1.0 Purpose
The purpose of this SOP is to describe the procedures for research involving children.

2.0 Policy
It is the policy of the IRB that the board will review all exempt and non-exempt research proposals involving participation of children in accordance with Health and Human Services regulations at 45 CFR §46 Subpart D and applicable state law. The IRB will classify the research in accordance with Subpart D and document how and why the proposal meets the requirements.

2.1 Definitions
A. **Age of majority** is defined, according to Nebraska State Statute 43-2101. It states that all persons under nineteen years of age are declared to be minors, but in case any person marries under age of nineteen years, his or her minority ends. If the potential participant is Native American living on federal tribal lands, regardless of the state, federal law has set the age of majority at age 18.

HRPP staff, in consultation with the IRB chair, will determine which individuals meet the DHHS definition of “children” in the cases that the research is conducted outside Nebraska or under Native American jurisdiction.

1. Nebraska law, with some exceptions, sets forth a higher age of majority (19 years) than all but two other states, those being Alabama (also 19 years) and Mississippi (21 years). By requiring the parents or guardians of all research participants under the age of 19 to be notified and provide their written consent prior to their child's participation in research, UNL goes above and beyond the standards of all other states (other than Mississippi) and also ensures compliance with relevant federal and local standards. When other legal conflicts arise the counsel to the IRB will provide a legal opinion and resolution to the IRB.

B. **Assent** is defined as a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

C. **Children** are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In Nebraska a child is an individual who is under 19 years of age and is not emancipated as set forth in Neb. Rev. Stat. §43-2102, which states:
All persons under nineteen years of age are declared to be minors, but in case any person marries under the age of nineteen years, his or her minority ends.

It should be noted that under Nebraska law minority status also ends when a minor enlists in the armed forces before his or her nineteenth birthday.

NOTE: The definition of informed consent under Nebraska law is found in Neb. Rev. Stat. §44-2816 which states:

*Informed consent shall mean consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice in the locality or in similar localities. Failure to obtained informed consent shall include failure to obtain any express or implied consent for any operation, treatment, or procedure in a case in which a reasonably prudent health care provider in the community or similar communities would have obtained an express or implied consent for such operation, treatment, or procedure under similar circumstances.*

When the research is conducted in Nebraska: In DHHS regulations “children” are persons who have not attained the legal age to consent to treatments or procedures involved in some research, under the applicable law of the jurisdiction in which the research will be conducted. In Nebraska, individuals under the age of 19 years with the exceptions noted below are considered to be “children” as defined by DHHS regulations because they have not attained the legal age to consent to treatments or procedures involved in some research and the additional protections of Subpart D are required. The exceptions to this rule are the following individuals who are able to consent to treatments or procedures involved in the research, so that they do not meet the DHHS definition of “children” and the additional protections if Subpart D are not required:

- Emancipated minors.
- Individuals of any age where the research procedures are limited to:
  - Use of contraceptives.
  - Treatment for venereal disease.
  - Treatment for drug abuse.

NOTE: For research conducted in jurisdictions other than Nebraska, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The General Counsel for the University’s Office will provide assistance with regard to the laws in other jurisdictions.

D. **Commensurate** is defined as the requirement that children and/or their guardians are familiar with procedures that are reasonably similar in nature and risk proportionally to those the child has experienced, or is expected to experience, and not restricted to specific situations the child has experienced or will likely experience in the future.

E. **Disorder or condition** is defined as a specific (or set of specific) physical, psychological, neuro developmental, or social characteristic(s) that an established
body of scientific evidence or clinical knowledge has shown to negatively affect children’s health and wellbeing or to increase their risk of developing a health problem in the future.

F. **Dissent** is defined as a child’s decision to decline participation in research.

G. **Emancipated minor** is defined as a legal status conferred upon persons who have not yet attained the age of legal competency as defined by Nebraska state law, but who are entitled to treatment as if they had. Some minors do not meet the DHHS definition of “children,” such as in Nebraska individuals under 19 years of age who are legally emancipated or who are otherwise able to consent to the procedures involved in research. Federal regulations require that to take part in research the legally effective consent must be obtained from such individuals or their legally authorized representative.

