SOP 7.01 – Vulnerable Subjects: Children

1. Objective

Children are considered a vulnerable population in need of special protections. The purpose of this SOP is to describe the additional considerations for research involving children and to comply with 45 CFR 46 Subpart D.

2. General Description

According to 45 CFR 46, children are persons who have not attained the legal age for consent to treatment or procedures involved in the research. In Nevada, NRS.129.010 defines the age of majority as18 years. Anyone under the age of 18 is a minor unless they have been emancipated in accordance with NRS. 129-080 – 128.140.

Definitions

Children - persons who have not attained the legal age for consent to treatment or procedures involved in the research.

Assent – a child's affirmative agreement to participate in the research. Failure to object, absent an affirmative agreement, does not constitute assent.

Permission – the agreement of parent(s) to the participation of their child or ward in research

Parent – a child's biological or adoptive parent.

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.

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

3. Roles & Responsibilities

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

IRB Responsibilities
Non-exempt research involving children will be reviewed by no less than two IRB members. See SOP 5.04 for exempt considerations.

The IRB shall determine whether or not children are capable of providing assent and whether or not adequate provisions are made for soliciting assent. Additionally, the IRB shall determine that adequate provisions are made for soliciting the permission of each child's parent(s). See SOP 6.02 for additional considerations regarding child assent and parent permission.

PI Responsibilities
For an investigator wishing to enroll children as subjects in a research study, the following additional safeguards must be considered and included as may be necessary.

Protocol Proposal Form
In addition to the standard requirements for protocol submission, protocols involving children will consider the following:

- The proposed number of children to be enrolled and their age ranges
- A description for obtaining parental permission and child assent, including:
  - Which member(s) of the research team will obtain assent
  - Where and when parental permission and child assent will be obtained
  - The types of assent documents that will be used (script, simplified form, assent form consistent with adult consent form)
  - How each child's assent will be documented by the researcher
  - How it will be determined whether children and parents understand the research.
- A plan for handling information disclosed by a child that compromises the child's safety or the safety of other children (e.g. suspected child abuse, threatening behavior, possession of a weapon, etc.).
  - This plan must be in accordance with NRS 432B.220 – State of Nevada Mandatory Reporting of Child Abuse and Neglect. Please reference the statute for a discussion about who is considered a mandatory reporter and general requirements for making a report.

Obtaining Permission and Assent
Unless otherwise determined by the IRB, PIs conducting research with children must ensure that written parental permission is obtained for all subjects, and that children have agreed to participate in the study. Most research should only proceed when both the parent and the child have agreed to take part in the study.

The parental permission form should clearly describe the aspects of the study that involve or affect the child and those that require parental involvement. Any limitations on parental access to the child's research data or responses should also be described. The permission of one parent may be sufficient for research not involving greater than minimal risk, or for research involving greater than minimal risk, but presenting the prospect of direct benefits to individual participants. Unless otherwise determined by the IRB, the permission of both parents is required for research involving greater than minimal risk and no prospect of direct benefit to individual participants, and for research, not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. The requirement for

permission of both parents is waived if one parent is deceased, unknown, or not reasonably available or when one only parent has sole legal responsibility for the care and custody of the child.

For children who are wards of the state or any other agency, PIs may select an advocate to provide permission to participate in a research study. An advocate is an individual who has the background and experience to act in the best interests of the child for the duration of the child's participation in the research.

Assent is similar to consent, although the information provided must be tailored to the developmental level of the child. The child must be able to identify the benefits and risks of the research, and be able to reason about the consequences of participation. Undue advantage should not be taken of the child's development limitations related to voluntariness of the research, such as acquiescence to an authority figure (i.e. a teacher).

Limits to confidentiality must be explained to children.

See SOP 6.02 for additional considerations concerning child assent and parent permission.

School-Based Research

PIs wishing to conduct school-based research must obtain approval from the applicable school district's research office and must provide a letter of acknowledgment from the schools involved. Letters of acknowledgment are submitted with the protocol proposal and informed consent form as appropriate.

When applicable, it is the responsibility of the PI to determine appropriate alternate activities for those students who decline to participate in the research study. The alternate activity must be described in the protocol proposal form and during informed consent as needed.

Providing information about an individual participant to anyone other than the child student or the child's parent is a breach of confidentiality. This includes providing individually identifiable information to the schools, whether or not it is in the best interest of the student. The confidentiality promised to the students and their parents govern any potential disclosure to the school.

4. Procedures

The following additional protections must be in place or waived for non-exempt research involving children.

1. Research must be approved under one or more of the following four categories:

    - Research not involving more than minimal risk
    - Research involving greater than minimal risk, but presenting the prospect of direct benefits to individual participants
    - 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
    - Research, not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

2. The IRB must determine that adequate provisions have been made for soliciting the permission of each child's parent.

   The IRB may waive parental permission under limited conditions:

   - When the consent of parents is not a reasonable requirement because it poses additional risk to the potential subject, or the parents' interests may not adequately reflect the child's interests (for example, research concerning neglected or abused children), the IRB may waive the requirement for parental or guardian consent. The researcher should propose an alternative mechanism in the application and explain how it will protect the child. The IRB may require an alternative mechanism for protecting the rights and welfare of children. The choice of an appropriate alternative mechanism depends on the nature and the purpose of the research, the risks and the anticipated benefit to the child, and the age, maturity, status, and condition.
   - When the subject is emancipated.

3. The IRB must determine that adequate provisions have been made to solicit the assent of children.

5. References

45 CFR 46 Subpart D
NRS 432B.220 – State of Nevada Mandatory Reporting of Child Abuse and Neglect
NRS.129.010