1.0 Purpose
The purpose of this SOP is to describe additional protections for decisionally impaired participants.

2.0 Policy
It is the policy of the IRB that research involving decisionally impaired participants who cannot provide voluntary informed consent must include appropriate additional protections in accordance with the requirements of Health and Human Services regulations at 45 CFR §46.111(b).

2.1 Definitions
A. Decisionally impaired participants
A person that lacks the ability to reason, exhibit sound judgment and provide voluntary consent to participate in research. The impairment may fluctuate (e.g., mental disorders), decline with time (e.g., Alzheimer’s), or result from health conditions (e.g., coma or other infirmity).

B. Legally Authorized Representative
The term “legally authorized representative” is not defined in the Nebraska revised statutes. Under Nebraska law there are essentially two different circumstances under which a person can act as a guardian or “legally authorized representative” for another adult. The investigator makes the decision about whether a person is a legally authorized representative, i.e., falls under the above. In general, researchers at UNL conducting research in Nebraska and enrolling adults unable to consent can get permission for those individuals to participate in research from:

- an individual’s court appointed guardian which includes de facto health care Power of Attorney; or
- a person having “Power of Attorney” for another person.

C. Institutionally Authorized Surrogate
In the absence of a legally authorized representative as described in 2.1(B), no one can provide legally effective consent on behalf of a participant to the participant’s participation in research. Under federal regulations Institutionally Authorized Surrogates who do not meet the DHHS definition of Legally Authorized Representatives may not provide consent on behalf of another individual unless the IRB has waived the requirement for informed consent.

2.2 Acceptable Research
A. A decisionally impaired participant may participate in research involving *greater than minimal risk* only if the research potentially offers an acceptable level of *direct therapeutic benefit* to that participant.

B. A decisionally impaired participant may participate in research involving *minimal or slightly above minimal risk* without direct participant benefit if a Legally Authorized Representative is available and provides proxy consent.

### 2.3 Use of Proxy Consent

A. If the prospective participant is decisionally impaired, the participant’s Legally Authorized Representative must provide written proxy consent.

B. If the prospective participant is decisionally impaired, but is capable of executing a Durable Power of Attorney, the prospective participant may grant authority to the holder of the Durable Power of Attorney to give written informed consent to participate in research on their behalf. The Durable Power of Attorney in this case is a Legally Authorized Representative.

1. The Durable Power of Attorney may already be in effect or one may be appointed to grant proxy consent for research participation.

2. The Durable Power of Attorney is to be used only with prior approval of the IRB.

3. The Durable Power of Attorney cannot be used if the prospective participant has a Legally Authorized Representative.

4. The prospective participant must understand the meaning of a Durable Power of Attorney and appoint someone of their choice.

5. The person appointed as a Durable Power of Attorney must be willing to do so and understand the responsibilities involved.

6. Employees of UNL are *not* eligible for appointment as holder of a Durable Power of Attorney for a prospective participant unless they are the spouse, adult child, parent, or relative of the prospective participant.

7. A nursing home (e.g., owner, part-owner, manager, administrator, or employee, as well as spouses of these individuals) providing residential care to a participant or a community based program is *not* eligible for appointment as holder of a Durable Power of Attorney for prospective participants.

8. Signed copies of the Durable Power of Attorney form should be maintained by the investigator.

9. The HRPP office must be contacted prior to appointing a Durable Power of Attorney (Ph# 402-472-6965).

C. If the potential participant does *not* have a Legally Authorized Representative and is judged by the investigator to both lack the capacity to give consent and execute a Durable Power of Attorney, the research may only be conducted if the IRB waives the requirement for consent.
2.4 Proxy Consent Form
The Proxy Consent Form must include all required elements of the informed consent and be written in the proxy consent style that indicates that the Legally Authorized Representative is providing permission to allow the decisionally impaired participant to participate in the study.

2.5 Adult Assent Form
The Adult Assent Form is based on the adult consent form, but should be written in simple language aimed at the appropriate cognitive level of the decisionally impaired participants to be enrolled in the study. The Adult Assent Form must contain all required elements of consent.

2.6 Application of Laws
IRB and/or investigators must apply State and local laws that reach beyond Federal laws relevant to research involving humans as participants. Examples of such laws are reporting of child abuse and educational privacy laws. University counsel is available for advice in all cases as needed and requested. UNL’s HRPP staff and or members of the IRB have access at all times to university legal counsel for assistance in applying laws to other than federal law regarding research involving human participants.

Administrative Approval:

Dan R. Hoyt, Ph.D.  
IRB Chair

Kimberly Andrews Espy, Ph.D.  
Associate Vice Chancellor for Research