Policy on Subjects with Impaired Capacity for Consent

Effective date: 9/20/2019

I. Background

According to the federal regulations governing human subjects research, “the IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.” This policy outlines IRB considerations for studies enrolling subjects with impaired capacity for consent.

II. IRB Review of Research Involving Subjects with Impaired Capacity for Consent

a. Subjects with impaired capacity for consent are likely to be vulnerable to coercion or undue influence due to diminished autonomy. The IRB must review these studies to ensure that researchers provide additional safeguards to protect the rights and wellbeing of this population. Safeguards will be determined based on degree of cognitive impairment, level of risk of study, and potential direct benefit to subject.

b. Adults are considered able to consent on their own behalf unless subjects have a condition that would impair their reasoning or judgement. The impairment condition may be intermittent or be constant.

c. For greater than minimal risk studies with subjects who may have possible cognitive impairment, the IRB may require the Principal Investigator (PI) to submit a decision-making capacity assessment.

d. For greater than minimal risk studies, the protocol must be reviewed by an IRB member or consultant with sufficient expertise in the ethical, clinical, and psychosocial issues impacting this population.

e. When reviewing research funded by the National Institute on Disability and Rehabilitation Research and where the research purposefully includes individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants, this may be a consultant for this project.

f. The IRB may require periodic re-consenting, 3rd party monitors for consent process, and/or waiting periods before enrollment.

III. Impaired Decisional Capacity Inclusion

a. The PI must determine capacity for providing consent for their subject population based on subjects’ ability to make choices, to understand information in the informed consent document, to appreciate the research
procedures and their risks, and the ability to rationally manipulate information provided to them.
b. Researchers must describe how they will assess capacity (e.g., post consent 'quiz', standardized tool, professional opinion, with consultation with another qualified professional) in IRB application.
c. The IRB may allow a Legally Authorized Representative (LAR) to give consent on behalf of a subject with impaired decisional capacity, or allow research procedures to proceed without consent, or without some elements of consent, when the study qualifies for a waiver or alteration of consent. Waiver of assent from the subject determined to have impaired decisional capacity may only be approved for studies with potential for direct benefit to the subject or where the study qualifies for a waiver or alteration of consent.
d. Researchers must provide rationale for use of this population in their application.

IV. Institutionalized Subjects
a. Surrogate consent to participate in research under California Health & Safety Code Section 24178 is not permitted for persons on an inpatient psychiatric ward, inpatients of a mental health facility, or persons on psychiatric hold.
b. The IRB must consider the rationale and justification for involvement of institutionalized participants, including an explanation as to why non-institutionalized individuals could not be used.
c. The IRB must assure for multisite research that all study sites “engaged” in research have approval from the IRB of Record for the proposed research to be conducted at the site.
d. When study procedures will be conducted at a site or facility that is not otherwise "engaged" in conducting the human subjects research and where the study site/facility does have its own IRB, the UCSC PI must obtain approval to conduct the research from the site’s IRB or provide documentation that the site’s IRB determined that approval is not necessary for UCSC to conduct the proposed research at the site.

V. References
a. UC Irvine Policy Individuals Who Are Cognitively Impaired or Mentally Disabled
b. 45 CFR 46.111