**SAINT AGNES MEDICAL CENTER**

**CLINICAL RESEARCH CENTER**

Fresno, California

# STANDARD OPERATING PROCEDURES

## Institutional Review Board

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**SUBJECT**: **SURROGATE INFORMED CONSENT**

1. PURPOSE

Define the process of the use of a surrogate to consent for participation in a clinical research protocol when the participant is unable to provide informed consent.

Identify and define those persons who may provide surrogate informed consent for a subject to participate in clinical research.

2. SCOPE

Applications to the Board involving populations that may be cognitively impaired or lack capacity to provide informed consent will require the use of Surrogate Informed Consent.

Identify the state law limitations on the types of medical experiments for which surrogate informed consent may be used.

3. POLICY

3.1. Types of medical experiments[1] for which surrogate informed consent may be used. Under California law, surrogate informed consent shall only be for "... medical experiments relating to maintaining or improving the health of the human subject or related to obtaining information about a pathological condition of the human subject."[2]

3.2. Who may give consent to clinical trial/medical experiment participation?

3.2.1. Under Federal law, the investigator is obligated to obtain "... the legally effective informed consent of the subject or the subject's legally authorized representative." [45 CFR § 46.116 and 21 CFR § 50.20]. "Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research." [21 CFR § 50.3(l) and 45 CFR § 46.102(c)]. The difficult question is whether authorization to consent to medical treatment includes authorization to consent to medical research. Federal law tends to defer to state law regarding definition of "authorized representative."

3.2.2. Under California law[3], informed surrogate consent for medical experiments is divided into two categories: (1) medical experiments "in a nonemergency room environment" and (2) medical experiments "in an emergency room environment". In addition, the following guidelines apply:

3.2.2.1. The person is unable to consent

3.2.2.2. The person does not express dissent or resistance to participation in the medical experiment

3.2.3. Informed consent by surrogate decision makers identified in Section 24178 "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.**" [Cal. H&S Code § 24178(b)]. Specific IRB prospective approval is required for surrogate informed consent for new or continuing research.

3.3 Under California law, **in a nonemergency room environment,** surrogate informed consent may be obtained from a surrogate decision maker with reasonable knowledge of the subject, "who may include any of the following persons, in the following descending order of priority:

3.3.1 "The person's agent pursuant to an advance health care directive."
3.3.2 "The conservator of guardian of the person having the authority to make health care decisions for the person."
3.3.3 "The spouse of the person."
3.3.4 "An individual as defined in Section 297 of the Family Code" [which defines "domestic partners"[4]]
3.3.5 "And adult son or daughter of the person."
3.3.6 "A custodial parent of the person."
3.3.7 "Any adult brother or sister of the person."
3.3.8 "Any adult grandchild of the person."
3.3.9 "An available adult relative with the closest degree of kinship to the person."

When there are two or more persons who are in the same order of priority, if any one of them expresses dissent, surrogate consent cannot be given.

When there are two ore more persons in different orders of priority, refusal by a person who is a higher priority cannot be superseded by consent of a person in lower priority.[5]

3.4 Under California law, **in an emergency room environment**, surrogate informed consent may be obtained from a surrogate decision maker, "who may include <u>any</u> of the following persons" (i.e. <u>no order of priority)</u>:

- 3.4.1 "The person's agent pursuant to an advance health care directive."
- 3.4.2 "The conservator of guardian of the person having the authority to make health care decisions for the person."
- 3.4.3 "The spouse of the person."
- 3.4.4 "An individual as defined in Section 297 of the Family Code" [which defines "domestic partners"[6]]
- 3.4.5 "And adult son or daughter of the person."
- 3.4.6 "A custodial parent of the person."
- 3.4.7 "Any adult brother or sister of the person."

Note that an adult grandchild and a closest available adult relative are not listed as surrogate decision makers in an emergency room environment.

