
Research with Children

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This module has 6 parts and will require 15 to 20 minutes to complete. Take the short quiz at the end of the module before proceeding to the next module.

Introduction

Conducting research with children presents unique challenges both for investigators and for the Institutional Review Board (IRB) reviewing the research. One of the basic tenets of research with human subjects is that participation should be based on an informed and voluntary decision. Therefore, children's assent to participate in research should be solicited when children are capable of providing it.



Another basic tenet of research with human subjects is that the risks must be reasonable in relationship to anticipated benefits. This balance must be applied carefully when dealing with children. In fact, federal regulations identify children as vulnerable subjects and include extra protections for them. These protections prescribe levels of review based on the balance of possible risks and potential benefits.

The regulations do allow for flexibility in the review and consent processes when the research carries no more than minimal risk for children. Research with children may qualify for exempt or expedited review. Also, in some circumstances, parental permission and child assent may not be required.

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6. Documentation of consent.

1.0 Regulations That Apply to Research with Children

1. The basic federal regulations for protecting research subjects known as the Common Rule: Department of Health and Human Services (DHHS) Regulations, Subpart A, adopted by numerous federal agencies and departments.



2. The provisions of Subpart D, of the DHHS regulations, Additional Protections for Children Involved as Subjects in Research.

The provisions of Subpart D must be applied to all research funded by the DHHS. However, not all federal agencies that have adopted the Common Rule have also adopted Subpart D. Only the Food and Drug Administration and the Department of Education have adopted it. Institutions may elect to apply the subpart to all research, regardless of the source of funding.

Subpart D includes:

- Restrictions on the applicability of the criteria for exemption when children are the subjects.
 - A hierarchy of four levels of risk and associated benefits.
 - Specifications for parental permission and child assent requirements at each level.
 - Criteria for waivers of parental permission and child assent.
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. The permissibility of such waivers may also be governed by institutional policies.

2.0 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 jurisdiction in which the research will be conducted. In the United States, state law dictates the age of majority. In most states, the age of majority is 18, but there are exceptions.

Investigators should be aware that the age of majority might be quite different in other countries. It is also possible that a nation may have no legal definition of majority. In such cases investigators will have to rely on community standards. For example, a researcher in Sierra Leone found that adulthood for the male population he wished to study was conferred through a Shamanic initiation process.

In the United States, 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 from state to state. Depending upon state law, emancipated minors may have the legal authority to provide permission for their children to become research subjects. Consult with your IRB if these issues are relevant to your research.



3.0 Exempt Research with Children as Subjects

The Common Rule describes activities that, although they **do** meet the definition of research with human subjects, are **not** subject to the provisions of the rule. Research eligible for exemption must include only activities that fall in one or more of [six categories](#). (Following a link will open a new window in your browser. To return to the module, close the new window.)

Subpart D restricts the use of exemptions with children as subjects.

The exemption categories that may be used with children include:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
2. Research about educational tests.
3. Observations of children in public settings when the researchers do not interact with the subjects.
4. Studies using existing data about children, (a) if the data are publicly

available, or (b) if they are recorded in such a way by the investigator that the identity of the children cannot be determined either directly or indirectly.

5. Studies conducted by federal departments or agencies about government programs, such as welfare programs.
6. Taste and food quality evaluations and consumer acceptance studies, under some circumstances.

According to Subpart D, exemptions may **not** be used for any of the following:

1. Research involving interviews.
2. Research involving surveys.
3. Observation in which the researcher participates in the activities observed.

Note: Consult your IRB about your institution's exemption policies and procedures.

4.0 Expedited Review When Children Are Subjects

With one exception for blood draws, there are no regulatory restrictions on using the expedited review process when children are subjects. Expedited review is an option when the research activities pose no more than minimal risk to subjects and fall within explicitly defined categories of activity.



Institutions are free to have more restrictive policies.

5.0 Parental Permission and Child Assent

5.1 The General Process

The basic consent model when working with children is that parents (or legal guardians) provide permission for their children (or wards) to participate in research and for the researcher to contact 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. Generally, parental permission can only override a child's dissent when the health of the child is at stake.

Although particulars vary, it is generally assumed that children have limited rights to decide what will happen to them, based on their age and maturity. On one end of the age and maturity continuum are toddlers who are not capable of making a decision about whether to participate, although they may evidence dissent if they become distressed. On the other end of the continuum are older adolescents who are both capable of making a decision and actively assenting or dissenting to participate in research.

5.2 How Much Information to Give Children

The federal regulations specifying what must be included in an adult consent process also apply to the parental permission process. However, there are no regulations that define the content of the child assent process.

