Research with Children - SBE

Content Author

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Introduction

Based on concerns for the welfare of children as research subjects, protections for children that exceed those for adults were incorporated into the federal regulations for protecting research subjects. At the same time, regulators recognized that some research presents no more than minimal risk to children and allowed for flexibility in the parental permission and child assent processes.

This module will describe both the required additional protections and the options for flexible application of the federal regulations.

In addition, it includes a case study about a waiver of parental permission for children to participate in research.

Learning Objectives

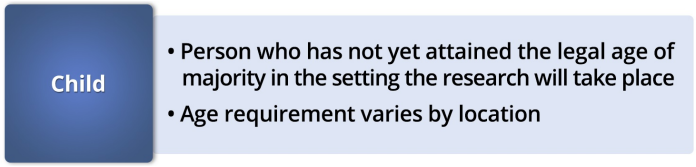
By the end of this module, you should be able to:

- Know how the federal regulations define "children."
- Identify the federal regulations for protecting research subjects that apply to research with children.
- Describe when research with children may be exempt from the federal regulations and when it may be expedited.
- Outline the parental permission and child assent processes.
- Apply the criteria for waivers of parental permission and child assent.
- Describe the requirements for documenting parental permission and child assent.

Defining Children

According to the federal regulations, children are persons who have not yet attained

the legal age of consent under the applicable laws in the setting in which the research will take place (Protection of Human Subjects 2018). Generally, though not always, the age of consent is the age at which minors reach the age of majority and are considered adults.



In the U.S., state law dictates the age of majority. In most, but not all states, the age of majority is 18. This means that a 17-year-old may be considered a child when applying the federal regulations for protecting research subjects. In Alabama and Nebraska, the age of majority is 19 and in Mississippi it is 21. Some states have a legal process of emancipation that confers adult status on those who are younger than the age of majority. The conditions under which children may be released from parental authority vary by state. In some states, emancipated minors may have the legal authority to provide permission for their own children to become research subjects, but may not be able to consent for themselves unless an Institutional Review Board (IRB) waives the requirement for parental permission.

The age of majority may be quite different in other countries. It also is possible that a country may have no legal definition of "majority." In such cases, researchers have to rely on community standards and practices to determine whether subjects are considered children or adults.

Regulations That Apply to Research with Children

There may be many layers of regulations and policies when children are involved as subjects in research, including federal regulations, state and local law, and institutional policies.

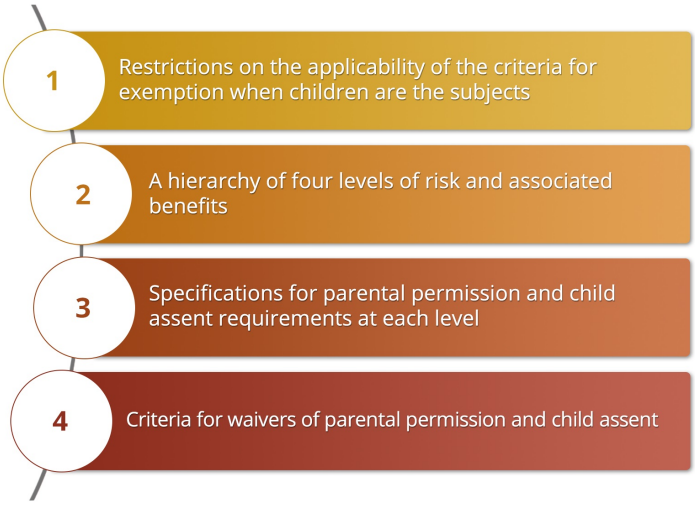
1. The basic federal regulations for protecting research subjects, known as the Common Rule (45 CFR 46, Subpart A), have been adopted by numerous federal agencies and departments.
2. The provisions of Subpart D, of the HHS regulations, "Additional Protections for Children Involved as Subjects in Research."

   The provisions of Subpart D must be applied to all research funded by U.S. Department of Health and Human Services (HHS). However, some federal agencies have agreed to apply the provisions of the Common Rule to research with human

   subjects, but not the provisions of Subpart D. In that case, institutional policies will

regulate research with children. It is important to always check with the reviewing IRB and the institutional policy for research involving children as subjects.

Subpart D includes:



3. State and local law, and institutional policy, as applicable. For example, provisions for waiving parental permission for neglected or abused children cannot violate federal, state, or local law.

Exempt Research with Children as Subjects

The Common Rule describes activities that meet the definition of research with human subjects but are not subject to the provisions of the rule. Subpart D restricts the use of exemptions with children as subjects. Only Exempt Categories 1, 4, 5, 6, 7, and 8 may be applied to research subject to Subpart D if the conditions of the exemption are met.

