



University of California
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Special Consent Requirements for Vulnerable Populations

There are unique consent requirements as well as some other special regulatory requirements for research that involves certain vulnerable populations:

Children and minors ^[1]: Federal regulations include requirements for parental permission (consent) and assent from children.

Pregnant women, fetuses, neonates or human in vitro fertilization ^[2]: Consent may be required from only the woman or the woman and the father. See the guidance page for specific requirements, as well as info to include in the consent form.

Prisoners ^[3]: There are a number of restrictions on research involving prisoners, and these studies require extra review time.

Individuals who are legally blind, illiterate, or physically cannot talk or write ^[4]: The consent process and/or documentation method may need to be altered for these individuals.

Individuals with cognitive impairments: ^[5] You need to assess whether subjects have the capacity to consent for themselves or use surrogate consent ^[6].

There are also special requirements for research conducted in some **emergency setting research** ^[7], situations in which **surrogate consent** ^[6] is required and studies that may enroll **non-English speakers** ^[8].

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