

Stem Cell Research Information and Resources

At USC, increasing opportunities exist to do stem cell research to further knowledge of and to treat difficult chronic diseases. Given their unique regenerative abilities, stem cells offer new potentials for treating diseases such as diabetes, and heart disease. However, much work remains to be done in the laboratory and the clinic to understand how to use these cells for cell-based therapies to treat disease, which is also referred to as regenerative or reparative medicine. Research on stem cells continues to advance knowledge about how an organism develops from a single cell and how healthy cells replace damaged cells in adult organisms. Stem cell research is one of the most fascinating areas of contemporary biology, but, as with many expanding fields of scientific inquiry, research on stem cells raises scientific questions as rapidly as it generates new discoveries.

Investigators who are interested in working with stem cells must be aware of the regulations governing the use of stem cells in research. The information and references below are general information and updates on various stem cell research policies and guidelines (as of January 1, 2009). Researchers should be well versed in stem cell regulations and understand their ethical requirements.

I. Highlighted developments in stem cell research include:

- A. induced pluripotent stem cells (iPSC): What review is required, how to review them, etc.,
- B. revised conditions for payment of somatic cell and gamete donors,
- C. new guidelines for stem cell based clinical trials,
- D. institutional reporting requirements to the CA Department of Public Health (DPH),
- E. Revised NAS guidelines that are more progressive than CIRM regulations.

II. The State of California has two separate stem cell regulatory agencies:

- 1. CIRM (for CIRM funded research)
- 2. CA DPH: for non-CIRM funded research

Currently, there is some discussion between CIRM and DPH about application of rules when non-CIRM funds are used for stem cell research primarily, but not totally, funded by CIRM (see: The CIRM Standards Working Group meeting transcripts July 2008 with discussion about application of CIRM v. DPH regs, beginning on page 183:

<http://www.cirm.ca.gov/transcripts/pdf/2008/07-25-08.pdf> of the transcript).

III. Regulations:

A. CIRM stem cell regulations are at: <http://www.cirm.ca.gov/reg/default.asp>

B. DPH regulations are at: <http://www.cdph.ca.gov/programs/HSCR/Pages/default.aspx>

Note that there are some significant differences between the two sets of regulations.

For example: CIRM now allows ESCROs to approve research in which stored embryos donated for research were originally created for clinical purposes and the donors of oocytes that were procured to create the embryos were paid for the clinical donation. CA DPH has not modified their regulations to ensure consistency with CIRM. The NAS guidelines were revised and are also consistent with CIRM regs on this issue (see below).

IV. Other Resources/Guidelines:

CLINICAL TRIALS:

The International Society for Stem Cell Research (ISSCR) recently promulgated guidelines for hESC clinical trials. Neither CIRM nor CA DPH really addressed this issue. The ISSCR guidelines are at: http://www.isscr.org/clinical_trans/index.cfm

GUIDELINES:

In 2008, the NAS also revised their guidelines to include information about iPSC and they clarified the types of expenses that can be reimbursed to women donating eggs specifically for stem cell research (including lost wages). The Guidelines also include information for IRBs. It is important to note that the NAS differ from CIRM in the following:

- a. iPSC guidelines are not necessarily harmonized with CIRM regulations, that is, NAS does not suggest ESCRO review of such research and CIRM regulations require ESCRO review.
- b. NAS allows for expedited review of some new hESC research and the CIRM regulations appear to not provide such flexibility.
- c. Periodic internal audits of the ESCRO.
- d. public notification of institutional stem cell research by posting projects on an institutional website.