HEALTH AND SAFETY CODE - HSC

DIVISION 106. PERSONAL HEALTH CARE (INCLUDING MATERNAL, CHILD, AND ADOLESCENT) [123100 - 125850] *(Division 106 added by Stats. 1995, Ch. 415, Sec. 8.)*

PART 5.5. USE OF HUMAN CELLS [125300 - 125356] *(Part 5.5 heading added by Stats. 2003, Ch. 507, Sec. 5.)*

CHAPTER 2. Procuring of Oocytes for Research [125330 - 125356] *(Chapter 2 added by Stats. 2006, Ch. 483, Sec. 7.)*

125330. The following definitions apply to this chapter:

(a) “Alternate method of oocyte retrieval” means a method of oocyte retrieval that does not involve the pharmaceutically induced manipulation of oocyte production.

(b) “Assisted oocyte production” or “AOP” means surgical extraction of oocytes following pharmaceutically induced manipulation of oocyte production through the use of ovarian stimulation.

(c) “Informed consent” means a research participant understands the material facts reasonably necessary to make a determination to participate or to refuse from participating in the medical research without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the research participant’s decision.

(d) “Institutional review board” means a body 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.

(e) “Oocyte” means a female egg or egg cell of a human female.

(f) “Research participant” means any person undergoing AOP or any alternative method of ovarian retrieval for research or for the development of medical therapies, including those who would not meet the definition of “subject” under 45 C.F.R. 46.102. The protections afforded to human subjects under an institutional review board apply to research participants in this chapter.

(Amended by Stats. 2019, Ch. 864, Sec. 2. (AB 922) Effective January 1, 2020.)

125331. (a) As used in this chapter, “Research Participants Undergoing Oocyte Retrieval for Medical Research Purposes Bill of Rights” means a list of the rights of a research participant providing human oocytes for the purposes of medical research. The list of rights shall be written in a language in which the research participant is fluent. The list shall incorporate all the rights and protections in this chapter, and include, but not be limited to, all of the following research participant rights as described in Section 24172:

(1) The right to be informed of the nature and purpose of the medical research.

(2) The right to be given an explanation of the procedures to be followed in the medical research, and any drug or device to be utilized.

(3) The right to be given a description of any attendant discomforts and reasonably foreseeable risks expected from participating in the medical research.

(4) The right to be given an explanation of any benefits to the research participant reasonably to be expected from the medical research, if applicable.

(5) The right to be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the research participant, and their relative risks and benefits.

(6) The right to be informed of the avenues of medical treatment, if any, available to the research participant after the medical research if complications should arise.

(7) The right to be given an opportunity to ask any questions concerning the experiment or the procedures involved.

(8) The right to be instructed that consent to participate in the medical research may be withdrawn at any time and the research participant may discontinue participation in the medical research without prejudice.

(9) The right to be given a copy of the signed and dated written consent form as provided for by Section 24173 or Section 24178.

(10) The right to be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the research participant's decision.

(b) The rights provided by this section do not supersede, but are in addition to, the rights afforded a research participant pursuant to the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).

(Added by Stats. 2019, Ch. 864, Sec. 3. (AB 922) Effective January 1, 2020.)

125335. (a) Prior to obtaining informed consent from a subject for AOP or any alternative method of ovarian retrieval on a subject for the purpose of procuring oocytes for research or the development of medical therapies, a physician and surgeon shall provide to the subject a standardized medically accurate written summary of health and consumer issues associated with AOP and any alternative methods of oocyte retrieval. The failure to provide to a subject this standardized medically accurate written summary constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

(b) The summary shall include, but not be limited to, medically accurate disclosures concerning the potential risks of AOP or any alternative method of oocyte retrieval, including the risks associated with the surgical procedure and with using the drugs, medications, and hormones prescribed for ovarian stimulation during the AOP process or any alternative method of oocyte retrieval.

(c) For purposes of subdivision (a), "written summary of health and consumer issues" means the guide published and updated by the American Society for Reproductive Medicine entitled, "Assisted Reproductive Technology: A Guide for Patients" or an alternative written medically accurate document prepared by a recognized authority on oocyte retrieval for medical research that also meets the criteria included in this section. This alternative document may be one that has been approved and recommended by the State Department of Public Health pursuant to Section 125118 and shall include all of the following:

(1) The document shall adhere to simplified reading standards, including, but not limited to, those generally accepted and required for government publications. The document shall be written in layperson's language and shall be made available in languages spoken by subjects in the study if their proficiency is largely in a language other than English. All information in the document shall be conveyed to the subject orally in easy to understand and nontechnical terms.