When there are two or more persons available, refusal to consent by one cannot be superseded by consent of another – i.e., no surrogate consent may be provided.[7]

3.5 <u>Other general restrictions</u> regarding surrogate consent under California law:

- 3.5.1 Surrogate informed consent must adhere to federal regulations governing informed consent pursuant to 45 CFR § 46.116.[8]
- 3.5.2 Any person, who provides surrogate consent as specified above, may not receive financial compensation for providing the consent.[9]
- 3.5.3 The above surrogate consent provisions do not apply to any of the following persons:
  - 3.5.3.1 Persons who lack capacity to give informed consent and who are involuntarily committed pursuant to California Welfare and Institutions Code § 5000 et seq.
  - 3.5.3.2 Persons who lack the capacity to give informed consent and who have been voluntarily admitted or had been admitted upon the request of a conservator pursuant to California Welfare and Institutions Code 6000 et seq.[10]

3.5.3.3 Subjects who dissent or resist participation in the research must be excluded as though no consent had been provided.

3.6 **Surrogate informed consent by the subject's conservator under a conservatorship of the person**:

3.6.1 If the informed consent is obtained from the conservatee who has not been adjudicated to lack capacity to give informed consent[11] or from the conservator if the conservatee has been adjudicated to lack capacity to given informed consent.[12]

3.6.2 Where the subject is "gravely disabled," if the conservator has the right to consent to medical treatment on behalf of the conservatee under the provisions governing conservatorship for gravely disabled persons (as defined, in the Lanterman-Petris-Short Act). [13]

3.7 **The director of a regional center for persons with developmental disabilities (or the director's designee)** where the subject is developmentally disabled (as defined) in accordance with the Lanterman Developmental Disabilities Services Act, if it is documented that: (a) the developmentally disabled person's, parent, guardian or conservator legally authorized to consent does not respond within a reasonable time to a request of the director of the regional center; or (b) the developmentally disabled person has no parent, guardian, or conservator legally authorized to consent; or (c) if the developmentally disabled person is adult, has no conservator and is mentally incapable of giving consent. [Cal. W&I Code § 4655]

3.8 **Consent by a surrogate designated by the subject** [14] at a time when the subject is in the hospital and has capacity to make health care decisions (but later loses capacity), and the patient's designation is recorded in the patient's health care record. However, the surrogate designation is effective only during the course of treatment or illness or during the stay in the hospital. It is unlikely that such surrogate designation would include authorization of the surrogate to consent to participation in medical experimentation. Therefore, inquiries should be made of the surrogate and other relatives or significant persons in order to ascertain the subject's intent or desires in regard to medical experimentation. If such inquiry does not produce clarification, then the surrogate's decision in regard to medical experimentation must be based on the patient's best interest.

3.9 **The "closest available relative" provision under California case law[15] may no longer be relied upon to provide surrogate informed consent to participate in medical experiments**. Such provision did not provide further specification of priority order in terms of who is the "closest available relative". The "closest available relative" provision is applicable

as the ninth category for nonemergency room environment situations. It is not specified for emergency room environment situations. Caution regarding reliance on consent of a "closest available relative." Serious consideration should be given to not relying upon authorization from the closest available relative if any of the following circumstances are present:

3.9.1 The closest available relative's capacity to make health care decisions or motives are questionable.

3.9.2 There is a substantial question as to whether the patient, if he or she had the capacity to make health care decisions, would consent to the procedure.

3.9.3 If another close relative objects, consent cannot be given per Section 24178(d).

3.4.4. The medical experiment results are uncertain, there are minimal expected benefits, the experiment will result in severe debilitation, and/or it involves a significant risk of a negative outcome, such as paralysis.

4. CAPACITY; INCAPACITY; PATIENT'S OBJECTION TO SURROGATE'S HEALTH CARE DECISION

4.1. Definitions under the California Health Care Decisions Law.

4.1.1. "'**Capacity**' means a patient's ability to understand the nature and consequences of proposed health care, including its significant benefits, risks, and alternatives, and to make and communicate a health care decision." [Cal. Prob. Code § 4609]

4.1.2. "'**Health care**' means any care, treatment, service, or procedure to maintain, diagnose, or otherwise affect a patient's physical or mental condition." [Cal. Prob. Code § 4615]

4.1.3. "'**Health care decision**' means a decision made by a patient or the patient's agent, conservator, or surrogate, regarding the patient's health care, including the following:

(a) selection and discharge of health care providers and institutions.

