



## **NIH & State Stem Cell Policy**

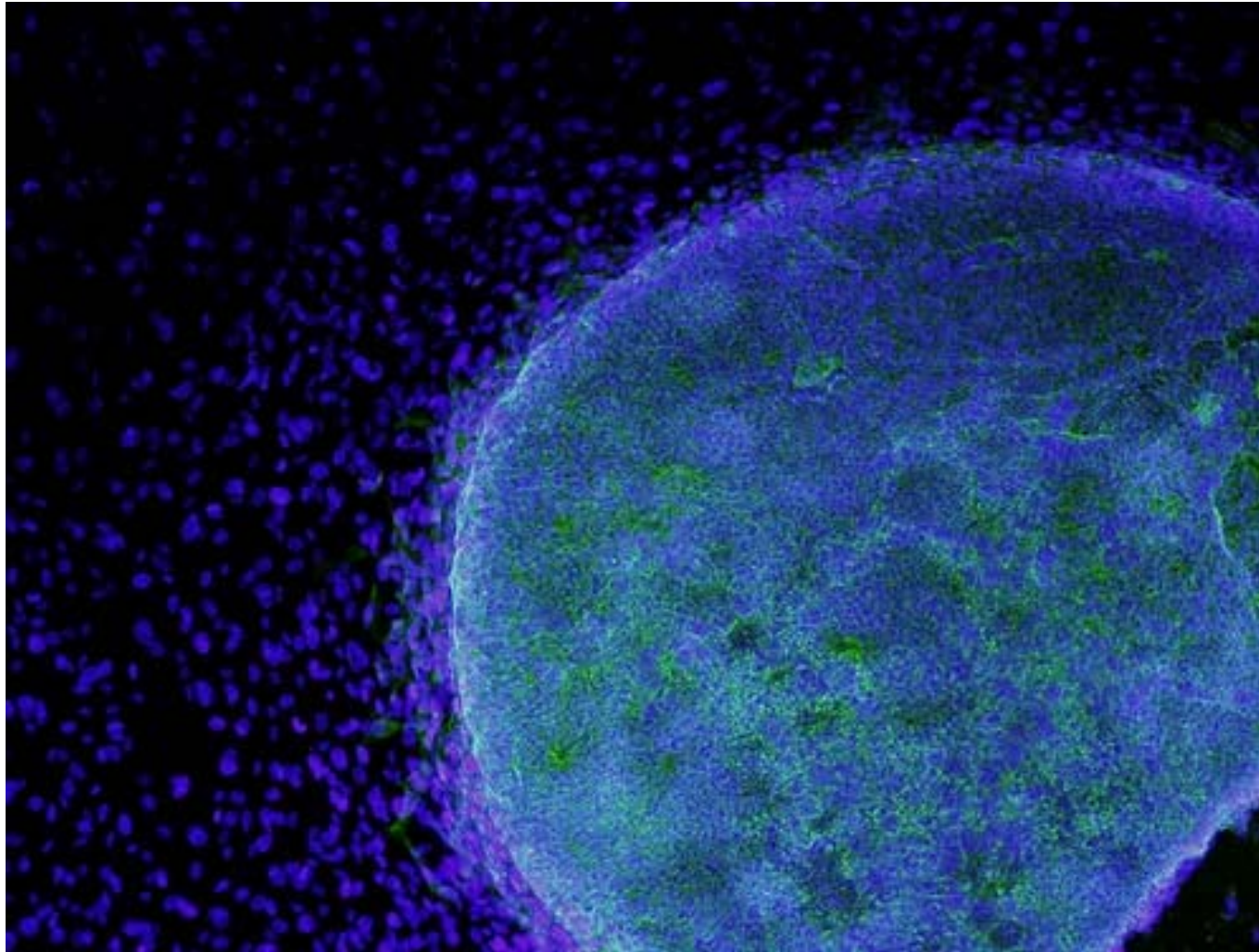
# **IASCR Science and Policy Briefing in Conjunction with The Canadian Stem Cell Network**

**October 7, 2009**

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[www.CIRM.ca.gov](http://www.CIRM.ca.gov)**



# General U.S. (NIH) Policy Framework



A colony of human embryonic stem cells (light blue) growing on fibroblasts (dark blue).



