AB-922 Reproductive health and research: oocyte procurement. (2019-2020)

Date Published: 10/14/2019 09:00 PM

Assembly Bill No. 922

CHAPTER 864

An act to amend Sections 125330, 125340, and 125341 of, to add Sections 125331 and 125356 to, and to repeal and add Section 125355 of, the Health and Safety Code, relating to reproductive health.

[Approved by Governor October 13, 2019. Filed with Secretary of State October 13, 2019.]

LEGISLATIVE COUNSEL'S DIGEST

AB 922, Burke. Reproductive health and research: oocyte procurement.

Existing law prohibits human oocytes or embryos from being acquired, sold, offered for sale, received, or otherwise transferred for valuable consideration for medical research or development of medical therapies, and prohibits payment in excess of the amount of reimbursement of direct expenses to be made to any research subject to encourage an individual to produce human oocytes for the purposes of medical research. Before obtaining informed consent from a subject for assisted oocyte production (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, existing law requires a physician and surgeon to provide to the subject a standardized medically accurate written summary of health and consumer issues associated with AOP, as specified. Existing law also requires all oocyte extractions for research to be approved by an institutional review board, as defined.

This bill, until January 1, 2024, would require individuals who provide human oocytes for research to be compensated for their time, discomfort, and inconvenience in the same manner as other research subjects, as prescribed and determined by a human subject research panel or institutional review board.

The bill would establish the Research Participants Undergoing Oocyte Retrieval for Medical Research Purposes Bill of Rights and would require the bill of rights to contain specified information relating to the rights of a research participant providing human oocytes. The bill would require a physician and surgeon to obtain written and oral informed consent prior to providing a procedure for ovarian retrieval, including a signed acknowledgment of the bill of rights.

The bill would require the institutional review board to disregard the amount of compensation paid to an individual providing human oocytes for fertility if certain requirements are met, including that the individual in fertility treatment does not want or need the oocytes for their own reproductive success. The bill would require an institutional review board to require any research program or project that comes under its review that involves AOP or any alternative method of oocyte retrieval to inform the research participant that ongoing studies are necessary to assess the long-term health impacts of ovarian stimulation and oocyte retrieval.

The bill would require a research program that offers compensation to research participants providing human oocytes, on or before January 16, 2023, to provide aggregated deidentified information to the Legislative Analyst regarding the research participants, including, among other things, the number of candidates and participants in the program, and basic demographic information and clinical data about the candidates and participants. The bill would require the Legislative Analyst to compile the

information received by the research programs and, on or before March 17, 2023, to prepare and submit a report to the Legislature containing the aggregated deidentified information.

The bill would change references in existing law that refer to an individual who provides human oocytes for research as a "subject" to "research participant."
Vote: majority Appropriation: no Fiscal Committee: no Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature finds and declares all of the following:

(a) The purpose of this act is to recognize and expand existing protections for research participants undergoing oocyte retrieval for medical research or medical therapy purposes.

(b) Scientific research can be most effectively achieved by establishing protocols to protect, respect, and promote human health, safety, dignity, autonomy, and rights in conducting research.

(c) This act seeks to support the requirements in law upholding the principle of voluntary and informed consent and to tailor them to this new area of pioneering research that utilizes human oocytes.

(d) As illustrated in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, there is a concern about exploitation of research participants who are asked to subject themselves to drugs, devices, or procedures they might not otherwise need for medical purposes, but who are asked to participate in research for the benefit of all. This concern can range from persons with terminal illnesses who might be so desperate for help they would subject themselves to a high-risk procedure with limited benefit to otherwise healthy people who might be motivated to participate in a study primarily for a financial award. To address this concern of exploitation, and to recognize the need for people to participate in research, mechanisms were created to balance the need to reward research participants without creating undue inducement.

(e) The Belmont Report summarizes three core principles for research involving human research participants: respect for persons, beneficence, and justice. In order to ensure the implementation of these core principles, the Belmont Report identified three areas of application that protect research participants: informed consent, assessment of risks and benefits, and selection of research participants. These principles and guidelines continue to be the foundation for the United States Department of Health and Human Services human subject protection regulations.

(f) In California, the mechanisms dedicated to judging this balance include human subject research panels, institutional review boards, and stem cell research organizations.

(g) Existing state and federal laws ensure that all research participants receive written information containing the medical research purpose and its risks and benefits in a language that they understand. The written information includes an acknowledgment that the participant understands and has made a determination to participate in the medical research. A research participant is required to provide their informed consent before participating in any medical research.

(h) Concerns that women will be exploited if compensated for providing human oocytes for research have not borne out in the states where compensation is allowed. Fewer than a handful of states, including California, have banned compensation, which creates barriers for research development.

(i) In the nascent days of stem cell research when the focus was on embryonic stem cell research where substantial numbers of human oocytes were expected to be needed, some individuals had concerns that the systems for protecting those providing oocytes would be overwhelmed despite there being no evidence in the United States. While not a direct target, as the ban on compensation captured all research, it included reproductive research.

