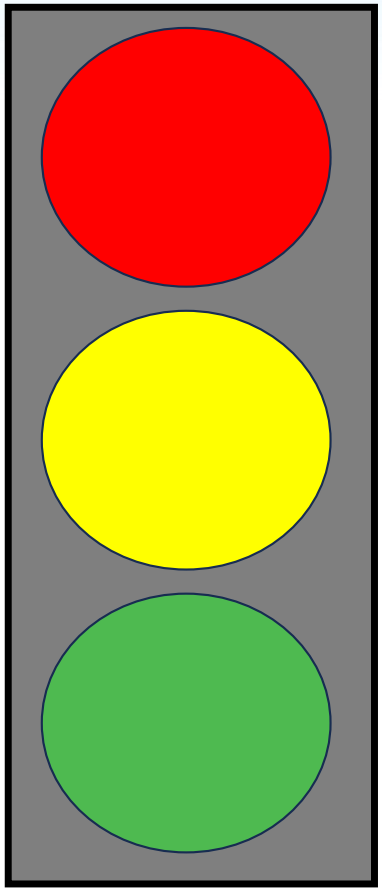
Geoffrey P. Lomax*, Zach W. Hall, Bernard Lo

CIRM Policy Framework

- Modeled after the NAS Guidelines for Human Embryonic Stem Cell Research (P-71 & P-14)
- Designed to address activities not covered by federal policy (e.g. embryo research, hESC derivation and utilization)
- NAS Guidelines Committee no longer constituted



Prohibitions and Levels of Review



Not Eligible for CIRM Funding

- Reproductive cloning and the transfer to a uterus of a genetically modified human embryo.

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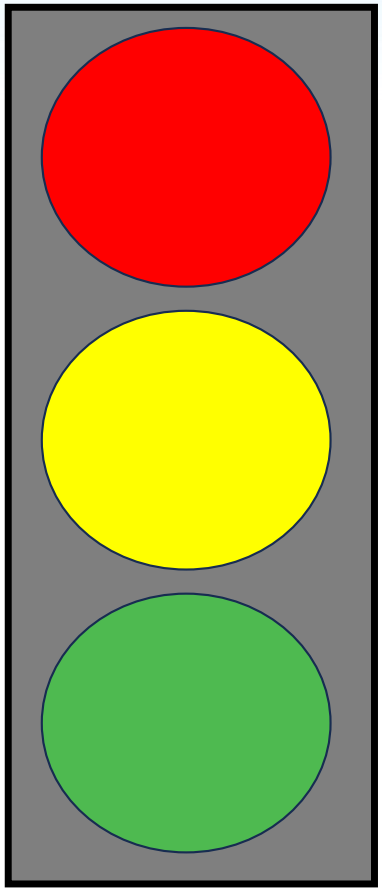

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Eligible with ESCRO Review, Oversight and Renewal

- Research involving human embryos (e.g. hESC derivation)
- Use of pluripotent stem cell for “sensitive uses” (e.g. gamete creation, integration of human neural cells to the brains of animals or the introduction of cells to humans)

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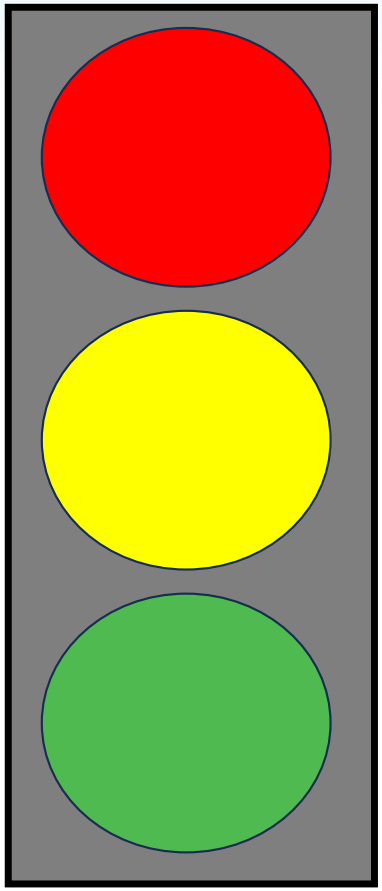

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Eligible with ESCRO Notification

- Most in-vitro research using hESCs and iPSCs (including embryo models)

ESCRO Review vs. Notification

Review: Requirements in the context of hESC derivation

- "Acceptable" scientific rationale
- Provide assurance that all cell lines are "acceptably derived"
- Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines

Notification:

- Provide assurance that all cell lines are "acceptably derived"

ESCRO Review vs. Notification

- Increased interest in using embryo models as their utility grows in developmental biology (scientific rationale)
- Committees are generally formulating institutional policies in the absence of CIRM guidance
- Participating committees indicated they were conducting full review
- Variance in protocol-specific requirements reflecting the diversity of experimental aims

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