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



EDMUND G. BROWN JR.
Governor

May 1, 2016

Dear Colleague:

This letter is being sent to the California Stem Cell Research Oversight (SCRO) Committees, university offices of research, and companies involved in human embryonic stem cell research (hESC) as a reminder of statutorily mandated reporting requirements for hESC research and research involving human oocyte retrieval.

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**). There is also an Excel flat file version available for both forms. The reporting period includes research conducted from July 1, 2015 to June 30, 2016. The forms are provided to help facilitate compliance with the mandates of California Health and Safety Code Sections 125118–125119.5, 125300 and 125330 et. seq. The completed forms are due to the California Department Public Health (CDPH) by **August 1, 2016** and can be sent via email to stemcell@cdph.ca.gov.

Human Embryonic Stem Cell Research (hESC)

California Health and Safety Codes §125119 and §125300 mandate that any hESC research project must be reviewed and receive approval by a SCRO Committee prior to being undertaken. SCRO Committees are required to review the research projects at least annually and report annually to the CDPH on the status and disposition of each project (Form HSCR1260-1).

Human Oocyte Retrieval for Research

Enacted statutes commencing with California Health and Safety Code §125330 specify that research projects involving human oocyte retrieval for research or the development of medical therapies must ensure a written record is maintained for each subject and donated oocyte as detailed in Form HSCR1260-2.

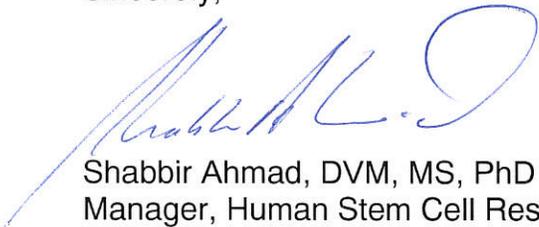
Furthermore, California Health and Safety Code §125335 specifies that no payment in excess of the amount of reimbursement of direct expenses incurred as a result of the procedure shall be made to any subject to encourage her to produce human oocytes for the purposes of medical research.

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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.

Further information and updated guidance regarding hESC research and research involving human oocyte retrieval as well as reporting forms HSCR 1260-1 and HSCR 1260-2 can be found at:
<http://www.cdph.ca.gov/programs/HSCR/Pages/HumanStemCellResearchReportingForms.aspx>. Please contact the Human Stem Cell Research Program at stemcell@cdph.ca.gov with reporting inquiries.

Sincerely,



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