



Regulatory Amendments

In January 2007, CIRM's governing board approved amendments to the institute's medical and ethical standards. These amendments do the following:

1. Authorize the use of all cell lines derived under *Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells* without additional review of provenance.
2. Authorize the use of somatic cells, which comply with federal Office for Human Research Protections (OHRP) guidance for research with existing biological materials, for use in experiments intended to derive new cell lines (iPS).

The text of the amendments may be found at:

http://www.cirm.ca.gov/reg/pdf/Reg100120_revised.pdf

Donation Guidelines

CIRM commissioned the Institute of Medicine and the National Research Council to form the Committee on Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research in September 2006. One conclusion from the workshop is that the medical risk to oocyte donors of ovarian hyperstimulation syndrome (OHSS) and other acute health outcomes can be mitigated through a combination of strategies including:

- Identifying and excluding from research donation, those women most at risk;
- For those women who do undergo ovarian stimulation, individualizing stimulation and retrieval protocols; and
- Once the process is initiated to provide careful monitoring.

CIRM commissioned a group of expert consultants from outside of California with clinical experience with assisted reproductive technologies (ART) to develop recommendations to reduce medical risk in donors providing oocytes exclusively for research. The advisors were charged with providing recommendations for how the following methods can be applied to reduce donor medical risks:

- Screening strategies for excluding from research donation, women at increased risk;
- Clinical strategies for individualizing stimulation protocols;
- Systems for monitoring donors to modify the stimulation protocol or cancel retrieval.

The recommendations can be obtained at:

http://www.cirm.ca.gov/workgroups/pdf/oocyte_guidelines.pdf

Facility Grants

The Scientific and Medical Facilities Working Group (FWG) of the California Institute for Regenerative Medicine, after hearing extensive public discussion here yesterday and earlier today, made recommendations for the distribution of \$262 million in stem cell research infrastructure funding made available through Proposition 71. These recommendations will be reviewed, potentially modified, and then approved by CIRM's board, the Independent Citizen's Oversight Committee (ICOC), at its meeting May 6 and 7.

If all 12 applicants complete the projects as proposed, using commitments of matching money and leveraged funds from donors and the institutions, the CIRM grants will result in more than \$750 million in new research facilities, delivering a significant economic stimulus to several communities throughout the state. Investment in research infrastructure to extend California's state-of-the-art research capacity is a critical part of CIRM's Scientific Strategic Plan to sustain and build California's global leadership in stem cell research.

Stem Cell Science New Directions

CIRM sponsored a workshop titled *Stem Cells & Environmental Health Research: Current Trends and Future Possibilities*. The workshop was designed to bring together experts from the fields of the environmental health sciences and stem cell biology to orient the participants to trends in each field and identify areas of research overlap. Participants discussed:

- How human stem cell system hold tremendous potential to enable fast and less expensive test systems for environmental toxicants that address limitations associated with current animal-based assays.
- The potential for disease-specific stem cell lines to inform research intended to explore the relationship between specific environmental exposures and disease.
- Progress in the development of model systems for testing the toxicity of drugs and environmental agents.
- Regulatory and policy developments that need to be considered for stem cell systems.

Based on the success of this workshop, CIRM is organizing a meeting *Stem Cells and Predictive Toxicology*. The anticipated date of the workshop is July 2008; contact glomax@cirm.ca.gov for future information.