(2) The document shall include additional resources for, or list additional sources of, medical information on health and safety issues surrounding oocyte retrieval.

(Amended by Stats. 2007, Ch. 483, Sec. 34. Effective January 1, 2008.)

125340. (a) Prior to providing AOP or any alternative method of ovarian retrieval to a research participant for the purposes of medical research or development of medical therapies, a physician and surgeon shall obtain written and oral informed consent for the procedure from the research participant. Informed consent for the purposes of this chapter shall include a signed acknowledgment of the rights contained in the Research Participants Undergoing Oocyte Retrieval for Medical Research Purposes Bill of Rights and comply with the informed consent requirements of the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).

(b) The failure to obtain written informed consent from the research participant constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code. This section does not relieve the physician and surgeon from other existing duties under the law, including, but not limited to, the duty to obtain a research participant's informed consent after fully explaining the proposed procedure. The requirement that a physician and surgeon provide the standardized written summary pursuant to Section 125335 is in addition to, and does not supplant, other existing legal requirements regarding informed consent, including, but not limited to, compliance with the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).

(c) This chapter does not affect the suitability or availability of oocytes procured for research before January 1, 2007, if the oocytes were donated pursuant to protocols or standards that are generally recognized and accepted by national or international scientific bodies.

(d) A written document required pursuant to this section shall adhere to simplified reading standards, including, but not limited to, those generally accepted and required for government publications, and in layperson's language. The document shall be made available in languages spoken by research participants in the study if their proficiency is largely in a language other than English. All information in the written informed consent document shall also be conveyed to the research participant orally in easy to understand and nontechnical terms.

(e) Research conducted pursuant to this chapter shall adhere to federal regulations governing informed consent pursuant to Section 46.116 of Title 45 of the Code of Federal Regulations.

(f) This section does not limit or expand the right of an injured research participant to recover damages under any applicable law.

(Amended by Stats. 2019, Ch. 864, Sec. 4. (AB 922) Effective January 1, 2020.)

125341. An institutional review board (IRB) that reviews and approves medical and scientific research shall require all of the following of any research program or project that comes under its review that involves AOP or any alternative method of oocyte retrieval:

(a) That it include a written summary as required under Section 125335 that would include information on health risks and potential adverse consequences of the procedure and describe the manner in which the research participant will receive and review this written summary.

(b) That it inform the research participant that ongoing studies are necessary to assess the long-term health impacts of ovarian stimulation and oocyte retrieval.

(c) That it obtain a signed acknowledgment of the Research Participants Undergoing Oocyte Retrieval for Medical Research Purposes Bill of Rights and obtain informed consent in compliance with the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20), including informed consent for information obtained pursuant to Section 125342.

(d) That it provide the research participant with an objective and accurate statement about the existing state of the research for which the research participant is providing oocytes.

(e) That it perform psychological and physical screening, in accordance with the appropriate standard of care, for all research participants prior to the oocyte retrieval procedure.

(f) That it ensure that after conducting AOP or any alternative method of oocyte retrieval on a research participant the research participant be given a postprocedure medical examination at a time within the standard of care to determine if the research participant has experienced an adverse health effect that is a result of the procedure. The research participant shall be informed that they have the right to a second opinion if they have any medical concerns.

(g) That it ensure that the research participant has access to and coverage for medically appropriate medical care that is required as a direct result of the procedure for research purposes. The research program or project shall ensure that payment or coverage of resulting medical expenses be provided at no cost to the research participant and that a summary of the arrangements the procuring entity has made for coverage or payment for medical care related to AOP or any alternative method of oocyte retrieval is provided to the research participant prior to the procedure.

(h) That it provide a summary informing the research participant that oocytes may not be sold or transferred for valuable consideration except as set forth in Section 125350.

(i) That it provide disclosure if the physician and surgeon and their immediate family members have any professional interest in the outcome of the research or of the oocyte retrieval procedure and, if so, that it provide disclosure that they carry the interest of both the research participant and the success of the research.

(Amended by Stats. 2019, Ch. 864, Sec. 5. (AB 922) Effective January 1, 2020.)

125342. (a) A research program or project that involves AOP or any alternative method of oocyte retrieval shall ensure that a written record is established and maintained to include, but not be limited to, all of the following components:

(1) The demographics of subjects, including, but not limited to, their age, race, primary language, ethnicity, income bracket, education level, and the first three digits of the ZIP Code of current residence.