Exempt Category 2 parts (i) and (ii) may only apply for research involving educational tests or observation of public behavior when the investigator does not participate in the activities being observed. Exempt Category 2 part (iii) may not be applied to research subject to Subpart D, nor may Exempt Category 3 (research involving benign behavioral interventions with adults).

The exemption categories that may be used under 46.104 with children when the conditions of the exemption are met are:

Category 1	**Research conducted in established or commonly accepted educational settings, specifically involving normal educational practices that are not likely to adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction.**
Category 4	Secondary research for which consent is not required.
Category 5	Studies conducted by federal departments or agencies about government programs (such as, welfare programs).
Category 6	Taste and food quality evaluations, and consumer acceptance studies under some circumstances.
Category 7	Storage or maintenance for secondary research for which broad consent is required.

	broad consent is required.
Category 8	Secondary research for which broad consent is required.

Limitations to Exempt Research

Exempt Category 2 under parts (i) and (ii) can be used for research with children under specific circumstances.

Limitations for Category 2 research subject to Subpart D include:

- Research activities are limited to educational tests and observation of public behavior
- If the research involves observation of public behavior, the researcher does not participate in the activities being observed
- Research approved with a limited IRB review under part (iii) of Category 2 (which involves recording information in such a manner that the identity of the subjects can be readily ascertained) is not permitted

Research involving benign behavioral interventions (Category 3), in conjunction with the collection of information, **cannot** be exempt for children as it is applicable only for adult subjects.

Expedited Review When Children Are Subjects

Expedited review is an option when the research activities pose no more than minimal risk to subjects and fall within **one or more of the explicitly defined categories of activity**.

With the exception of limits on the amount and frequency of blood that may be drawn from children, there are no regulatory restrictions on using the expedited review process when children (minors) are subjects.

Parental Permission and Child Assent

Parental permission is generally required when children participate in research as subjects.

The General Process

By definition, children are unable to provide informed consent to participate in research. The basic model when working with children is that parents (or legal guardians) provide permission for their children (or wards) to participate in research and then subsequent to the parental permission the researcher contacts the children. Children then provide their assent to become subjects. Assent is a child's affirmative agreement to participate. The absence of dissent should not be construed as assent when the child is old enough that assent is meaningful. Generally, parental permission can only override a child's dissent when the health of the child is at stake.

Although particulars vary, it generally is assumed that children have limited rights to decide what will happen to them, based on their age and maturity. At one end of the age and maturity continuum are infants and toddlers, who are not capable of making a

decision about whether to participate, although they may communicate their dissent if

they become distressed. At the other end of the continuum are older adolescents who are capable of both making a decision and actively assenting or dissenting to participate in research.

No guidelines can replace a researcher's knowledge about the children to be recruited for a study. Researchers should be prepared to support their proposed assent process either with data or experience-based evidence, particularly if the children involved have vulnerabilities other than their youth, or live in a country, community, or society unfamiliar to the IRB.

Child Assent

Federal regulations specify what kinds of information should be included in an adult consent process. Subpart D notes that the same kinds of information should be provided to parents when asking them to provide permission for their children to be research subjects. However, there are no regulations about the content of the child assent process.

A number of factors should be considered when developing child assent processes, including the proposed research activity and the age and maturity of the children involved. When research activities involve adolescents, whose capacity to understand resembles that of adults, the assent procedure should be similar to informed consent procedures designed for adults. If children's age and maturity level limit their ability to fully comprehend the nature of the research activity, but they are still capable of being consulted about participation in research, the assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.

If a study involves children of different ages, appropriate assent processes need to be developed for each age group.

Cultural Differences

Researchers may need to take into account the nationality, ethnicity, and socioeconomic status of their potential subjects in order to design appropriate parental permission and child assent processes.

Cultural assumptions about the rights of children vary widely. In some countries or subgroups, it may be inappropriate and perhaps offensive to ask children to make research-related decisions.

Longitudinal Studies

In order to respect the emerging maturity and autonomy of children and adolescents in longitudinal studies, some researchers advocate revising the child assent process as the child grows older, providing more detail about the study, and reaffirming assent. Once children reach the age of majority they may sign a consent form for adults.

Risk Level, Parental Permission, and Child Assent

As the risk level of the research increases, Subpart D has increasing requirements for parental permission and child assent.

Categorizing Risk Level

Subpart D divides research with children into four categories of risk and related benefits. Each category carries specific review requirements, as well as parental permission and child assent requirements. As levels of risk increase and benefits to individual children decrease, review criteria become more stringent, and the requirements for permission and assent increase.

