Surrogate Consent

Background

Following UCOP Guidelines

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Federal regulations require that consent be sought from a research subject or ?the subject?s legally authorized representative? and defer to ?applicable law? to define who is legally authorized (45 CFR 46.116 [1] and 21 CFR 50.20 [2]).

In California, Health and Safety Code 24178 [3] describes who may serve as a legally authorized representative to give consent for an incapacitated prospective research subject. The state law uses the terms ?surrogate decisionmaker? or simply ?surrogate? to refer to the legally authorized representative.

Note: If you may enroll **subjects with cognitive impairments** [4], please review IRB guidance on that topic first.

Following UCOP Guidelines

University of California Office of the President (UCOP) has has issued guidelines for following the law and designed a form for surrogates to self-certify their eligibility. UCSF researchers should follow the UCOP guidelines [5] and use the Self-Certification of Surrogate Decision Makers for Potential Subject's Participation in University of California Research form [6].

In iRIS, complete the "Surrogate Consent" section of the IRB Application, which ensures that the application will meet the criteria for approval and describe the additional safeguards for subjects required by state law.

Of special note:

- No surrogates may be asked for consent unless the IRB has specifically approved use of surrogates in the specific study.
- The protocol should include a process for formal evaluation [4] of the prospective subject's ability to participate in the consent process.
- If surrogate consent will be sought for a responsive patient, the patient must be told of the investigator's plan to consult a surrogate.
- If a subject in any way objects to or resists study participation or the use of surrogate consent, that subject may not be included in the study.
- The rules for who may act as a surrogate are slightly different in emergency room and non-emergency room settings.
- Surrogates may not give consent for inpatients in a psychiatric ward or mental health facility or on psychiatric hold.

See the UCOP Guidance on Surrogate Consent for Research [7] for the complete text and link to the Self-Certification form.

Note: For requirements of the SFVAMC (which in most ways agree with UCOP guidance), see Research at the SFVAMC [8] and the "Surrogate Consent" section of the IRB Application in iRIS.

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Links
[1] http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50
[3] http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=24001-25000&file=24170-24179.5
[4] https://irb.ucsf.edu/enrolling-individuals-cognitive-impairments-and-assessing-decisional-capacity
[5] http://www.ucop.edu/research-policy-analysis-coordination/_files/srrgte_cnsnt_guide.pdf
[6] http://researchmemos.ucop.edu/php-app/index.php/site/document?memo=UlBBQy0xNy0wNQ==&doc=3717
[7] http://researchmemos.ucop.edu/index.php/site/memoDetail/memo_id/RPAC-17-05

[8] https://irb.ucsf.edu/research-sfvamc