Fwd: Agenda Item 19 File 21-0878

1 message

Office of the City Clerk <cityclerk@lacity.org> Wed, Aug 11, 2021 at 11:41 AM
To: City Clerk Council and Public Services <clerk.cps@lacity.org>

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From: **Abby Relic** <abby.relic@gmail.com>
Date: Wed, Aug 11, 2021 at 11:34 AM
Subject: Agenda Item 19 File 21-0878
To: <cityclerk@lacity.org>

Please be advised of the following California Law.

https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=20.&title=&part=&chapter=1.3.&article

HEALTH AND SAFETY CODE - HSC
DIVISION 20. MISCELLANEOUS HEALTH AND SAFETY PROVISIONS [24000 - 26250] *(Division 20 enacted by Stats. 1939, Ch. 60.)*

CHAPTER 1.3. Human Experimentation [24170 - 24179.5] *(Chapter 1.3 added by Stats. 1978, Ch. 360.)*

24170. This chapter shall be known and may be cited as the Protection of Human Subjects in Medical Experimentation Act.

(Added by Stats. 1978, Ch. 360.)

24171. The Legislature hereby finds and declares that medical experimentation on human subjects is vital for the benefit of mankind, however such experimentation shall be undertaken with due respect to the preciousness of human life and the right of individuals to determine what is done to their own bodies.

The Legislature further finds and declares that:

(a) The Nuremberg Code of Ethics in Medical Research was developed after the trial of Nazi war criminals for unethical use of persons in medical experiments; subsequently, the Declaration of Helsinki additionally established recommendations guiding doctors in experimentation involving human subjects.

(b) Neither the Nuremberg Code nor the Declaration of Helsinki are codified under law and are, therefore, unenforceable.

(c) It is necessary that medical experimentation be done in such a way as to protect the rights of the human subjects involved.

(d) There is, and will continue to be, a growing need for protection for citizens of the state from unauthorized, needless, hazardous, or negligently performed medical experiments on human beings.

It is, therefore, the intent of the Legislature, in the enacting of this chapter, to provide minimum statutory protection for the citizens of this state with regard to human experimentation and to provide penalties for those who violate such provisions.

(Added by Stats. 1978, Ch. 360.)

24172. As used in the chapter, "experimental subject's bill of rights," means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent. Except as otherwise provided in

Section 24175, this list shall include, but not be limited to the subject's right to:

(a) Be informed of the nature and purpose of the experiment.

(b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

(e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

(g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

(i) Be given a copy of the signed and dated written consent form as provided for by Section 24173 or 24178.

(j) 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 subject's decision.

(Added by Stats. 1978, Ch. 360.)

24173. As used in this chapter, "informed consent" means the authorization given pursuant to Section 24175 to have a medical experiment performed after each of the following conditions have been satisfied:

(a) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by Section 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.

(b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.

(c) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:

(1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.

(2) A description of any attendant discomfort and risks to the subject reasonably to be expected.

(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.

(4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(5) An estimate of the expected recovery time of the subject after the experiment.

(6) An offer to answer any inquiries concerning the experiment or the procedures involved.

(7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.

(8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.

(9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.

(10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

(11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, "material" means ten thousand dollars ($10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.

(d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in Section 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by Section 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.

(Amended by Stats. 2003, Ch. 397, Sec. 1. Effective January 1, 2004.)

24174. As used in this chapter, "medical experiment" means:

(a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.

(b) The investigational use of a drug or device as provided in Sections 111590 and 111595.

(c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

(Amended by Stats. 1996, Ch. 1023, Sec. 205. Effective September 29, 1996.)

24175. (a) Except as otherwise provided in this section, no person shall be subjected to any medical experiment unless the informed consent of such person is obtained.

(b) If a person is under a conservatorship of the person or of the person and estate, pursuant to Division 4 (commencing with Section 1400) of the Probate Code, informed consent for a medical experiment involving such person shall be obtained:

(1) As provided in Section 2354 of the Probate Code if the person has not been adjudicated to lack the capacity to give informed consent for medical treatment.

(2) As provided in Section 2355 of the Probate Code if the person has been adjudicated to lack the capacity to give informed consent for medical treatment.

(c) If an adult person is gravely disabled, as defined in subdivision (h) of Section 5008 of the Welfare and Institutions Code, and is under a conservatorship of the person or of the person and estate, pursuant to Chapter 3 (commencing with Section 5350) of Part 1 of Division 5 of the Welfare and Institutions Code, informed consent for a medical experiment involving such person shall be obtained from such person, unless the conservator of such person has the right to consent to medical treatment on behalf of the conservatee, pursuant to subdivisions (c) and (d) of Section 5357 and Section 5358 of the Welfare and Institutions Code.

