



**Report to Department of Public Health,
Human Stem Cell Research (HSCR)
Advisory Committee**

September 21, 2007

In response to your September 5, 2007 request, we are providing the following update regarding progress in awarding CIRM stem cell research grants. As of September 2007, the Independent Citizens Oversight Committee has approved approximately \$208 million in funding pursuant to four requests for applications:

- ▶ CIRM Training Grants 9/05 \$37.5 million
- ▶ Scientific Excellence through Exploration and Development (SEED) Grants 2/07 \$45.9 million
- ▶ CIRM's comprehensive grants 3/07 \$75.7 million
- ▶ Shared laboratory grants 6/07 \$50 million

We anticipate the ICOC will consider applications for major facilities and new faculty awards in early 2008.

At this time, specific applications pursuant to our Communities of Science and Responsibility to the Public initiatives have not been developed. In advance of any specific application, CIRM welcomes input to identify how such funding can be used most effectively to advance our common mission of advancing stem cell research under the highest ethical standards. This process would benefit from the experience and expertise of the HSCR advisory committee, and we look forward to keeping you advised of the process.

There are some additional developments that may be of interest to the HSCR advisory committee.

Bond Sales:

After nearly three years, the first bonds authorized by Proposition 71, the California Stem Cell Research and Cures Act, will be sold by the State Treasurer on Tuesday, October 4th. The \$250 million issue is historic, as it's the first time any government has funded the development of intellectual capital with general obligation bonds, which are normally used for infrastructure. Proceeds of the bond sale will be used to fund many of the 136 research, training, and facilities grants the California Institute for Regenerative Medicine (CIRM) has already approved; a portion of the more than \$300 million in additional grants slated for approval by early 2008; and to repay loans extended to CIRM by the State of California and private philanthropists.

Personnel:

The ICOC has named Alan O. Trounson, Ph.D. as the new permanent president of CIRM. Dr. Trounson, 61, is currently the Director of the Immunology and Stem Cell Laboratories at Monash University in Australia. He is a founder of the Australian Stem Cell Centre; he is one of the leading international experts in the field; and he was an early pioneer of both in vitro fertilization and embryonic stem cell research. Richard A. Murphy, Ph.D. will remain interim president, and will continue consulting with the agency for several months after Dr. Trounson's tenure begins.

Regulatory Developments:

On August 8, 2007 the Independent Citizens Oversight Committee approved modifications to the CIRM Medical and Ethical Standards regulations. A complete copy the proposed modifications are attached. The modifications are designed to:

1. Authorize the use of cell lines derived under *Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells*;
2. Establish limitations on derivation and payment for cells consistent with the *California Stem Cell Research and Cures Initiative*;
3. Authorize the derivation and use of stem cell lines from human somatic cells and tissue that are compliant with federal Office for Human Research Protections (OHRP) guidance for research with existing biological materials.

To implement the ICOC-approved modifications, CIRM is proposing substantive revisions in sections 100080, 100085, 100090, and 100100.

[1] Section 100080(a)(1) identifies covered stem cell lines determined to be "acceptably derived" because they are recognized by an authorized authority. The proposed modifications would include lines derived under *Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells* on the list of authorized lines.

[2] Section 100080(b) establishes limitations of derivation and payment for cells consistent with the *California Stem Cell Research and Cures Initiative*. Section 100080(b)(1) affirms a 12 day limits for the culture of cells. Section 100080(b)(1) references existing limitations on payments for cells pursuant to the *California Stem Cell Research and Cures Initiative*.

[3] Section 100080(b)(3) authorizes the use of stem cell lines derived from non-identifiable human somatic cells. This section identifies a number of conditions that must be met for the cells to be considered acceptably derived.

Section 100090(b) authorizes the derivation of stem cell lines by CIRM-funded researchers from non-identifiable human somatic cells. Section 100080(b)(3) is cited.

Thank your interest in program activities at CIRM.