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Subpart D – Research involving Children

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Definition of Children

- Federal regulations define children as:

  45 CFR 46.402(a)

"persons who have not attained the legal age of consent…jurisdiction where research will be conducted"

- Age of legal majority is a matter of state and local law

  Georgia law: 17 years of age and younger

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Federal Regulations

- Belmont Report – Respect for Persons
- OHRP Common Rule – Subpart D
- FDA 21 CFR 50 – Subpart D
- AAHRPP

Meeting Approval Criteria

- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, additional safeguards have been included in the study to protect the rights and welfare of these subjects

Risk Level & Benefits

OHRP 45 CFR FDA 21 CFR	Risk Level	Benefit Possibilities
46.404 50.51	Not > Minimal	Not specified
46.405 50.52	> Minimal	Prospect of direct benefit
46.406 50.53	> Minimal	No prospect of direct benefit, but likely to yield generalizable knowledge
46.407 50.54	Research not otherwise approvable	

Requirements for Permission and Assent

45 CFR 46.408 and 21 CFR 50.55

- One or two signatures may be required for the research
- Regulations all state “adequate provisions are made for soliciting assent of the child and permission of the parents or guardians”

Minor Assent

- The IRB must consider: Age, health status, mental capacity, psychological state, maturity, cultural norms
- The IRB determines the capability of children to assent

Regulatory Requirements for a Waiver of Parent/Guardian Permission

The requirement for permission from parent(s) or guardian(s) described in 46.116 and 46.408(b) may be waived if:

- The provisions for a waiver of some or all of the elements of informed consent in 46.116 are met;

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

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The requirement for permission may also be waived if:

(1) A research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children);

(2) An appropriate mechanism* for protecting the children who will participate as subjects in the research is substituted; **AND**

(3) The waiver is not inconsistent with Federal, State or local law

*The choice of an appropriate mechanism depends 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. (46.408(c)

Minor's Assess to Reproductive Health Care in Georgia

A minor who understands the risks, benefits and proposed alternatives to certain health services may give informed consent. (without parental permission)

- Contraceptive Care and Counseling
- Emergency Contraception
- All health care services related to pregnancy
- Testing and treatment for an STD
- HIV testing
- Substance abuse

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Takeaways…

As an IRB, perhaps we should take some of this information and determine how we may want to consider these minors and their rights.

Discussion…