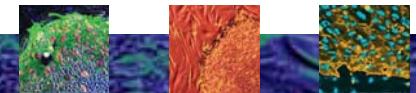
# NIH Policy: Use of hESCs Only

## *SEC. 509.*

*(a) None of the funds made available in this Act may be used for--*

*(1) the creation of a human embryo or embryos for research purposes; or*  
*(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act [1](42 U.S.C. 289g(b)) (Title 42, Section 289g(b), United States Code).*

*(b) For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 (the Human Subject Protection regulations) . . . that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes (sperm or egg) or human diploid cells (cells that have two sets of chromosomes, such as somatic cells).*



# NIH Guidelines Process

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institutes of Health Guidelines for Human Stem Cell Research

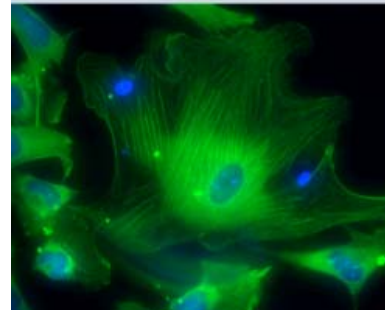
**SUMMARY:** The National Institutes of Health (NIH) is hereby publishing final “National Institutes of Health Guidelines for Human Stem Cell Research” (Guidelines).

On March 9, 2009, President Barack H. Obama issued Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*. The Executive Order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law.



### Advancing the Promise: Leading Research Institutions, Patients and Scholars Comment on the Draft NIH Guidelines for Human Stem Cell Research

June 10, 2009



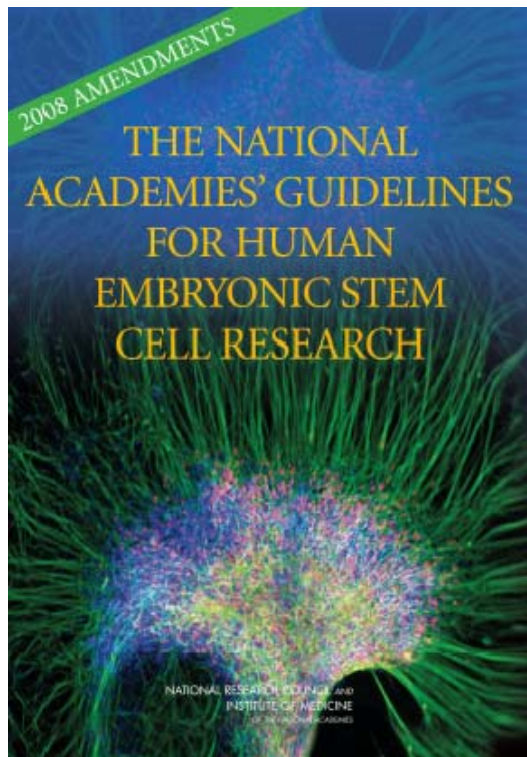
Medical miracles do not happen simply by accident. They result from painstaking and costly research – from years of lonely trial and error, much of which never bears fruit – and from a government willing to support that work.

President Obama March 9, 2009

# General Policy Framework for NIH



# The U.S. State Regulatory Framework



BNA, INC.

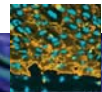
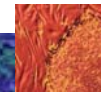
## MEDICAL RESEARCH LAW & POLICY



