



State of California—Health and Human Services Agency
Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

May 29, 2008

Dear Colleague,

This letter is being sent to California Institutional Review Boards, university offices of research, and various companies in an effort to educate and inform those parties affected by new research guidelines and State legislation concerning **human stem cell research**.

In September 2006, the California Legislature passed Senate Bill 1260 (SB 1260, Ortiz, Chapter 483, Statutes of 2006), which addresses research involving **human embryonic stem cells** and **human oocyte procurement**. This law **does not** apply to human embryonic stem cell research that is fully funded by the California Institute for Regenerative Medicine (CIRM). However, if a project is partially funded by CIRM, those non-CIRM funded components of the project must abide by the mandates of SB 1260.

Scope of New Statutory Mandates

SB 1260 amended California Health and Safety Code §125118–125119.5, §125300 and added Chapter 2 (commencing with §125330) to Part 5.5 of Division 106 to include specific reporting and review requirements for research involving the derivation or use of human embryonic stem cells as well as for procurement of human oocytes for research or the development of medical therapies.

Human Embryonic Stem Cell Research (hESC)

The amended California Health and Safety Code §125119 and §125300 mandate that any hESC research project must be reviewed and receive approval by a Stem Cell Research Oversight (SCRO) Committee prior to being undertaken. This mandate supersedes previous statutory language that required Institutional Review Board (IRB) review and approval for hESC research in California (enacted by SB 253, Ortiz, 2002). [Note: Institutional review and approval may still be necessary for some projects per federal regulations or institution policy (e.g., if research involves human subjects)]. SCRO Committees are required to review the research projects at least annually and report annually to the California Department of Public Health (CDPH) on the status and disposition of each project (**Form HSCR1260-1**, version May 2008).

Human Oocyte Procurement for Research

Enacted statutes commencing with California Health and Safety Code §125330 specify new mandates for research projects involving assisted oocyte production (AOP) or alternative methods of human oocyte retrieval for research or the development of medical therapies. The mandates apply to oocytes retrieved after January 1, 2007.

IRBs are charged with ensuring that various informed consent provisions and subject protections are provided for research subjects donating oocytes for research purposes.

Research projects involving AOP must ensure a written record is maintained of subject demographics, adverse health outcomes, and the provenance and disposition of every oocyte

donated or used as detailed in **Form HSCR1260-2** (version May 2008). The research projects or clinics/facilities should submit this record to their IRB or SCRO Committee, as determined by their review committee, who will then transmit the information to CDPH.

The information included in the records is deemed confidential and protected by subject privacy provisions of law.

CDPH Guidelines for Human Stem Cell Research

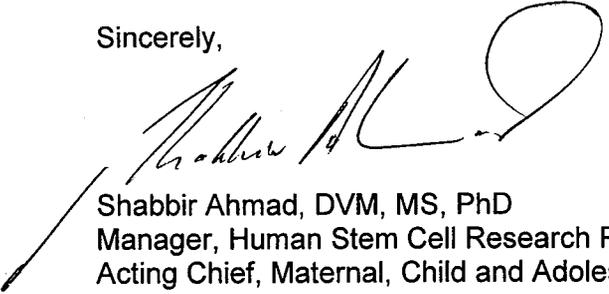
Per Health and Safety Code §125118, CDPH has developed and issued comprehensive statewide guidelines for most human stem cell research:
<http://www.cdph.ca.gov/services/boards/HSCR/Documents/MO-HSCRGuidelines-08-2007.pdf>.
The guidelines are principally consistent with established state and national standards. They outline ethical stem cell research practices, SCRO Committee and institutional review committee functions and responsibilities, as well as offer direction for clinical trials involving human progenitor stem cells. The guidelines are a living document and may be amended as the field of stem cell research evolves. Any future revisions to the guidelines will be posted to the CDPH Human Stem Cell Research website.

Annual Reporting and Reporting Forms

Annual reporting is required on any hESC research project not fully funded by CIRM and any human oocyte procured after January 1, 2007 for research or the development of medical therapies. Reporting forms have been developed for both SCRO Committees overseeing hESC research (**Form HSCR1260-1**) and research projects involving human oocyte retrieval (**Form HSCR1260-2**). Reporting for the first year includes research conducted from January 1, 2007 – June 30, 2008. The forms are provided to help facilitate compliance with the mandates of Health and Safety Code Sections 125118–125119.5, 125300 and 125330 et. seq. The completed forms are due to CDPH by **August 1, 2008**. Subsequent annual reports are due August 1 immediately following the reporting period (July 1 - June 30).

The guidelines, reporting forms for hESC research and research involving human oocyte procurement, applicable statute in the Health and Safety Code, and other helpful information can be found at: <http://www.cdph.ca.gov/programs/HSCR/Pages/default.aspx>.

Sincerely,



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