

California has enacted a new law, Section 24178 of the Health and Safety Code, which addresses surrogate decision making in most research situations. It is effective as of January 1, 2003. Federal human subjects regulations require that consent for research be obtained from the subject's "legally authorized representative," if the subject lacks the capacity to consent. The new state law specifies the legally authorized representative of the subject in most (but not all) research situations.

Surrogate decision makers under Section 24178 may be used, WHEN:

- (1) The informed consent has not been waived by the IRB; AND
- (2) The individual is "**unable to consent and does not express dissent or resistance to participation;**" AND
- (3) The individual is **not an inpatient on a psychiatric unit or in a mental health facility or a patient on a psychiatric hold;** AND
- (4) The research involves "**medical experimentation,**" defined as:
 - (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, 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; or
 - (b) The investigational use of a drug or device; or
 - (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject. AND
- (5) The medical experiments "**relate to the cognitive impairment, lack of capacity or serious or life threatening diseases and conditions of research participants.**"

Then the following surrogate decision makers under the following circumstances may give informed consent for the individual to participate in the research.	
For <u>nonemergency room</u> environment: surrogate informed consent may be obtained from a surrogate decision maker <u>with reasonable knowledge of the subject</u> , who shall include any of the following persons, in the following <u>descending order of priority</u> : (1) Agent pursuant to an advance health care directive, (2) The conservator or guardian having the authority to make health care decisions for the person, (3) The spouse, (4) The domestic partner (as defined in Section 297 of the Family Code), (5) An adult son or daughter, (6) A custodial parent of the person,	For an <u>emergency room</u> environment: from a surrogate decision maker who is <u>any of the following persons</u> : (1) Agent pursuant to an advance health care directive, (2) The conservator or guardian having the authority to make health care decisions for the person, (3) The spouse, (4) The domestic partner (as defined in Section 297 of the Family Code), (5) An adult son or daughter (6) A custodial parent of the person,

(7) Any adult brother or sister, (8) Any adult grandchild, (9) An available adult relative with the closest degree of kinship to the person.	(7) Any adult brother or sister.
When there are two or more available persons 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. When there are two or more available persons who are in different orders of priority, 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.	When there are two or more available persons, refusal to consent by one person shall not be superseded by any other of those persons.

Lack of capacity to consent (for treatment or research) should be determined in the customary manner, and documented in the medical record. If the individual lacks the capacity to consent, the investigator should inform the individual, if conscious, of the intent to seek consent from a surrogate. If the individual expresses any resistance or dissent to participation, then the individual should be excluded from the study. Additionally, in a non-emergency room setting, the investigator should document (e.g., on the consent form, in the medical record) the relationship of the surrogate and the basis for the surrogate’s “reasonable knowledge” of the individual. (The signature lines on the consent form may need to be modified for this purpose.)

Notes:

1. Surrogates for an inpatient on a psychiatric unit or in a mental health facility or a patient on a psychiatric hold may be able to consent for research under different state laws, particularly if the research subject has been adjudicated to lack the capacity to consent and a conservator appointed. If your protocol will involve such subjects with the possible need for surrogate decision makers, please discuss the situation with the IRB staff or contact Ann James (736-1554; anjames@stanford.edu) or Elizabeth Engel (724-3132; eaengel@stanford.edu) in the General Counsel’s Office.
2. If the research is “medical experimentation” but does not “relate to the cognitive impairment, lack of capacity, or serious or life threatening diseases and conditions of research participants,” then a surrogate decision maker may not be utilized.
3. If the research does not meet the definition of “medical experimentation” but is treatment, then informed consent for research may be obtained from the same individual who provides informed consent for the treatment.

*Section 24178 of the California Health and Safety Code
(Effective January 1, 2003)*

Section 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.

**If you have any questions about the new law, you can contact
Ann James (736-1554; anjames@stanford.edu) or
Elizabeth Engel (724-3132; eaengel@stanford.edu)
in the General Counsel's Office.**