

Guidance and Procedures Number: 29a

Title: The Use of Legally Authorized Representatives or Surrogate Consent

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I. Overview

In general, participation in research should be limited to individuals who can give informed consent for themselves. In special cases where this is not possible, federal and state regulations provide that consent may be given by the subject's *surrogate* or *legally authorized representative*. This document describes these provisions.

Federal Regulations: Federal regulations ([45 CFR 46.116](#) and [21 CFR 50.20](#)) for the protection of human subjects in research require that an investigator obtain the legally effective informed consent of the subject or “the subject’s legally authorized representative” unless (1) the research is exempt under [45 CFR 46.101\(b\)](#); (2) the IRB finds and documents that informed consent can be waived ([45 CFR 46.116\(c\) or \(d\)](#)); or (3) the IRB finds and documents that the research meets the requirements of the HHS Secretarial waiver under [45 CFR 46.101\(j\)](#) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings. When informed consent is required, it must be sought prospectively, and documented to the extent required under HHS regulations at [45 CFR 46.117](#). Food and Drug Administration (FDA) regulations at [21 CFR part 50](#) may also apply if the research involves a clinical investigation regulated by FDA.

California State Law: Federal regulations also defer to “applicable law” to define who is legally authorized to provide consent. [California Health & Safety Code 24178](#) authorizes specific individuals to give surrogate or proxy informed consent for the enrollment of subjects in limited circumstances and specifies in detail who may serve as a legally authorized representative to give consent for an incapacitated prospective research subject. The law distinguishes between emergency room and non-emergency room research and describes specific surrogate trees or surrogate options for each type of research. Individuals authorized under state law are considered to meet the DHHS and FDA definitions of “legally authorized representatives.”

University of California Office of the President (UCOP) has designed a [Self-Certification of Surrogate Decision Makers for Potential Subject’s Participation in University of California Research](#) form for surrogates to self-certify their eligibility and has issued guidelines for following California Health & Safety Code 24178.

UCLA Investigators are required to submit an [Application Supplement for the Use of Surrogate Consent](#) with their applications in order for the UCLA IRB to review and approve the use of surrogate consent/legally authorized representatives to provide consent on behalf of the subjects.

II. Definition

Legally Authorized Representative: 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 [[45 CFR 46.102\(c\)](#) and [21 CFR 50.3\(l\)](#)]. This term is sometimes abbreviated as "LAR."

Surrogate Consent: The use of a surrogate decision maker with reasonable knowledge of the subject, who shall include any of the following persons, in the descending order of priority as described in [CA Health and Safety Code 24178\(c\)](#) and below. 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 decision maker. California law defines the "Legally Authorized Representative" noted in the federal regulations.

Proxy Consent: This term is sometimes used interchangeably with "surrogate consent." However, the term "surrogate consent" is preferable.

III. Policy

UCLA adheres to the provisions for the use of surrogate consent as described in [California Health & Safety Code, Section 24178](#). When potential participants lack the capacity to provide consent, state law determines the situations in which the consent of a legally authorized person, that is, consent surrogate, may be sought. The proposed research and the involvement of subjects based on consent provided by legally authorized representatives must meet the following conditions of California Health & Safety Code, Section 24178:

IV. Guidelines and Procedures

- A. UCLA researchers should follow the [guidance for investigators](#) developed by the University of California.
- B. UCLA investigator should also complete and attach the UCLA [Application Supplement for the Use of Surrogate Consent](#) with their applications that propose using surrogates in the consent process of their study.
- C. UCLA investigators should note and apply the following restrictions for the use of surrogate consent:
 1. No surrogates may be asked for consent unless the IRB has specifically approved use of surrogates in the specific study.
 2. The protocol should include a process for formal evaluation of the prospective subject's ability to participate in the consent process.
 3. If surrogate consent will be sought for a responsive subject/patient, the subject/patient must be told of the investigator's plan to consult a surrogate.

4. The consent of a legally authorized representative does not override any objection by the potential subject even though the potential subject may lack the capacity to provide consent. *An incapacitated person may not be included in research over his or her dissent or resistance to participation.*
5. The rules for who may act as a surrogate are slightly different in emergency room and non-emergency room settings. There are different IRB application processes and review requirements for these types of research.
6. Surrogates may not give consent for inpatients in a psychiatric ward or mental health facility or on psychiatric hold.
7. State law prohibits legally authorized representatives from receiving any financial compensation for providing consent. This does not prohibit legally authorized representatives from receiving reimbursement for expenses related to participation in the research.

V. Continuing Consent

- A. Some subjects who are able to consent for entry into research may lose their capacity to consent during the course of research.
 1. If the IRB has not approved the research for consent by legally authorized representatives, participation of subjects who lose capacity to consent must cease. If allowed by the IRB-approved protocol, such subjects may resume participation upon regaining capacity to consent and providing continuing consent.
 2. If the IRB approved the research for consent by legally authorized representatives, participation of a subject who loses capacity to consent may continue upon consent from a legally authorized representative.
- B. Subject may also regain their capacity to consent during the course of research. In this event, the consent of a legally authorized representative is no longer valid and consent must be obtained from the subject prior to continued participation. The considerations are as follows:
 1. The consent may be for the continuation of participation in the full study.
 2. The consent may be for the use of the data already collected for the study but not for future data collection.
 3. The consent may be for the use of all data collected, including any follow up data.
 4. The subject may refuse to consent for the use of any data.
- C. Informed consent documents should describe for subjects and/or legally authorized representatives how changes in capacity will be handled. For example, representatives should be aware that if the subject regains capacity, the decisions of the subject will prevail.

Regulations

45 CFR 46.101(b)
45 CFR 46.101(i)
45 CFR 46.102(c)
45 CFR 46.116
45 CFR 46.116 (c) or (d)
45 CFR 46.117
21 CFR 50
21 CFR 50.20
21 CFR 50.3(1)

References

UCOP Surrogate Consent Policy (effective January 1, 2003)

California Health & Safety Code §24178