(b) approval or disapproval of diagnostic tests, surgical procedures, and programs of medication.

c) directions to provide, withhold, or withdraw artificial nutrition and hydration and all other forms of health care, including cardiopulmonary resuscitation." [Cal. Prob. Code § 4617]

4.2 Presumption of capacity. "A patient is presumed to have the capacity to make a health care decision, to give or revoke an advance health care directive, and to designate or disqualify a surrogate. This presumption is a presumption affecting the burden of proof." [Cal. Prob. Code § 4657]

4.3 Objection to medical experiment after surrogate provides informed consent. The California Health Care Decisions Law does not authorize an agent under a power of attorney for health care to make a health care decision if the principal objects to the decision. "If the principal objects to the health care decision of the agent under a power of attorney, the matter shall be governed by the law that would apply if there were no power of attorney for health care." [Cal. Prob. Code § 4689]

## 5. APPLICATION TO THE IRB

The application regarding the clinical trial/medical experiment to the IRB will identify if eligible participants will be able to the provide informed consent. If not, then the application must indicate that a surrogate informed consent will be used. The investigator should provide an explanation of his/her plan for protecting the rights of the participants.

## 6. DOCUMENTATION OF CAPACITY, LACK OF CAPACITY, AND REGAINING CAPACITY

6.1. The patient's "primary physician" and the principal investigator or sub-investigator shall make a determination that the patient has capacity, lacks capacity or has recovered capacity (when this occurs), or that another condition exists that affects an individual health care instruction or the authority of the agent or surrogate.[16] Such determination shall be recorded in the patient's health care record.[17]

6.2. If the patient regains capacity, the principal investigator or sub-investigator should attempt to obtain informed consent from the patient as soon as reasonably feasible because the patient may then give informed consent or withdraw informed consent and refuse any further participation in the clinical trial/medical experiment. **For research on conditions where subjects may regain the capacity to provide consent,** the consent document should indicate that should the subject regain the capacity to provide informed consent while participating in the research, informed consent to continued participation will be obtained from the subject.

6.3. A physician on staff at SAMC not involved with the research study will be required to confirm that the patient lacks capacity--that is, lacks the ability to understand the nature and consequences of the proposed clinical

trial/medical experiment, including its significant benefits, risks, and alternatives, and lacks the ability to make and communicate a health care decision. The consulting physician will document his/her validation in the medical record.

6.4. **For research on conditions where subjects may lose their capacity to provide informed consent during the course of the research, such as dementia,** the investigator should indicate in the consent document, when applicable, that if the subject loses his/her capacity to provide continuing informed consent to participation in the research, the surrogate may be asked to provide continuing informed consent.

6.5. Investigators must document the assessment of the subject's and the surrogate's ability to provide informed consent.

6.6. For conscious subjects who may lack the capacity to provide informed consent, investigators must document in the research record the process of informing the subject of the intent to seek surrogate consent.

6.7. Investigators must document their contact with surrogates and the consent process in the research record.

6.8. **Non-emergency room research.** The investigator must document:

6.8.1. The surrogate has reasonable knowledge of the subject,

6.8.2. The order of priority the surrogate holds, and

6.8.3. Whether possible surrogate decision makers in higher categories disagree on enrolling the subject of the continued participation of the subject in the research.

## 7. OBTAINING SURROGATE INFORMED CONSENT

7.1. Clinical staff will document in the patient's record attempts to contact each potential surrogate. If informed consent is not obtained from any authorized surrogate and documented, the patient will not be eligible for the study. A signature produced by facsimile transmission may be considered an original.[18]

7.2. Under California law, surrogate informed consent means the authorization given pursuant to Section 24175 under the Protection of Human Subjects in Medical Experimentation Act to have a medical experiment performed after each of the following conditions have been satisfied [as specified in Cal. Prob. Code § 24173]:

7.2.1. "The subject or subject's conservator or guardian, or other representative ... 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... [to be in the 'experimental subject's bill of rights'] and such copy is signed

and dated by the subject or the subject's conservator or guardian, or other representative...."

7.2.2. "A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative...."

7.2.3. "The subject or subject's conservator or guardian, or other representative ... 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 ... 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:

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

7.2.3.2. "A description of any attendant discomfort and risks to the subject reasonably to be expected.

7.2.3.3. "An explanation of any benefits to the subject reasonably to be expected, if applicable.

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

7.2.3.5. "An estimate of the expected recovery time of the subject after the experiment.

7.2.3.6. "An offer to answer any inquiries concerning the experiment or the procedures involved.