(2) Information regarding every oocyte that has been donated or used. This record should be sufficient to determine the provenance and disposition of those materials.

(3) A record of all adverse health outcomes, including, but not limited to, incidences and degrees of severity, resulting from the AOP or any alternative method of oocyte retrieval.

(b) (1) The information included in the written record pursuant to subdivision (a) shall not disclose personally identifiable information about subjects, and shall be confidential and is deemed protected by subject privacy provisions of law. This information shall be reported to the State Department of Public Health, which shall aggregate the data and make it publicly available, as set forth in paragraph (2), in a manner that does not reveal personally identifiable information about the subjects.

(2) The department shall provide public access to information that it is required to release pursuant to the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government Code). The department shall

disseminate the information to the general public via governmental and other websites in a manner that is understandable to the average person. The information shall be made available to the public when the biennial review pursuant to Section 125119.5 is provided to the Legislature.

(Amended by Stats. 2021, Ch. 615, Sec. 287. (AB 474) Effective January 1, 2022. Operative January 1, 2023, pursuant to Sec. 463 of Stats. 2021, Ch. 615.)

125343. Any employee who works in the unit conducting stem cell research using human oocytes, persons who report to, or are supervised by, the principal investigator or key personnel of the project, or both, along with the principal investigator and the key personnel of the project, and the immediate family members of any of the above persons are prohibited from being a subject in the research.

(Added by Stats. 2006, Ch. 483, Sec. 7. Effective January 1, 2007.)

125344. The physician and surgeon performing the AOP or any alternative method of oocyte retrieval shall not have a financial interest in the outcome of the research.

(Added by Stats. 2006, Ch. 483, Sec. 7. Effective January 1, 2007.)

125345. Pursuant to guidelines adopted by the Research Council and Institute of Medicine of the National Academies, researchers shall offer subjects an opportunity to document their preferences regarding future uses of their donated materials. The consent process shall fully explore whether subjects have objections to any specific forms of research to ensure that their wishes are honored.

(Added by Stats. 2006, Ch. 483, Sec. 7. Effective January 1, 2007.)

125346. Any procedures for procuring oocytes in this state for research or the development of medical therapies shall meet all of the standards for subjects included in this chapter. All oocytes procured outside of this state for research taking place in this state shall meet these same standards. All egg extractions for research shall be approved by an institutional review board pursuant to Section 125341.

(Added by Stats. 2006, Ch. 483, Sec. 7. Effective January 1, 2007.)

125350. No human oocyte or embryo shall be acquired, sold, offered for sale, received, or otherwise transferred for valuable consideration for the purposes of medical research or development of medical therapies. For purposes of this section, “valuable consideration” does not include reasonable payment for the removal, processing, disposal, preservation, quality control, and storage of oocytes or embryos.

(Added by Stats. 2006, Ch. 483, Sec. 7. Effective January 1, 2007.)

125355. (a) 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 the subject to produce human oocytes for the purposes of medical research.

(b) This section shall become operative on January 1, 2024.

(Repealed (in Sec. 7) and added by Stats. 2019, Ch. 864, Sec. 8. (AB 922) Effective January 1, 2020. Section operative January 1, 2024, by its own provisions.)

125356. If an individual providing human oocytes for the purposes of fertility is compensated, and any human oocytes or embryos in excess of those needed for fertility are offered for research, the institutional review board shall disregard the amount of compensation if all of the following conditions are met:

(a) The individual in infertility treatment, after being provided with the necessary disclosures as required for research participants under subdivision (a) of Section 125335, makes the determination that the individual does not want or need the oocytes for their own reproductive success, and provides informed consent to donate the oocytes for medical research.

(b) The procurement and disposition for research purposes of human oocytes that were initially provided for reproductive uses, either for use by the donor or another individual, shall not knowingly compromise the optimal reproductive success of the individual in the infertility treatment.

(c) The infertility treatment protocol is established prior to requesting or obtaining consent for donation for research purposes and the prospect of donation for research does not alter the timing, method, or procedures selected for clinical care.

(d) The clinic performing oocyte retrieval is a member of the Society for Assisted Reproductive Technology.

(e) The donation of oocytes for research is done without valuable consideration.

(Added by Stats. 2019, Ch. 864, Sec. 9. (AB 922) Effective January 1, 2020.)