(j) Without compensation, few women participate in research, creating barriers to reproductive research that could benefit all women. As an example, more research could be done on embryo quality so that women undergoing in vitro fertilization (IVF) can confidently choose to have a single embryo implanted with a high probability of achieving a successful pregnancy, instead of multiple embryos. Lowering the rate of multiple pregnancies in IVF is a high-priority goal that benefits pregnant individuals, parents, the resulting children, and society. The best source of available embryos for research comes from embryos created for fertility using a compensated donor, as that person is more likely to produce a higher volume of oocytes and excess viable embryos than the infertile individual. Due to the ban on compensation, oocytes and embryos not needed for fertility will be unsuitable for research and will likely be discarded.

(k) All patients, including those participating in research, are due a reasonable duty of care. In addition, all women undergoing ovarian stimulation and oocyte retrieval have another layer of regulation as all cycles are reported to the federal Centers for

Disease Control and Prevention.

(l) Protections are in place for all research participants, including participants providing human oocytes for research. The Legislature acknowledges the need to extend existing laws protecting research participants to those providing human oocytes while also protecting all research participants' autonomy over their bodies.

(m) This act repeals the ban on compensation for individuals providing human oocytes for medical research. Reasonable compensation amounts shall be determined by human subject research panels and institutional review boards.

SEC. 2. Section 125330 of the Health and Safety Code is amended to read:

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.

SEC. 3. Section 125331 is added to the Health and Safety Code, to read:

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).

SEC. 4. Section 125340 of the Health and Safety Code is amended to read:

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.

SEC. 5. Section 125341 of the Health and Safety Code is amended to read:

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.

SEC. 6. Section 125355 of the Health and Safety Code is repealed.

SEC. 7. Section 125355 is added to the Health and Safety Code, to read:

125355. (a) Notwithstanding Section 125350, an individual providing human oocytes for research shall be compensated for their time, discomfort, and inconvenience in the same manner as other research participants. Payment pursuant to this section shall not be for the human oocytes themselves or predicated on the number of oocytes obtained, including if no human oocytes are obtained. Whether a proposed compensation amount is appropriate shall be determined by a human subject research panel or institutional review board.

(b) A research participant providing human oocytes for research shall be provided with a summary of health and consumer issues associated with AOP as required under Section 125335, informed consent requirements as described in Section 125340, an authorized consent form containing the research participant's signature as required under Section 24173, and the Research Participants Undergoing Oocyte Retrieval for Medical Research Purposes Bill of Rights as required under Section 12531.

(c) A research program that offers compensation to research participants providing human oocytes for research pursuant to subdivision (a) is subject to the requirements of Sections 125341 and 125342, including, but not limited to, coverage for medically appropriate medical care that is required as a direct result of the procedure for research purposes, regardless of the level of compensation offered.

(d) (1) A research program that offers compensation to research participants providing human oocytes shall, on or before January 16, 2023, provide aggregated deidentified information to the Legislative Analyst regarding the research participants. The research program shall advise a research participant of the data collection as part of the informed consent process required by Section 125340.

(2) The aggregated deidentified information provided by a research program to the Legislative Analyst shall include all of the following:

(A) The total number of candidates expressing an interest in providing human oocytes for research.

(B) The total number of candidates giving written and oral informed consent for the procedure.

(C) The total number of participants providing human oocytes for research.

(D) Basic demographic information about the candidates and participants, including all of the following:

(i) Age.

(ii) Race and ethnicity.

(iii) Gender, including self-identifying gender, which may include female, male, and nonbinary.

(iv) Primary language, and all languages in which the research participant is proficient in both oral and written form.

(v) Childbearing history, including gravida and parity.

(vi) The number of times of previous oocyte donations for research and the number of times of previous oocyte donations for fertility.

(vii) Education level.

(viii) Income level and annual income.

(ix) Amount of compensation, including expenses, for the oocyte research donation.

(E) Clinical data for oocyte research candidates and participants, including all of the following:

(i) Median anti-Mullerian hormone levels.

(ii) Antral follicle count.

(iii) Days of stimulation.

(iv) Peak estradiol levels.

(v) Number of oocytes retrieved.

(vi) Complications, including interruption of cycles, postcycle complications, and procedure complications, and a discussion of how the complications were managed.

(vii) Notable medical conditions.

(viii) Summary of information obtained through followup surveys.

(e) (1) The Legislative Analyst shall compile the information received pursuant to subdivision (d) and shall, on or before March 17, 2023, prepare and submit a report to the Legislature containing the aggregated deidentified information. The report shall be submitted in compliance with Section 9795 of the Government Code.

(2) The Legislative Analyst's report shall be reviewed by an institutional review board, prior to submission to the Legislature, to ensure the protection and privacy of research participants.

(f) This section shall remain in effect only until January 1, 2024, and as of that date is repealed.

SEC. 8. Section 125355 is added to the Health and Safety Code, to read:

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.

SEC. 9. Section 125356 is added to the Health and Safety Code, to read:

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.