Emancipated minor shall mean a person under nineteen years of age who is married or in the military, and it shall also mean a person under nineteen years of age who resides apart from his or her parents; is not under the care, custody, control, or supervision of his or her parents; and who receives no financial support or services from his or her parents and is responsible for securing his or her own support. The emancipation of a child is a question of fact, to be determined by the peculiar facts and circumstances of each case, and may be proved by circumstantial evidence, by an express agreement, or implied from the conduct of the parties. Emancipation may be terminated by a change of circumstances. For a general discussion of emancipation of minors, see Accent Service Company v. Ebsen, 209 Neb. 616(1993).

H. **Guardian.** A guardian is defined as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care (45 CFR 46.402 (e)). Under Nebraska law, a person becomes a guardian by acceptance of a testamentary appointment (in other words, via a will) or upon appointment by the court (Neb. Rev. Stat §30-2605). Under Nebraska law, individuals appointed as guardians can consent to medical care on behalf of the ward, therefore such individuals would be guardians according to the DHHS definition.

**NOTE:** For research conducted in jurisdictions other than Nebraska, the research must comply with the laws regarding legally authorized representative in all relevant jurisdictions. The General Counsel of the University’s Office will provide assistance to the investigator with regard to the laws in other jurisdictions.

**Note:** For additional information on Guardianship, refer to the Guardian Guidance Document.

I. **Legally authorized representative.** Legally authorized representative is defined as an individual or judicial body authorized under applicable law to give informed consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research (21 CFR 50.3 (m)). IRBs and clinical investigators should familiarize themselves with applicable local statutes and regulations pertaining to the definition of a legally authorized representative.

Parents and guardians meet the DHHS and Nebraska definitions of a legally authorized representative. For persons with a “Power of Attorney”, whether the
power of attorney in a given case will convey the authority to consent to participation on behalf of the principal in research depends on the specific language used in the durable power of attorney document.

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.

**NOTE:** For research conducted in jurisdictions other than Nebraska, the research must comply with the laws regarding legally authorized representative in all relevant jurisdictions. The General Counsel of the University’s Office will provide assistance to the investigator with regard to the laws in other jurisdictions.

Note: For additional information on Legally Authorized Representatives, refer to the Guardian Guidance Document.

**J. Minimal risk** is defined as the risks that normal, average, healthy children encounter while living in safe environments or the risks associated with routine physical or psychological examinations or tests. The determination of minimal risk should take into account that 1) children face differing risks at different ages, 2) risks associated with repetitive tests may increase, and 3) special/unique characteristics may make a certain population more vulnerable than average children (e.g., hemophilia). The risks associated with routine examinations or tests are equivalent to a routine well-child examination.

**K. Minor increase over minimal risk** is defined as the determination whether the research procedures or interventions present a minor increase over minimal risk. The IRB will consider the following five criteria: magnitude, probability, duration, cumulative characteristics, and irreversibility of risk to the child.

**L. Parent** is defined as a child’s biological or adoptive parent. Under Nebraska law, parents are the natural guardians of their minor children. Neb. Rev. Stat. §30-2608(a) states:

> The father and mother are the natural guardians of their minor children and are duly entitled to their custody and to direct their education, being themselves competent to transact their own business and not otherwise unsuitable. If either dies or is disqualified for action, or has abandoned his or her family, the guardianship devolves upon the other....

Therefore, in Nebraska a father or mother of a child under the age of nineteen can act as a “legally authorized representative” of that child so long as their rights have not been terminated by law and so long as their minor child is not married or in the
armed forces. For research conducted in jurisdictions other than Nebraska, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The Office of General Counsel will provide assistance with regard to the laws in other jurisdictions.

M. **Permission** is defined as the agreement of parent(s) or guardian(s) to the participation of his/her (their) child or ward in research.

N. **Vital importance** is defined as the research is essential for the scientific understanding or evaluation of procedures to alleviate the disorder or condition and perceived as essential to the understanding or amelioration of the child’s disorder by practitioners and family stakeholders.

### 2.2 Categories of Research

Health and Human Services regulations specify that research involving children must be approvable under one or more of the following four (4) categories:

**A. Research not involving greater than minimal risk** (e.g. most educational studies, studies in which behavior is not manipulated) *(45 CFR §46.404)*

1. The potential risks must be outweighed, or balanced, by the potential benefits to the participants and/or society.

2. Adequate provisions must be made for soliciting assent of the children and permission of the parent(s) or guardian(s).

