Guidance on who may provide surrogate consent for research studies involving participants lacking decision-making capacity due to cognitive impairment.

(This guidance does not apply to research studies involving children. The parent or legal guardian acts as the legally authorized representative for the purpose of obtaining valid informed consent for the participation of a child)

For purpose of obtaining informed consent as required for research studies, if a prospective participant lacks decision-making capability due to cognitive impairment and cannot provide valid informed consent, valid informed consent may be obtained from a surrogate or legally authorized representative (LAR). An LAR is a person who has reasonable knowledge or the prospective participant and could be any of the following persons, in the following descending order of priority [Ref. California Health and Safety Code 24178(c)]:

1. The prospective participant’s agent pursuant to an advance health care directive.
2. The conservator or guardian of the prospective participant having the authority to make health care decisions for the prospective participant.
3. The spouse of the prospective participant.
4. An individual as defined in Section 297 of the Family Code. This section defines domestic partners for the purpose of domestic partner registration.
   i. Specifically, domestic partners are “two adults who have chosen to share one another’s lives in an intimate and committed relationship of mutual caring”. They may not be married to someone else or a member of another domestic partnership. They must not be related by blood in a way that would prevent them from being married to each other. They must both be 18 years of age. They may be persons of the same sex.
5. An adult son or daughter of the prospective participant.
6. A custodial parent of the prospective participant.
7. Any adult brother or sister of the prospective participant.
8. Any adult grandchild of the participant.
9. An available adult relative with the closest degree of kinship to the prospective participant.

Note:

1. When there are two or more available persons who may give consent and are in the same order of priority pursuant to the information listed above in items 1-9, if any of these persons expresses dissent as to the participation of the prospective participant in the research study, the prospective participant may not be enrolled in the study. For example, if the persons available to provide surrogate consent are the adult children of the prospective participant and one of them expresses dissent, then the prospective participant may not be enrolled in the study.
2. When there are two or more available persons who are in different orders of priority as listed above, refusal to provide consent by a person who is a higher priority surrogate shall not be superseded by the consent of the person who is a lower priority surrogate. For example, if the spouse of the prospective participant refuses to provide surrogate consent, then the adult child of the participant cannot provide surrogate consent; thus, superseding the wishes of the spouse.

Important: If the prospective participant her/him self expresses dissent or resistance to participation, they may not be enrolled in the study regardless of whether a surrogate informed consent is obtained.

If, for any reason, a researcher cannot or elects not to follow this guidance, the study protocol must include a written plan describing how they will determine who will provide surrogate informed consent for a research participant who lacks decision-making ability due to cognitive impairment. Any such alternate plan is subject to IRB review and approval.