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

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

7.2.3.9. "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.

7.2.3.10. "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."

These requirements are either identical to or very similar to the elements of informed consent specified in Federal Regulations. See attached comparison entitled "Elements of Informed Consent". However, the Federal Regulations have the following additional requirements:

7.2.3.11. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

7.2.3.12. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

7.2.3.13. Any additional costs to the subject that may result from participation in the research.

7.2.3.14. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

7.2.3.15. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

7.2.3.16. The approximate number of subjects involved in the study. [45 CFR § 46.116(b); 21 CFR 50.25(b)]

7.2.4. "The written consent form is signed and dated by <u>any person other than</u> <u>the subject</u> or the conservator or guardian, or other representative of the subject ... <u>who can attest that the requirements for informed consent to the medical experiment have been satisfied</u>." [Cal. H&S Code § 24173(d)]. This attestation can be done by the principal investigator or sub-investigator.

7.2.5. "Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative ... without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence." [Cal. H&S Code §24173(e)].

8. NOTIFICATION TO THE IRB

- The principal investigator or sub-investigator will continuously assess the patient's mental status and if the patient has recovered capacity attempt to obtain informed consent from the patient to continue participation. The patient may refuse any further participation at this time.
- The principal investigator or sub-investigator will be responsible for notifying the IRB within 72 hours of obtaining informed surrogate consent and provide the name of the protocol, name of patient and date of consent.
- The principal investigator or sub-investigator will notify IRB within 72 hours when a patient is no longer participating under surrogate consent.

REGULATORY REFERENCES

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| 45 CFR 46 | Protection of Human Subjects ("The Common Rule") |
| 21 CFR 50 | Informed Consent of Human Subjects |
| ICH E6 | Good Clinical Practice: Consolidated Guidance (April 1996) |
| CA Probate Code §§ 4600-4805 | CA Healthcare Decisions Law |
| CA Welfare and Institutions Code §§ 4500-4905 | CA Lanterman Developmental Disabilities Services Act |
| CA Welfare and Institutions Code §§ 5000-5550 | CA Lanterman-Petris-Short Act |
| CA H&S Code 24170-24179.5 | Protection of Human Subjects in Medical Experimentation |
| OIP – 10 | SAMC SOP: OIP Education |

ENDNOTES:

1. Cal. H&S Code §§ 24173-24175. Under California law, surrogate informed consent for medical experiments is governed by the **Protection of Human Subjects in Medical Experimentation Act** (Cal. Health and Safety Code §§ 24170-24179.5). Under the Act, "medical experiment is defined as follows:

> "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 of 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 benefitting 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. [Cal. H&S Code § 24174].

The California Health Care Decisions Law (Cal. Probate Code §§ 4600-4805) "…applies to health care decisions for adults who lack capacity to make health care decisions for themselves." [§ 4651 (a)]. "**To the extent of any conflict, …[the California Health Care Decisions Law] prevails over the provisions of …[the Protection of Human Subjects in Medical Experimentation Act].**" [Cal. H&S Code § 24179.5]. Under the California Health Care Decisions Law;

"'**Advance health care directive**' or **'advance directive'** means either an individual health care instruction or a power of attorney for health care." [Cal. Prob. Code § 4605]

"'**Individual health care instruction**' or '**individual instruction**' means a patient's written or oral direction concerning a health care decision for the patient." [Cal. Prob. Code § 4623].

"'**Power of attorney for health care**' means a written instrument designating an agent to make health care decisions for the principal." [Cal. Prob. Code § 4629]

"'**Primary physician**' means a physician designated by a patient or the patient's agent, conservator, or surrogate, to have primary responsibility for the patient's health care or, in the absence of a designation or if the

designated physician is not reasonably available or declines to act as primary physician, a physician who undertakes the responsibility." [Cal. Prob. Code § 4631].

"'**Reasonably available**' means readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the patient's health care needs." [Cal. Prob. Code § 4635].

**Scope of agent's authority**

"Subject to any limitation in the power of attorney for health care:

(a) An agent designated in the power of attorney may make health care decisions for the principal to the same extent the principal could make health care decisions if the principal had the capacity to do so…" [Cal. Prob. Code § 4683].

