

State of California Human Oocyte Retrieval Mandates

Senate Bill 1260 (Ortiz, 2006) became law January 1, 2007, amending Health and Safety Code Section 125330 and Chapter 2 (commencing with §125330). The amended Sections mandate detailed reporting requirements as well as specific practices for the procurement of oocytes for stem cell or medical research.

Per SB 1260, all facilities or research projects involved in the procurement of oocytes for medical or stem cell research are required to submit a written record of specific information regarding each oocyte donor to the California Department of Public Health (CDPH) annually.

If your facility or project has collected oocytes that were or will be used or sent for use in stem cell or other medical research after January 1, 2007, please complete the accompanying "Reporting Form" (Excel tabs: 'Facility Information', 'Subject Information', and 'Medical Research'). The attached form must be completed in full and transmitted to CDPH, email@dhs.ca.gov, by June 30, 2008.

Note: The "Reporting Form" is not intended to replace the IRB or Stem Cell Research Oversight Committee reporting requirements for an oocyte retrieval research project, unless otherwise authorized by the review committee.

Reporting Form Instructions

Subject data submitted to CDPH **must not** contain any personal identifiers (e.g. Social Security Number). Please assign a unique identifier to each donor or retain the corresponding "Donor" numbers from the attached form. This is necessary in the event CDPH requires additional information on a specific donor.

Please provide information for each oocyte donor supplying oocytes for medical or stem cell research. If an answer is the same for all subjects, only place the answer in the "All Subjects" column. Please copy and paste additional "Donor" columns as needed.

Please note: Several questions list specific answers with a corresponding number (e.g. 1 = White, 2 = Black). Please insert only the corresponding number in the appropriate box. Text may be directly entered into the appropriate boxes or cut and pasted from another program, such as Microsoft Word.

If you have any questions or experience problems with the form, please email: email@dhs.ca.gov ?

Supporting Materials

**Pursuant to section 125118.5, CDPH has issued guidelines for stem cell research projects and designated review committees: Please visit http://www.mch.dhs.ca.gov/programs/STEM_CELL for more information.

American Society for Reproductive Medicine. Assisted Reproductive Technologies: A Guide for Patients. 2003. <http://www.asrm.org/Patients/patientbooklets/ART.pdf>

American Society for Reproductive Medicine. Informed Consent and the Use of Gametes and Embryos for Research. Fertil Steril 2004;82(Suppl 1):S251-S252. <http://www.asrm.org/Media/Ethics/informedconsent.pdf>
(*under revision; check ASRM before distributing*)

American Society for Reproductive Medicine. Human Somatic Cell Nuclear Transfer (Cloning). Fertil Steril 2000;74(5):873-6. <http://www.asrm.org/Media/Ethics/cloning.pdf>

Senate Bill 1260 (Ortiz, 2006): http://leginfo.ca.gov/pub/05-06/bill/sen/sb_1251-1300/sb_1260_bill_20060926_chaptered.pdf

California Department of Public Health
MCAH/OFP Branch
Human Stem Cell Research Unit