**B. Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual participants** *(45 CFR §46.405)*

1. The risk is justified by the anticipated benefit to the participants.

2. The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.

3. Adequate provisions are made for soliciting the assent of the children and permission of their parent(s) or guardian(s).

**C. Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant’s disorder or condition** *(45 CFR §46.406)*

1. The risk represents a minor increase over minimal risk.

2. The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

3. The intervention or procedure is likely to yield generalizable knowledge about the participant’s disorder or condition, which is of vital importance for the understanding or amelioration of disorder, or condition.

4. Adequate provisions are made for soliciting assent of the children and permission of their parent(s) or guardian(s).
D. Research, not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR §46.407).

The IRB will submit this category of research to Health and Human Services for approval, if the research is funded by Health and Human Services. If the research is not Health and Human Services-funded, the IRB will, at the board’s discretion, convene an equivalent expert review panel.

2.3 Process of Consent/Assent

A. In accordance with 45 CFR 46.408(b) the IRB must determine that adequate provisions have been made for soliciting the permission of each child’s parent or guardian.

In general, if an individual is not a parent, they can permit a child to take part in research only if that individual is legally authorized to make health care decisions for the child. Under federal law this is the case even for social and behavioral research. Before obtaining permission from an individual who is not a parent, make sure that the person is legally authorized to make health care decisions for the child. If needed, ask for written documentation of the individual’s authority to make health care decisions on behalf of the child. If the person has such authorization, the individual can permit the child to take part in the research. If the person does not have such authorization, the individual cannot permit the child to take part in the research.

Parents or guardians must be provided with the basic elements of consent as stated in 45 CFR 46.116(a) (1-8) and any additional elements the IRB deems necessary.

The IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 or 45 CFR 46.405. The IRB’s determination of whether consent must be obtained from one or both parents will be documented in the consent checklist when a protocol receives expedited review, and in meeting minutes when reviewed by the convened committee.

Consent from both parents is required for research to be conducted under 45 CFR 46.406 and 45 CFR 46.407 unless:

1) One parent is deceased, unknown, incompetent, or not reasonably available; or

2) When only one parent has legal responsibility for the care and custody of the child.

B. Consent of a Mature Minor

A minor may, with IRB approval, legally consent on his/her own behalf when he/she do not meet the DHHS definition of “child”. In Nebraska, if a participant under the age of 19 is legally declared emancipated, he/she may consent to participate in research because the individual no longer meets the DHHS definition of a child and therefore, Subpart D does not apply.

C. Assent of Children

In addition to the obtainment of parental/legal guardian consent (permission), the investigator must also solicit assent of minor participants age 7 years or older, unless the participants displays intellectual or emotional development below that of the average 7-year-old child. Obtainment of assent shows respect for a child’s
developing autonomy. In most circumstances (non-therapeutic research), a child’s deliberate objection should be regarded as a veto to his/her involvement in the research.

D. Purpose of Assent
Assent serves to provide information to the child and to allow the child to dissent. With these purposes in mind, the following points should be considered when writing the Youth or Child Assent Form.

1. In deciding whether to seek assent, the minor’s age is an important criterion, but intellectual and emotional development also need be considered. The child must be able to identify the benefits and risks of the research, and to be able to reason about the consequences of participation as well as a typical 7 year old;

2. When there is uncertainty as to whether assent should be sought from the child or adolescent, an independent psychological examiner should be employed to help evaluate the minor’s decision-making capacities;

3. A valuable function of seeking assent from the minor is to provide information that the minor and his/her parents may use in their decisions concerning the research; and

4. In seeking assent, undue advantage should not be taken of the child’s developmental limitations related to his/her voluntariness (acquiescence to authority figures and any lack of ability to express his/her rights).

E. Dissent of Children
Dissent from participation or withdrawal from research is always to be honored unless the protocol affords access to a therapeutic intervention that is not otherwise available. In that case, parental consent for therapeutic intervention may override a child’s dissent. However that information must be provided to the child prior to the intervention procedure.

F. Waiver of Assent
Parents or guardians may, with IRB approval, override a young child’s objections to interventions that hold the prospect of direct benefit to the child in accordance with 45 CFR §46.408(a). Assent may also be waived by the IRB under 45 CFR §46.116(d).

G. Situations Where Minors Are Not Children
Under the following circumstances, minors are not considered “children” and can consent for themselves:

1. If the research only involves a treatment for, which a minor’s consent is permissible under applicable law (e.g., use of contraceptives, treatment for venereal disease or substance use).

