

# Real Life™

**Geoffrey Lomax DrPH**  
Senior Science Officer  
ICOC September 29, 2022

**CIRM**  
CALIFORNIA'S STEM CELL AGENCY

## OUR MISSION

Accelerating world class science  
to deliver transformative  
regenerative medicine treatments  
in an equitable manner to a  
diverse California and world



## CIRM Medical and Ethical Standards Working Group (SWG)

- Provide and Overview of SWG Charge and History
- Identify Contemporary Ethics-Policy Topics
- Describe Working Group Composition and Recruitment Process
- Identify Working Group Co-chair Candidates for Consideration

*Recommend to the ICOC standards for all medical, socioeconomic, and financial aspects of clinical trials and therapy delivery to patients, including, among others, standards for safe and ethical procedures for obtaining materials and cells for research and clinical efforts for the appropriate treatment of human subjects in medical research.*

The California Stem Cell Research, Treatments, and Cures Initiative of 2020

## Foundational Standards (2005-2006)

- Standards Requiring Review and Oversight of Human Gamete and Embryo Research
- Generally Aligned with Standards Adopted by the National Academy of Sciences (NAS)
- First Formal Codification of Stem Cell Research Oversight Committees

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## Evaluation & Amendments (2007-2010)

- On Site Compliance Evaluation and Awardee Feedback
- Three Workshops Involving Institutional Officials (ESCRO Committees 2007, 2008 and 2010)
- Ongoing Interaction with NAS Embryonic Stem Cell Research Oversight

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## iPSC Consent & Banking (2009-2011)

- Model Consent for iPSC Derivation, Banking and Distribution
- Template Utilized in Seven Tissue Collection Awards
- Continues to be Recognized as a Robust Consent Template for iPSC Research

- NAS Human Genome Editing Initiative
- Embryo Model Systems (NAS, 2020)
- Human Neural Organoids (NAS, 2021)
- Blastocyst Complementation
- Unauthorized Treatments | Stem Cell Clinics

Questions relating to the review and oversight of these techniques have arisen from CIRM awardees and during CIRM's strategic planning process



## Proposition 14 Specifies SWG Membership:

- Five ICOC Patient Advocate or Nurse Members
- Nine MDs/scientists with stem cell / gene therapy expertise
- Four medical ethicists (one appointed co-chair)
- Chairperson of the ICOC (one appointed co-chair)

### ○ Ethicists:

- ✓ Ethical Principles Applied in Biomedical Research
- ✓ Application of Law and Regulatory Policy to Support Research Ethics
- ✓ Experience with Research Oversight Mechanisms in Biomedical Research (e.g. IRB, IACUC, DSMB)

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- MD / Scientists:
    - ✓ MDs Recognized for Patient / Community Engagement With Cell / Gene Therapies
    - ✓ Range of Research (clinical, translational, discovery)
    - ✓ Experience with Novel Research Methods (genome editing, embryo models, embryo research, human-animal models)

Search for  
expertise



Identifying Experts:  
CIRM – ICOC Chair

Who can fill  
identified  
expertise needs  
and gaps?

Expert  
Recommendations



Assessment:  
CIRM – ICOC Chair

What is  
reviewer's level  
of commitment,  
knowledge and  
proficiency?

Nomination  
for SWG



CIRM Concurrence:  
Leadership

Does CIRM  
Leadership agree  
that nominee will  
serve CIRM  
needs?

SWG  
Appointment



Final Approval:  
ICOC

Does ICOC agree  
that nominee  
should be  
appointed to  
SWG?

CIRM will provide list of nominees to ICOC for ethicists and scientists with:

- ✓ Biography that includes description of area of expertise, ethical/scientific/medical training, affiliations, honors/accomplishments
- ✓ Specific gap or need that nominee fulfills
- ✓ How nominee was identified (e.g., recommendation from ISSCR)
- ✓ History of service to CIRM (e.g., GWG reviewer, CAP advisor)

Ethicist Co-Chair: Jeffrey Kahn, PhD, MPH

- Member, National Academy of Medicine
- Andreas C. Dracopoulos Director

Robert Henry Levi and Ryda Hecht Levi Professor of Bioethics and Public Policy Berman Institute of Bioethics

- Professor Dept. of Health Policy and Management, Johns Hopkins Bloomberg School of Public Health

ICOC Co-Chair:

- Fred Fisher, MSW, LCSW

ICOC Nurse & Patient Advocate Members

- Christine Miaskowski, RN, PhD, FAAN
- Le Ondra Clark Harvey, Ph.D.
- Elena Flowers Ph.D., R.N.
- Karol E. Watson, M.D., Ph.D.,

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