SOP 6.02 - Informed Consent: Research Involving Children

1. Objective

In accordance with the Belmont Report ethical principle "Respect for persons" and 45 CFR 46 Subpart D, this SOP describes the basic requirements and guidelines for obtaining ethically informed assent from child research subjects and parent permission.

2. General Description

With limited exception, no investigator may involve a human being as a subject in research unless the investigator has obtained informed consent/permission/assent of the subject or the subject's legally authorized representative. This SOP outlines the basic considerations surrounding child assent and parent permission. Please closely reference SOP 6.01 for baseline considerations concerning informed consent process, documentation, and waivers.

Definitions

I*nformed 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.

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 approval is required before a guardian may give consent for a ward to participate in research (in the state of Nevada).

Legally Authorized Representative – 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 (ORI) Staff.

Investigators
An investigator shall seek such child assent and parent permission only under circumstances that provide sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information that is given to the child and parent shall be in language understandable to the child and parent.

No child assent or parent permission, whether oral or written, may include any exculpatory language through which the child or parent is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

With limited exception, Investigators must keep signed child assent and parent permission forms in a secure location for a minimum of three years following completion of the research.

IRB
It is the general responsibility of the IRB or reviewing entities to ensure that the basic and applicable elements of informed consent, child assent, and parent permission have been met satisfactorily, with the idea that respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.

The IRB is responsible for reviewing the child assent and parent permission process to ensure that it meets the ethical and regulatory requirements for fully informed and voluntary assent/permission to participate in research.

With exception to a claim for Exemption from the need for IRB review, consideration towards a waiver of some or all elements of informed consent (child assent/parent permission) must be justified and properly documented during the course of a review. However, even in the case of a claim for Exemption, the IRB-related review should strongly consider the basic elements of informed consent as they are discussed in SOP 6.01.

4. Procedures

Child Assent
The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the child subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived as discussed in 45 CFR 46.116, 46.117, and in this document SOP 6.01.

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented. The use of modified and/or simplified language is recommended and should seek to cover the basic elements of consent as discussed in SOP 6.01.

Special consideration is given to obtaining and documenting child assent in research designated as exempt from the need for IRB review (SOP 5.04). Certain elements or procedures may not be required, while attention should be given to relevant elements of informed consent and study procedures.

Parent Permission

In addition to the extent that consent is required as discussed in 45 CFR 46.116 (SOP 6.01), the IRB shall determine that adequate provisions are made for soliciting the permission of each child's parents. Permission from parents is required for all research involving children unless a waiver or alteration of permission is approved. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 or 46.405 (Subpart D).

Where research is covered by 45 CFR 46.06 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Permission by parents shall be documented in accordance with and to the extent required by 45 CFR 46.117 (SOP 6.01). In addition to the information generally required in an adult consent form, the parental permission form should clearly describe aspects of the study that involve or affect the child. In some circumstances it may be beneficial to discuss the level of parental involvement, and limitations on parental access to their child's research data or responses.

In addition to the provisions for waiver contained in 45 CFR 46.116 (SOP 6.01), if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements as discussed in 45 CFR 46.116 (SOP 6.01), provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Special consideration is given to obtaining and documenting parent permission in research designated as exempt from the need for IRB review (SOP 5.04). Parent permission is not expressly required in research with children determined to be exempt from the need for IRB review. However, parent permission, similar to child assent, should be sought where it is feasible and with regard to the relevant elements of informed consent and study procedures.

For Guardians, please see the definition below.

45 CFR 46.409, Wards

Children who are wards of the state or any other agency, institution, or entity can be included in research approved under 45 CFR 46.406 or 46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research is approved under this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Informed Consent/Assent Approval
The consent/assent process and associated document(s) approved for use will be documented in the ORI-HS study file. A stamped informed consent/assent document(s) with the IRB approved protocol number and study expiration date will be issued to the Principle Investigator upon approval.

5. References

45 CFR 46.116, 46.117, 46.406, 46.407, "Subpart D"
UNLV Rules and Procedures for Conducting Human Subject Research, 2.2, 5.1.4
Institutional Review Board Management and Function, Bankert & Amdur – Chapter 9-7