

Standards Working Group Meeting

Stem Cell-Based Human Embryo Model Research Policy Review

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2.9.24



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

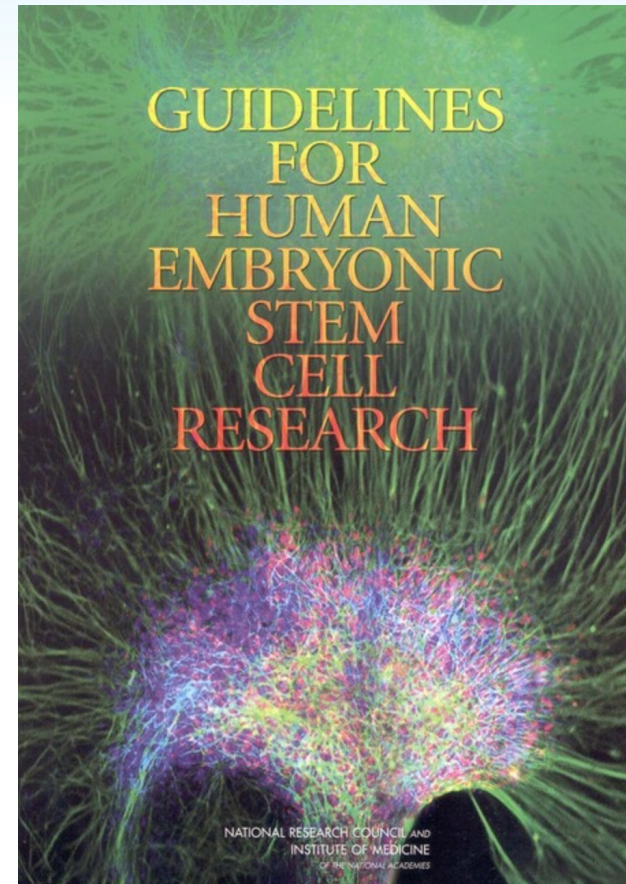
➤ Stem Cell-Based Embryo Models

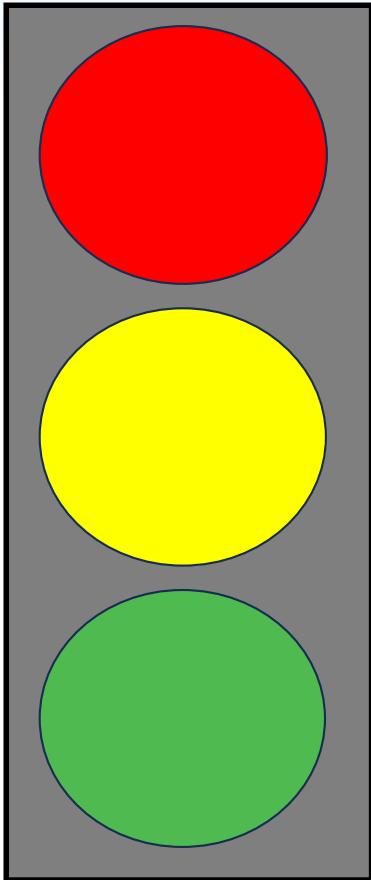
Responsible Oversight of Human Stem Cell Research: The California Institute for Regenerative Medicine's Medical and Ethical Standards

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



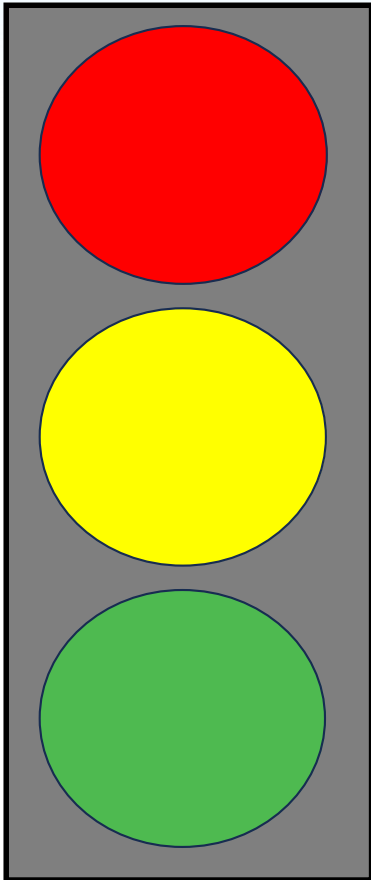
- Modeled after the NAS Guidelines for Human Embryonic Stem Cell Research (P-71 & P-14)
- Designed to address activities not covered by federal policy (e.g. embryo research, hESC derivation and utilization)
- NAS Guidelines Committee no longer constituted





Not Eligible for CIRM Funding

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

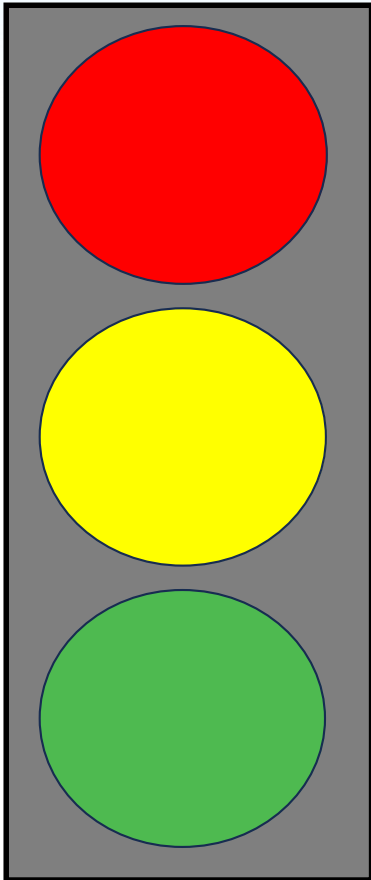


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Eligible with ESCRO Review, Oversight and Renewal

- 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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Eligible with ESCRO Notification

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

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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