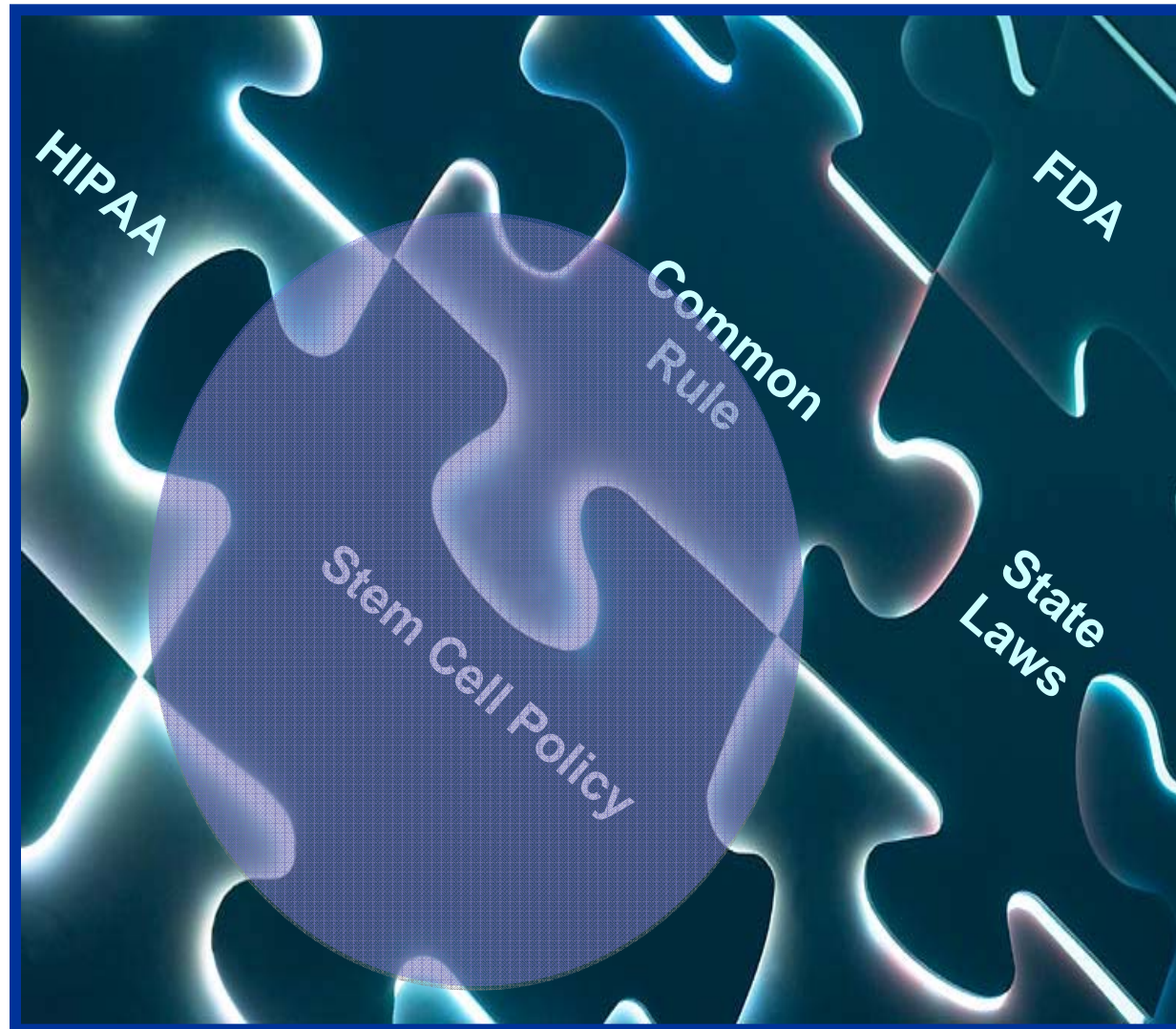
REPORT

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**Similarities and Differences Among Stem Cell Research Policies:  
Opportunities for Policymakers, Patients, and Researchers**



# General Policy Framework for States



# General Framework for Oversight

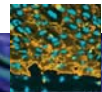
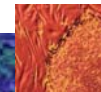
No Human Reproductive Cloning

No Germline Gene Therapy

Research Embryos / SCNT Authorized in Some U.S. states

## NAS / States Generally Requires

- Scientific Evaluation
- Ethical Reviews in Place of hESC Derivation [**Special Review Committees / Human Rights Approach?**]
- Measures to Support Informed Consent
- Approval by Relevant Committees



# Research Review & Oversight for Creation of Pluripotent Human Cell Lines

## Origin of Cell Line

## Oversight Committee Review

Gamete Creation or Human Oocyte Donation for SCNT
Embryo Use for hESC Derivation
Somatic Cells for iPS Derivation

Full Review with Expert in Assisted Reproduction

Full Review

Oversight Committee Notification

