

 Office of Research Integrity - Human Subjects			SOP #: ORI(HS)-7.08
			Revision #: 1.0
			Page #: Page 1 of 4
Approved By: ORI Executive Director	*Signature on file	Date:	Date First Effective: 01/25/2017
Approved by: Biomedical Chair	*Signature on file	Date:	
Approved by: Social Behavioral Chair	*Signature on file	Date:	Revision Date:

SOP 7.08 – Adults with Questionable Decision Making Capability

1. Objective

This procedure recognizes and identifies the additional safeguards needed to approve the participation of adult individuals with impaired consent capacity in biomedical and social/behavioral research studies. The principles of beneficence and justice necessitate allowing the opportunity, when relevant, for persons with impaired consent capacity to be participants in research projects with recognition that decision-making capacity to provide consent may be compromised or may fluctuate over time.

2. General Description

Impaired decision making capability may be associated with psychiatric disorders, organic impairments, or developmental disorders that affect cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Persons under the influence of or dependent on drugs or alcohol, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests. In some instances, these individuals may have a court-appointed guardian empowered to sign a consent form, but, even in those instances, assent of the participant should be sought in addition to the consent of a legally authorized representative (LAR) when the individual is sufficiently cognitively capable of understanding the nature of his or her participation in a research study. Additional safeguards to insure an informed consent and/or assent result in added responsibilities for investigators, the IRB, and ORI-HS as detailed in the following section.

Definitions

Guardian (per NRS 159.017) – is any person appointed as guardian of the person, of the estate, or of the person and estate for any other person. The term includes, without limitation, a special guardian or, if the context so requires, a person appointed in another state who serves in the same capacity as a guardian in this State.

Note: Per Chapter 159 (159.0805) of the Nevada Revised Statutes, court approval is required before a guardian may give consent for a ward to participate in research (in the state of Nevada).

Informed consent - includes all of the processes and documentation that allow human subjects to be made aware and give permission for participation in a research project.

UNLV Office of Research Integrity - Human Subjects and Institutional Review Board Standard Operating Procedures		
SOP #:ORI(HS)- 7.08 Revision #:	TITLE: Adults with Questionable Decision Making Capability	Page 2 of 4

Legally Authorized Representative (LAR)– is 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 procedures involved in the research.

3. Roles & Responsibilities

Execution of SOP: Principal Investigators (PI)/Study Personnel (SP), IRB Chair, IRB, Office of Research Integrity – Human Subjects (ORI-HS) Staff.

Investigators

Investigators proposing research targeting adult individuals with impaired consent capacity as participants must provide a thorough justification for their proposed research design, including how capacity will be assessed, plans to include surrogate permission, plans for subject assent (where appropriate) and a description of the procedures that are designed to minimize risks to participants. A research study specifically designed to include individuals with impaired consent capacity must have as its goal either to study treatment designed to directly benefit the individual, or the development of important generalizable knowledge regarding the disease or condition of the targeted population.

Research studies designed to involve individuals with impaired consent capacity must include a means to assess a potential participant’s capacity to provide consent and the criteria for identifying individuals who are impaired. At a minimum, this assessment must include a method to evaluate the potential participant’s ability to understand the relevant study information, e.g., the nature of the research and its likely consequences, to process information about the research rationally, and to communicate a choice clearly as to whether or not he/she wishes to participate. The method(s) used to assess capacity to provide initial and continued consent vary and must be consistent with the level of risk to the participant and the complexity of the research. The assessment method must allow for a repeat assessment of the capacity to consent if the potential participant’s condition changes or is expected to change.

Individuals who are temporarily impaired due to environmental or other factors should not be asked to participate in research until they regain their decision-making ability and can provide consent. If the research is designed to study individuals while in a state of temporary impairment, investigators are encouraged to design the research project so that participants will be appropriately consented and enrolled prior to the temporary decisional impairments.

IRB

The IRB review of projects involving adult participants with impaired consent capacity must include one or more members or consultants who are familiar with the conditions that may affect the prospective participant’s capacity to provide consent and with the concerns of the population being studied.

ORI-HS

The ORI-HS is responsible for providing assistance to the IRB to identify consultants familiar with the conditions that may affect a prospective participant’s capacity to provide consent and with the concerns of the population being studied. Legal counsel will be sought as may be needed to help determine the legal rights of individuals and to facilitate IRB review.

4. Procedures

UNLV Office of Research Integrity - Human Subjects and Institutional Review Board Standard Operating Procedures		
SOP #:ORI(HS)- 7.08 Revision #:	TITLE: Adults with Questionable Decision Making Capability	Page 3 of 4

The critical feature in the additional safeguards required for participation by persons who may have impaired decision making capabilities is an assessment of the participant's capacity to consent. At a minimum, this assessment must include a method to evaluate the potential participant's ability to understand the relevant study information and to communicate a choice clearly as to whether or not he/she wishes to participate. The method(s) used to assess capacity to provide initial and continued consent must be commensurate with the level of risk to the participant and the complexity of the research. The assessment of capacity to provide consent is required regardless of risk.

It is the responsibility of the investigator to communicate clearly to the IRB the process to be used for assessment of decision making capability. The investigator must ensure that the individual who is responsible for determining whether a potential participant has the capacity to consent has the appropriate expertise necessary to determine and monitor the participant's capacity initially and on an ongoing basis. The determination may be made by a professional who has appropriate expertise. The assessment may also include opinions from one or more caregivers. The assessment method must allow for a repeat assessment of the capacity to consent if the potential participant's condition changes or is expected to change. If no clinical assessment has been made prior to and separate from a study initiated assessment, care must be given to the possibility of inflicted knowledge borne from such an assessment, and a plan established for the disclosure, or non-disclosure, of possibly sensitive information.

Assessment of Capacity to Consent

In general, an assessment of an individual's capacity to consent should be based on her/his:

1. Ability to communicate a reasoned choice regarding participation;
2. Ability to understand relevant information about the study, including consequences of participation for the participant's own situation (such as health condition) and consequences of the alternatives to participation;
3. Ability to comprehend the nature of the situation and its likely consequences; and
4. Ability to manipulate information rationally.

IRB Considerations for Approval

The IRB may approve research projects which propose to include individuals with impaired consent capacity only after consideration of safeguards in addition to the requirements for approval. The IRB must find that their participation in research:

1. presents no more than minimal risk; or
2. presents greater than minimal risk, provided that the IRB finds that the risks are justified given the potential benefits of the research either a) to the participants or b) to the development of generalizable knowledge likely to benefit others with comparable conditions.

The IRB deliberations shall include consideration of the nature and degree of anticipated impairment of the targeted study populations, the risk level of the proposed study, and the potential for direct benefit to the study participants. The IRB must consider whether the protocol includes a reasonable rationale for inclusion of individuals with impaired consent capacity as a target population.

UNLV Office of Research Integrity - Human Subjects and Institutional Review Board Standard Operating Procedures		
SOP #:ORI(HS)- 7.08 Revision #:	TITLE: Adults with Questionable Decision Making Capability	Page 4 of 4

5. References

45 CFR 46.111(b)
21 CFR 56.111(b).

Institutional Review Board Management and Function, Bankert & Amdur – Chapter 9-8