2. If a participant under the age of 19 is legally declared emancipated, he/she may consent to participate in research.

H. Waiver of Parental Permission
Situations may be encountered where, with appropriate scientific rationale and justification, the IRB may approve a waiver of the requirements for parental consent.

1. The research meets the criteria for waiver of informed consent in 46.116(d):
   a) The research involves no more than minimal risk to the subjects;
   b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
   c) The research could not practicably be carried out without the waiver or alteration; and
   d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

I. Wards
   Health and Human Services regulations at 45 CFR §46.408 set specific requirements for children who have been declared wards of the state or any other agency, institution, or entity.

Wards can participate in research approved under §46.406 or § 46.407 if:
1. The research is related to their status as a ward.
2. The research is conducted in schools, camps, hospitals, institutions, or similar settings where the majority of children involved in research are not wards.
3. The IRB will require appointment of an advocate for each child who is a ward:
   a) The advocate serves in addition to any other individual acting on behalf of the child as a guardian or in the absence of the parent(s).
   b) The advocate may represent more than one child.
   c) The advocate must have the background and experience to act in the best interest of the child for the duration of the child’s participation in research.
   d) The advocate must not be associated in any way with the research, the investigator(s), or the guardian organization. The federal regulations do not specifically exclude IRB members from serving as a child advocate if the other conditions are met.

J. Re-consent of participants reaching the age of majority
1. All minor participants actively participating in an IRB-approved study must be consented using the adult IRB-approved informed consent document at the first visit after reaching the legal age of majority. If the minor participated in a study that is completed, except for data analysis, re-consent is not required.
2. If, upon reaching the age of majority, the now adult participant is found decisionally impaired or is of diminished capacity, the participant remains vulnerable and the proxy/parental consent remains in effect. This must be documented in the study records and the IRB must be notified.
3. The now adult participant has the right to refuse to continue participation in the study. This is to be respected and undue pressure or coercion to continue may
not be applied. While new data may not be collected on participants refusing participation, existing prior data collected under the assent/proxy consent process can be used.

2.4 Consent and Assent Documents

A. Parental/Guardian Consent Form
If the participant is under the age of 7 years, only a Parental/Guardian Consent Form is required. The Parental/Guardian Consent Form should include all relevant elements of informed consent as outlined previously and be written in a proxy consent style that indicates it is the parent, or legal representative, who is consenting to allow the minor to participate in the study. The standard statements must be modified for the Parent Consent form (e.g., all references to “you” must be changed to “your child”).

B. Youth Assent Form
If the participant is 13-18 years of age, a Youth Assent Form is required. The Youth Assent Form is based on the adult consent form, but should be revised to meet the cognitive and educational level of an average youth. The assent form must contain simple language written at the appropriate educational level of the youngest prospective participant in the youth age range. In some research projects, it may be necessary to utilize two assent forms written to accommodate participants at either end of the age range. The Youth Assent Form must contain all of the required elements of consent previously outlined in the IRB Guidelines except instructions about emergency care and rights of research participants, and should follow the general format of the adult consent form.

C. Child Assent Form
1. If the participant is under the age of 7 years, only a Parental/Guardian Consent Form is required. However, verbal assent should be obtained as appropriate.

2. If the participant is 7 through 12 years of age, a Child Assent Form is required. The Child Assent Form must be brief, without subheadings, and contain extremely simple language arranged in brief paragraphs. The assent form must contain the following elements: title of the research study; opportunity to ask questions; basis for participant selection; purpose of the study; explanation of procedures; potential risks/discomforts; potential benefits; statement concerning consultation with parents; freedom to withdraw; and confidentiality statement. ([http://research/orr/forms.shtml](http://research/orr/forms.shtml)).

2.5 Documentation of IRB Findings
Per federal regulations, the IRB will prepare and maintain adequate documentation of IRB activities. For the purposes of Subpart D, the IRB activities including making the specific findings required under Health and Human Services regulations along with protocol-specific findings justifying those determinations. OHRP accepts documentation of protocol-specific information justifying the IRB finding under Health and Human Services regulations at 45 CFR §46.404, §405, or §406. IRB actions will be documented in the approval letter.
Administrative Approval:

___________________________________
William Thomas, Ph.D.
IRB Chair

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