Assembly Bill No. 2328

Passed the Assembly August 26, 2002

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Chief Clerk of the Assembly

Passed the Senate August 22, 2002

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Secretary of the Senate

This bill was received by the Governor this _____ day of

_____, 2002, at _____ o'clock __M.

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Private Secretary of the Governor

CHAPTER _____

An act to amend Section 24178 of the Health and Safety Code, relating to health.

LEGISLATIVE COUNSEL'S DIGEST

AB 2328, Wayne. Medical experiments.

Existing law, the Protection of Human Subjects in Medical Experimentation Act, prohibits any person from being subjected to any medical experiment unless the informed consent of the person is obtained.

This bill would authorize certain persons to give surrogate informed consent for a person to be subjected to a medical experiment when conducted within an institution that holds an assurance with the United States Department of Health and Human Services in accordance with specified regulations, if that person is unable to give that consent. This bill would provide that these provisions 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.

The people of the State of California do enact as follows:

SECTION 1. Section 24178 of the Health and Safety Code is amended to read:

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 (f) 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) 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.

(e) 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.

(f) 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.

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there are two or more available persons described in subdivision (f), refusal to consent by one person shall not be superceded by any other of those persons.

(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 (f) may not receive financial compensation for providing the consent.

(j) Subdivisions (c) and (f) 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.

Approved _____, 2002

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Governor