LSU Health NEW ORLEANS

Human Research Protection Program

Institutional Review Board (IRB) Researcher Education Series

VULNERABLE POPULATIONS

SUBPART D: CHILDREN

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Defining Vulnerable Populations

"Vulnerability, in the context of research, should be understood to be a condition, either intrinsic or situational, of some individuals that puts them at greater risk of being used in eithically inappropriate ways in research" (National Bioethics Advisory Counsel, 2001)

Two general themes:

1. Have difficulty providing voluntary, informed consent arising from limitations in decision-making capacity or situations circumstances
2. Especially at risk for explotation or coercion

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Vulnerable Populations as defined by DHHS

As defined in the Common Rule:

subpart B: Pregnant Women, Fetuses, & Neonates

subpart C: Prisoners

subpart D: Children

Adults with Impaired Decision-Making Capacity

While the subparts outline additional requirements for each vulnerable population, those requirements are in addition to the ones outlined in 45 CFR 46 which apply to all research conducted using Human Subjects.

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Defining Children

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

According to Louisiana Children's Code, anyone under the age of 18 is considered a child.

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Important Definitions

Parent: child's biological or adoptive parent

Guardian: individual who is authorized under law to consent on behalf of a child for their medical care

Assent: child's affirmative agreement to participate in research

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

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Considerations of the National Commission in the Belmont Report

The National Commission in the Belmont Report wanted to provide special provisions for respecting children, including:

- children cannot be enrolled in research that exceeds a level of justified risk
- in most cases, children have the opportunity to actively provide assent
- set an order of preference in the selection of classes of subjects (adults before children) so that children do not bear the burdens of research unnecessarily
- considering the scope of parental authority for certain types of research

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Categories of Permitted Research

Research not involving greater than minimal risk

[45 CFR 46.404]

Requirements to Approve the Research:

1. Assent from the child
2. Permission from the parent(s) or guardian(s)

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Categories of Permitted Research

Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects

[45 CFR 46.405]

Requirements to Approve the Research:

1. Risk must be justified by anticipated benefit to the child participating
2. Risk/Benefit ratio is at least as favorable to the subjects as that presented by available alternative approaches
3. Assent from the child
4. Permission from the parent(s) or guardian(s)

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Categories of Permitted Research

Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition

[45 CFR 46.406]

Requirements to Approve the Research:

1. Risk is only slightly greater than minimal
2. Intervention/procedure presents experiences that are comparable to the child's actual or expected medical, dental, psychological, social, or educational situations
3. Intervention/procedure is likely to yield generalizable knowledge of vital importance for the understanding the child's disorder or condition
4. Assent from the child
5. Permission from the parent(s) or guardian(s)

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Categories of Permitted Research

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]

Requirements for Approval of Research:

1. Reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
2. The DHHS Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has made a determination

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Soliciting Assent of a Child

Considerations:

- Age
- Maturity
- Psychological State

The IRB can determine that only some children need to be assented or that none of the children enrolled need to be assented based on the above considerations.

LSUHSC uses the assent form templates created by Children's Hospital New Orleans when research involving children is being conducted by our investigators

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Soliciting Permission from the Parent(s) or Guardian(s)

The IRB will determine if the permission of one or both parents is required.

- In cases where the IRB determines both parents must provide their permission, exceptions are made when parents who are deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child

The IRB may determine, for protocols studying certain conditions or populations, that a waiver or parent/guardian permission is appropriate

- An example of this would be neglected or abused children
- The IRB will determine an appropriate mechanism for protecting the children

LSUHSC uses the joint LSUHSC/CHNOLA Informed Consent Template for obtaining parent/guardian permission.

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Wards of the State

Wards of the state or any other entity/institution can be included in research if:

1. The research is related to their status as a ward; or
2. The research is conducted in a setting where the majority of children involved are not wards of the state (i.e. school, camp, hospital, etc.)

The IRB requires appointment of an advocate for each child, in addition to any other individual acting on behalf of the child.

- The advocate should 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 with the research, the investigator(s), or the guardian organization

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Limitations on Review Type

Can children be subjects in Expedited-reviewed research?
Yes. There is additional consideration from the IRB reviewer for Expedited Category 2, which relates to the volume and frequency of blood draws that can be considered minimal risk.

Can children be subjects in Exempt-reviewed research?
Yes, except for Exempt Category 2.

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Additional Resources

45 CFR 46, subpart D (HHS)
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html

21 CFR 50, subpart D (FDA)
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.20.4

LSUHSC - NO HRPP Policies and Procedures 7.01
https://www.lsuhsc.edu/administration/academic/ors/policies_procedures.aspx