Category	Parental Permission / Child Assent Requirements	Risk/Potential Benefit to Child
46.404	At least one parent*	No more than minimal risk
46.405	At least one parent*	Greater than minimal risk with the prospect of direct benefit
46.406	Both parents**	Greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition
46.407	Both parents**	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children

***** The IRB may find that permission of one parent is sufficient.
****** Research falling under 46.406-7 requires permission to be obtained from both parents, 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.

Note: The IRB shall determine that adequate provisions are made for soliciting the child's assent, when in the IRB's judgment the child is capable of providing assent.

Most research in the social, behavioral, and educational sciences will fall in two of the four categories:

- The first is research with no more than minimal risk (46.404)
- The second is research with more than minimal risk that has the prospect of directly benefiting the children, provided the risk is justified in relation to the anticipated benefits (46.405)

The requirements for parental permission and child assent are the same for both categories: the permission of one parent and assent of the child, as appropriate.

The definition of minimal risk for children is the same as the definition for adults.

Minimal Risk:

- The probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical or psychological examinations or tests (Protection of Human Subjects 2018)
- "Daily life" refers to the daily life of normal children.

The remaining two categories (46.406 and 46.407) are relevant for health-related research with greater than minimal risk and no prospect of direct benefit to the children and, finally, research that is not otherwise approvable, but may provide an

opportunity to understand, prevent, or alleviate a serious problem affecting the health

or welfare of children.

Wards

When the research includes children who are wards of the state or any other institution or entity, there are additional considerations required by HHS regulations. Pursuant to 46.409, before wards can be included in research that is greater than minimal risk and approved by an IRB pursuant to 46.406 or 407 (and referred to the Secretary of HHS if under 407), it must meet the following conditions:

- The research must be either related to the children's status as wards; or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
- The IRB must 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.

State laws and institutional policies may dictate additional protections for wards as well.

Documentation of Parental Permission and Child Assent

There are documentation requirements when obtaining parental permission and child assent.

Child Assent

IRBs have the authority to determine the appropriate manner, if any, of documenting child assent. Based on such considerations as the child's age, maturity, and degree of literacy, the IRB should decide what form of documentation, if any, is most appropriate. If adolescents are involved in research where a consent form would have been used if the subjects were adults, it generally would be appropriate to use a similar form to document an adolescent's assent. If young children are involved who are as yet unable to read, documentation should take a form that is appropriate for the purpose of recording that assent took place.

Parent or Guardian Permission

Documentation of parental or guardian permission for children to become research subjects is required unless waived by an IRB in accordance with the regulations.

Waivers of the requirement to document parental or guardian permission may be approved by an IRB in accordance with the same regulations that govern waivers of the requirement to document adult consent. Therefore, such waivers may be permitted under the following three conditions:

- The documentation of consent (informed consent form) is the only record linking the child to the research, and the principal risk would be potential harm resulting from a breach of confidentiality. If subjects wish to have a signed consent form, their wishes will govern.
- The research presents no more than minimal risk of harm and involves no

procedures for which consent is normally required outside the research environment.

- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

When the requirement for documentation is waived, the IRB may require the researcher to present each subject (or parent or guardian) with a written statement regarding the research.

Waivers of Parental Permission and Child Assent

An IRB may waive the requirement to secure child assent if either:

1. The capability of some or all of the children is so limited that they cannot reasonably be consulted.
2. The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.

The IRB may also waive the assent requirement if the research meets the same criteria as for waivers of informed consent for adults.

The same criteria may be used for waivers of the requirement to secure parental permission.

Both the Common Rule and Subpart D include provisions for waiving the requirement to secure parental or guardian permission if an IRB determines that the research is designed for conditions or for a subject population for which permission is not a reasonable requirement to protect the subjects. However, an appropriate mechanism must be in place to protect the children and the waiver needs to be consistent with federal, state, or local law. For example, an important area of inquiry is why and how certain teenagers come to live on the streets. An anthropologist wishing to interview teenagers who are runaways or who have severed ties with their families could not do so if parental permission was required.

It is also important to note that there are different criteria for a public benefit or service program.

Waiver of Parental Permission

Summary

The federal regulations include special protections for children that include specific criteria for the kinds of review that may be used. When conducting research with children, researchers must develop parental permission and appropriate child assent processes. Requests to waive the requirements to secure parental permission and child

assent, and the requirement to document parental permission may be approved by an

IRB.

Reference

- Protection of Human Subjects, 45 CFR § 46 (2018).

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