

CALIFORNIA CODES  
HEALTH AND SAFETY CODE  
SECTION 125118- 125119.5

125118. (a) On or before January 1, 2005, the department shall develop guidelines for research involving the derivation or use of human embryonic stem cells in California.

(b) In developing the guidelines specified in subdivision (a), the department may consider other applicable guidelines developed or in use in the United States and in other countries, including, but not limited to, the Guidelines for Research Using Human Pluripotent Stem Cells developed by the National Institutes of Health and published in August 2000, and corrected in November 2000.

(c) The department may contract with a public or private organization, to the extent permitted by state law, for assistance in developing the guidelines.

(d) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

125118.5. (a) For purposes of developing the guidelines required by Section 125118, the director shall establish a Human Stem Cell Research Advisory Committee.

(b) The advisory committee shall consist of 13 members, as follows:

(1) Seven scientists with experience in biomedical research in the fields of cell differentiation, nuclear reprogramming, tissue formation and regeneration, stem cell biology, developmental biology, regenerative medicine, or related fields.

(2) Two medical ethicists.

(3) Two persons with backgrounds in legal issues related to human embryonic stem cell research, in vitro fertilization, or family law, as it applies to the donation of embryos and oocytes.

(4) Two persons who are members or leaders of religious organizations.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

125119. (a) (1) All research projects involving the derivation or use of human embryonic stem cells shall be reviewed and approved by an institutional review board that is established in accordance with federal regulations, including Part 46 (commencing with Section 46.101) of Subchapter A of Subtitle A of Title 45 of the Code of Federal Regulations, prior to being undertaken. Any such institutional review board shall, in its review of human embryonic stem cell research projects, consider and apply the guidelines developed by the department pursuant to Section 125118. An institutional review board may require modifications to the plan or design of a proposed human embryonic

stem cell research project as a condition of approving the research project.

(2) For purposes of this article, "IRB" means an institutional review board described in paragraph (1).

(b) Not less than once per year, an IRB shall conduct continuing review of human embryonic stem cell research projects reviewed and approved under this section in order to ensure that the research continues to meet the standards for IRB approval. Pursuant to its review in accordance with this subdivision, an IRB may revoke its prior approval of research under this section and require modifications to the plan or design of a continuing research project before permitting the research to continue.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

125119.3. (a) Each IRB that has reviewed human embryonic stem cell research pursuant to Section 125119 shall report to the department, annually, on the number of human embryonic stem cell research projects that the IRB has reviewed, and the status and disposition of each of those projects.

(b) Each IRB shall also report to the department regarding unanticipated problems, unforeseen issues, or serious continuing investigator noncompliance with the requirements or determinations of the IRB with respect to the review of human embryonic stem cell research projects, and the actions taken by the IRB to respond to these situations.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

125119.5. (a) The department shall at least annually review reports from IRBs pursuant to Section 125120, and may revise the guidelines developed pursuant to Section 125118, as it deems necessary.

(b) The department shall report annually to the Legislature on human embryonic stem cell research activity. These annual reports shall be compiled from the reports from IRBs pursuant to Section 125120.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.