(d) If an adult person is developmentally disabled, as defined in subdivision (a) of Section 4512 of the Welfare and Institutions Code, and has no conservator and is mentally incapable of giving informed consent, informed consent shall be obtained for a medical experiment involving such person, pursuant to subdivision (c) of Section 4655 of the Welfare and Institutions Code.

(e) Informed consent given by a person other than the human subject pursuant to subdivisions (b) through (d), inclusive, of this section shall only be for medical experiments related to maintaining or improving the health of the human subject or related to obtaining information about a pathological condition of the human subject.

(Amended by Stats. 1979, Ch. 730.)

24176. (a) Any person who is primarily responsible for conduct of a medical experiment and who negligently allows the experiment to be conducted without a subject's informed consent, as provided in this chapter, shall be liable to the subject in an amount not to exceed ten thousand dollars ($10,000), as determined by the court. The minimum amount of damages awarded shall be five hundred dollars ($500).

(b) Any person who is primarily responsible for the conduct of a medical experiment and who willfully fails to obtain the subject's informed consent, as provided in this chapter, shall be liable to the subject in an amount not to exceed twenty-five thousand dollars ($25,000) as determined by the court. The minimum amount of damages awarded shall be one thousand dollars ($1,000).

(c) Any person who is primarily responsible for the conduct of a medical experiment and who willfully fails to obtain the subject's informed consent, as provided in this chapter, and thereby exposes a subject to a known substantial risk of serious injury, either bodily harm or psychological harm, shall be guilty of a misdemeanor punishable by imprisonment in the county jail for a period not to exceed one year or a fine of fifty thousand dollars ($50,000), or both.

(d) Any representative or employee of a pharmaceutical company, who is directly responsible for contracting with another person for the conduct of a medical experiment, and who has knowledge of risks or hazards with respect to the experiment, and who willfully withholds information of the risks and hazards from the person contracting for the conduct of the medical experiment, and thereby exposes a subject to substantial risk of serious injury, either bodily harm or psychological harm, shall be guilty of a misdemeanor punishable by imprisonment in the county jail for a period not to exceed one year or a fine of fifty thousand dollars ($50,000), or both.

(e) Each and every medical experiment performed in violation of any provision of this chapter is a separate and actionable offense.

(f) Any attempted or purported waiver of the rights guaranteed, or requirements prescribed by this chapter, whether by a subject or by a subject's conservator or guardian, or other representative, as specified in Section 24175, is void.

(g) Nothing in this section shall be construed to limit or expand the right of an injured subject to recover damages under any other applicable law.

(Amended by Stats. 2003, Ch. 397, Sec. 2. Effective January 1, 2004.)

24177. This chapter shall not supersede, but shall be in addition to, Article 4 (commencing with Section 111515) of Chapter 6 of Part 5 of Division 104 of this code and Title 2.1 (commencing with Section 3500) of Part 3 of the Penal Code.

(Amended by Stats. 1996, Ch. 1023, Sec. 206. Effective September 29, 1996.)

24177.5. (a) This chapter does not apply to a medical experimental treatment that benefits a patient subject to a life-threatening emergency if all of the following conditions are met:

(1) Care is provided in accordance with the procedures and the additional protections of the rights and welfare of the patient set forth in Part 50 of Title 21 of, and Part 46 of Title 45 of, the Code of Federal Regulations, in effect on April 1, 2012.

(2) The patient is in a life-threatening emergency necessitating urgent intervention and available treatments are unproven or unsatisfactory.

(3) The patient is unable to give informed consent as a result of the patient's medical condition.

(4) Obtaining informed consent from the patient's legally authorized representatives is not feasible before the treatment must be administered. The proposed investigational plan shall define the length of time of the potential therapeutic window based on scientific evidence, and the investigator shall commit to attempting to contact a legally authorized representative for each subject within that length of time and, if feasible, to asking the legally authorized representative contacted for consent within that length of time rather than proceeding without consent.

(5) There is no reasonable way to prospectively identify the individuals likely to become eligible for participation in the clinical investigation.

(6) Valid scientific studies have been conducted that support the potential for the intervention to provide a direct benefit to the patient. Risks associated with the investigation shall be reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

(7) The institutional review board has reviewed and approved the informed consent procedures and these procedures are to be used with subjects or their legally authorized representatives in situations where use of the procedures and documents is feasible.

(8) Additional protections of the rights and welfare of the subjects will be provided, including, but not limited to, all of the following:

(A) Consultation, including, where appropriate, consultation carried out by the institutional review board, with representatives of the communities in which the research will be conducted and from which the subjects will be drawn.