**Authority of agent – when effective**

"Unless otherwise provided in a power of attorney for health care, the authority of an agent becomes effective only on a determination that the principal lacks capacity, and ceases to be effective on a determination that the principal has recovered capacity" [Cal. Prob. Code § 4682]

**Agent; priority in making health care decisions**

"Unless the power of attorney for health care provides otherwise, the agent designated in the power of attorney who is known to the health care provider to be reasonably available and willing to make health care decisions has priority over any other person in making health care decisions for the principal." [Cal. Prob. Code § 4685]

2. "Informed consent given by a person other than the human subject pursuant to subdivisions (b) through (d), inclusive, of this section [24175] 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." [Cal. H&S Code § 24175(e)]

3. Cal. Health & Safety Code § 24178 (effective January 1, 2003)

4. Requirements for "domestic partnership"
Section 297 of the Family Code provides:

"(a) Domestic partners are two adults who have chosen to share one another's lives in an intimate and committed relationship of mutual caring.

(b) A domestic partnership shall be established in California when all of the following requirements are met:

(1) Both persons have a common residence.

(2) Both persons agree to be jointly responsible for each other's basic living expenses incurred during the domestic partnership.

(3) Neither person is married or a member of another domestic partnership.

(4) The two persons are not related by blood in a way that would prevent them from being married to each other in this state.

(5) Both persons are at least 18 years of age.

(6) Either of the following:

(A) Both persons are members of the same sex

(B) One or both of the persons meet the eligibility criteria under Title II of the Social Security Act as defined in 42 U.S.C. Section 402(a) for old-age insurance benefits or Title XVI of the Social Security Act as defined in 42 U.S.C. Section 1381 for aged individuals. Notwithstanding any other provision of this section, persons of opposite sexes may not constitute a domestic partnership unless one or both of the persons are over the age of 62.

(7) Both persons are capable of consenting to the domestic partnership

(8) Neither person has previously filed a Declaration of Domestic Partnership with the Secretary of State pursuant to this division that has not been terminated under Section 299.

(9) Both file a Declaration of Domestic Partnership with the Secretary of State pursuant to this division.

(c) "Have a common residence" means that both domestic partners share the same residence. It is not necessary that the legal right to possess the common residence be in both their names. Two people have a common residence even if one or both have additional residences. Domestic partners do not cease to have a common residence if one leaves the common residence but intends to return.

(d) "Basic living expenses" means shelter, utilities, and all other costs directly related to the maintenance of the common household of the common residence of the domestic partners. It also means any other cost, such as medical care, if some or all of the cost is paid as a benefit because a person is another person's domestic partner.

(e) "Joint responsibility" means that each partner agrees to provide for the other partner's basic living expenses if the partner is unable to provide for herself or himself. Persons to whom these expenses are owed may enforce this responsibility if, in extending credit or providing goods or services, they relied on the existence of the domestic partnership and the agreement of both partners to be jointly responsible for those specific expenses."

[5] Cal. H&S Code § 24178(c), (d) & (e)

[6] See endnote regarding "domestic partners," above.

[7] Cal. H&S Code § 24178(f) & (g).

[8] Cal. H&S Code § 24178(h).

[9] Cal. H&S Code § 24178(i).

[10] Cal. H&S Code § 24178(j).

[11] **Medical experiment; informed consent**

"(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." [Cal. Prob. Code § 24175(a) & (b)]

**Medical treatment of conservatee <u>not adjudicated</u> to lack capacity to give informed consent**

"(a) If the conservatee has not been adjudicated to lack the capacity to give informed consent for medical treatment, the conservatee may consent to his or her medical treatment. The conservator may also give consent to the medical treatment, but the consent of the conservator is not required if the conservatee has the capacity to give informed consent to the medical treatment, and the consent of the conservator alone is not sufficient under this subdivision if the conservatee objects to the medical treatment.

(b) The conservator may require the conservatee to receive medical treatment, whether or not the conservatee consents to the treatment, if a court order specifically authorizing the medical treatment has been obtained pursuant to Section 2357.

(c) The conservator may consent to medical treatment to be performed upon the conservatee, and may require the conservatee to receive the medical treatment, in any case where the conservator determines in good faith based upon medical advice that the case is an emergency case in which the medical treatment is required because

(1) the treatment is required for the alleviation of severe pain or

(2) the conservatee has a medical condition which, if not immediately diagnosed and treated, will lead to serious disability or death. In such a case, the consent of the conservator alone is sufficient and no person is liable because the medical treatment is performed upon the conservatee without the conservatee's consent." [Cal. Prob. Code § 2354]

[12] **Medical treatment of conservatee <u>adjudicated</u> to lack capacity to make health care decisions**

"(a) If the conservatee has been adjudicated to lack the capacity to make health care decisions, the conservator has the exclusive authority to make health care decisions for the conservatee that the conservator in good faith based on medical advice determines to be necessary. The conservator shall make health care decisions for the conservatee in accordance with the conservatee's individual health care instructions, if any, and other wishes to the extent known to the conservator. Otherwise, the conservator shall make the decision in accordance with the conservator's determination of the conservatee's best interest. In determining the conservatee's best interest, the conservator shall consider the conservatee's personal values to the extent known to the conservator. The conservator may require the conservatee to receive the

health care, whether or not the conservatee objects. In this case, the health care decision of the conservator alone is sufficient and no person is liable because the health care is administered to the conservatee without the conservatee's consent. For the purposes of this subdivision, "health care" and "health care decision" have the meanings provided in Sections 4615 and 4617, respectively.

(b) If prior to the establishment of the conservatorship the conservatee was an adherent of a religion whose tenets and practices call for reliance on prayer alone for healing, the treatment required by the conservator under the provisions of this section shall be by an accredited practitioner of that religion." [Cal. Prob. Code § 2355]

13 **Medical experiment; informed consent**

"…

(d) 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." [Cal. Prob. Code § 24175(c)]

14 **Designation of surrogate**

"A patient may designate an adult as a surrogate to make health care decisions by personally informing the supervising health care provider. An oral designation of a surrogate shall be promptly recorded in the patient's health care record and is effective only during the course of treatment or illness or during the stay in the health care institution when the designation is made." [Cal. Prob. Code § 4711]

**Decisions based on patient's best interests**

"A surrogate, including a person acting as a surrogate, shall make a health care decision in accordance with the patient's individual health care instructions, if any, and other wishes to the extent known to the surrogate. Otherwise, the

surrogate shall make the decision in accordance with the surrogate's determination of the patient's best interest. In determining the patient's best interest, the surrogate shall consider the patient's personal values to the extent known to the surrogate." [Cal. Prob. Code § 4714]

15 Cobbs v. Grant (1972) 8 Cal.3d 229, 244 ("…if the patient is a minor or incompetent, the authority to consent is transferred to the patient's legal guardian or closest available relative…") "[A]ny surrogate, court appointed or otherwise, ought to be guided in his or her decisions first by his knowledge of the patient's own desires and feelings, to the extent that they are expressed before the patient became incompetent… If it is not possible to ascertain the choice the patient would have made, the surrogate ought to be guided in his decision by the patient's best interests. Under this standard, such factors as the relief of suffering, the preservation or restoration of functioning and the quality as well as the extent of life sustained may be considered. Finally, since most people are concerned about the well-being of their loved ones, the surrogate may take into account the impact of the decision on those people closest to the patient." Barber v. Superior Court (1983) 147 Cal.App.3d 1006, 1021.

16 **Determination regarding patient's capacity to be made by primary physician**

"... a determination that a patient lacks or has recovered capacity, or that another condition exists that affects an individual health care instruction or the authority of an agent or surrogate, shall be made by the primary physician." [Cal. Prob. Code § 4658].

17 **Primary physician; duty to record information regarding patient's capacity**

"A primary physician who makes or is informed of a determination that a patient lacks or has recovered capacity, or that another condition exists affecting an individual health care instruction or the authority of an agent, conservator of the person, or surrogate, shall promptly record the determination in the patient' s health care record and communicate the determination to the patient, if possible, and to a person then authorized to make health care decisions for the patient." [Cal. Prob. Code § 4732]

[18] The surrogate consent law is silent as to facsimile signatures. Some guidance may be gained from the following:

14.1. The California Health Care Decisions Law provides: "A copy of a written advance health care directive, revocation of an advance directive, or designation or disqualification of a surrogate has the same effect as the original." [Cal. Prob. Code § 4660].

14.2. In regard to court papers, "... a signature produced by facsimile transmission is an original." [Cal. Rule of Court, Rule 2007(d)].