(B) Public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to the initiation of the research, of plans for the research and its risks and expected benefits.

(C) Public disclosure of sufficient information following the completion of the research to apprise the community and researchers of the study, including demographic characteristics of the research population and the results of the study.

(D) Establishment of an independent data monitoring committee to exercise oversight of the research.

(b) This section does not relieve any party of any other legal duty, including, but not limited to, the duty to act in a nonnegligent manner.

(Amended by Stats. 2013, Ch. 547, Sec. 1. (AB 58) Effective January 1, 2014.)

24178. (a) Except for this section and the requirements set forth in Sections 24172 and 24176, this chapter shall not apply to any person who is conducting a medical experiment as an investigator within an institution that holds an assurance with the United States Department of Health and Human Services pursuant to Part 46 of Title 45 of the Code of Federal Regulations and who obtains informed consent in the method and manner required by those regulations.

(b) Subdivisions (c) and (e) shall apply only to medical experiments that relate to the cognitive impairment, lack of capacity, or serious or life-threatening diseases and conditions of research participants.

(c) For purposes of obtaining informed consent required for medical experiments in a nonemergency room environment, and pursuant to subdivision (a), if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a surrogate decisionmaker with reasonable knowledge of the subject, who shall include any of the following persons, in the following descending order of priority:

(1) The person's agent pursuant to an advance health care directive.

(2) The conservator or guardian of the person having the authority to make health care decisions for the person.

(3) The spouse of the person.

(4) An individual as defined in Section 297 of the Family Code.

(5) An adult son or daughter of the person.

(6) A custodial parent of the person.

(7) Any adult brother or sister of the person.

(8) Any adult grandchild of the person.

(9) An available adult relative with the closest degree of kinship to the person.

(d) (1) When there are two or more available persons who, pursuant to subdivision (c), may give surrogate informed consent and who are in the same order of priority, if any of those persons expresses dissent as to the participation of the person in the medical experiment, consent shall not be considered as having been given.

(2) When there are two or more available persons who are in different orders of priority pursuant to subdivision (c), refusal to consent by a person who is a higher priority surrogate shall not be superseded by the consent of a person who is a lower priority surrogate.

(e) For purposes of obtaining informed consent required for medical experiments in an emergency room environment, and pursuant to subdivision (a), if a person is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from a surrogate decisionmaker who is any of the following persons:

(1) The person's agent pursuant to an advance health care directive.

(2) The conservator or guardian of the person having the authority to make health care decisions for the person.

(3) The spouse of the person.

(4) An individual defined in Section 297 of the Family Code.

(5) An adult son or daughter of the person.

(6) A custodial parent of the person.

(7) Any adult brother or sister of the person.

(f) When there are two or more available persons described in subdivision (e), refusal to consent by one person shall not be superseded by any other of those persons.

(g) Surrogate decisionmakers described in this section shall exercise substituted judgment, and base decisions about participation in accordance with the person's individual health care instructions, if any, and other wishes, to the extent known to the surrogate decisionmaker. Otherwise, the surrogate decisionmaker shall make the decision in accordance with the person's best interests. In determining the person's best interests, the decisionmaker shall consider the person's personal values and his or her best estimation of what the person would have chosen if he or she were capable of making a decision.

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

(i) Any person who provides surrogate consent pursuant to subdivisions (c) and (e) may not receive financial compensation for providing the consent.

(j) Subdivisions (c) and (e) do not apply to any of the following persons, except as otherwise provided by law:

(1) Persons who lack the capacity to give informed consent and who are involuntarily committed pursuant to Part 1 (commencing with Section 5000) of Division 5 of the Welfare and Institutions Code.

(2) Persons who lack the capacity to give informed consent and who have been voluntarily admitted or have been admitted upon the request of a conservator pursuant to Chapter 1 (commencing with Section 6000) of Part 1 of Division 6 of the Welfare and Institutions Code.

(Amended by Stats. 2003, Ch. 397, Sec. 3. Effective January 1, 2004.)

24179. This chapter shall not apply to a pharmacist dispensing drugs upon a prescription.

(Added by Stats. 1978, Ch. 360.)

24179.5. Notwithstanding any other provision of this chapter, this chapter does not apply to an adult in a terminal condition who executes a directive directing the withholding or withdrawal of life-sustaining procedures pursuant to Section 7188. To the extent of any conflict, Division 4.7 (commencing with Section 4600) of the Probate Code prevails over the provisions of this chapter.

(Amended by Stats. 1999, Ch. 658, Sec. 8. Effective January 1, 2000. Operative July 1, 2000, by Sec. 43 of Ch. 658.)

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Abigail Campus