Research about children's decision-making skills supports the common institutional practice of defining different assent processes for children and for adolescents, with the level of disclosure increasing as children grow older. Mature adolescents should generally be provided with study information

comparable to that provided to adults.

Many institutions provide general guidelines for the assent process, suggesting appropriate methods for securing assent for children of various ages. These may include oral presentations and simple written assent forms.



Obviously, no guidelines can replace an investigator's knowledge about the children to be recruited for a study. Investigators should be prepared to support their 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.

5.3 Cultural Differences

Investigators may need to take into account the nationality, ethnicity, and socio-economic status of their potential subjects in order to design appropriate permission and 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.

5.4 Longitudinal Studies

In order to respect the emerging maturity and autonomy of child and adolescent subjects, some investigators advocate revising the assent and permission processes appropriately and reaffirming assent as the child grows older. Once the child reaches the age of majority (typically 18) he or she may sign a consent form for adults.

5.5 Parental Permission, Child Assent, and Risk Level

Categorizing Risk Level

According to Subpart D, research with children can be divided 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.

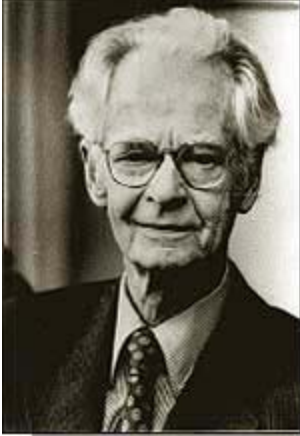


Most research in the social and behavioral sciences will fall into the first two of the four research categories.

1. **Research with no more than minimal risk.**⁽¹⁾ Adequate provisions must be made for securing permission of one parent and assent of the child, as appropriate. The regulations allow for waivers of some or all of the provisions of consent parental permission and child assent, under defined circumstances (see section 5.6).
2. **Research involving more than minimal risk but presenting the prospect of direct benefit to the children participating in the study.** The parental permission and child assent requirements are the same as those for studies with no more than minimal risk. The risk must be justified in relationship to the anticipated benefits.

The two remaining categories primarily cover research on therapy for a disease or condition. They are:

1. 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.
2. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.



5.6 Waivers of Parental Permission and Child Assent

An IRB may decide that child assent is not required because a child is not capable of providing assent. The regulations offer the following guideline: "In determining whether children are capable of assenting, the IRB should take into account the ages, maturity, and psychological status of the children involved."

In addition, Subpart D allows waivers of some or all of the required elements of consent for the parental permission and child assent processes, according to criteria established in the Common Rule. The criteria are:

1. The research involves no more than minimal risk to subjects.
2. The waiver will not adversely affect the rights and welfare of the subjects.
3. The research could not practicably be carried out without the waiver.
4. Whenever appropriate, the subjects will be debriefed after the study.

In addition to permitting waivers of parental permission and child assent in accordance with the Common Rule, Subpart D provides additional leeway in waiving parental or guardian permission if an IRB determines that a research protocol is designed for conditions or for a subject population for which permission is not a reasonable requirement to protect the subjects. 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 were required.

Case Study: Waiver of Parental Permission

Prevention of Sexually Transmitted Diseases (STDs) in Adolescents

Investigators wish to contact minors who have accessed the services of a clinic for treatment of STDs. In the state in which the research is being conducted, minors are legally permitted to access these services without parental consent. The goal of the research is to identify the kinds of information the teenagers had before they acquired the STD and whether and how possessing the information affected their sexual behavior. The researchers are asking for a waiver of parental permission to talk with the teenagers who respond to their recruitment efforts. The request is based on the grounds that if parental permission were

required, it would pose a serious threat to the subjects' privacy and further, the adolescents' concerns about potential loss of confidentiality would limit enrollment and make the research impracticable.

Based on the regulations, the following questions would have to be asked to determine whether the study meets the criteria for a waiver of parental permission:

1. Is the level of risk more than minimal?

- ▶ **Answer:** The investigators want to interview teenagers who have already sought treatment. The research does not involve treatment, but is limited to evaluation. Demographics will not be collected. Therefore, it can be argued that the probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in daily life; that is, that the research involves no more than minimal risk.

2. Would the waiver affect the rights and welfare of the subjects?

- ▶ **Answer:** Assent will be obtained from the adolescents. Therefore, their right to make decisions about whether they will become research subjects will not be adversely affected. Parents' rights to make decisions about whether their child becomes a research subject, while of concern, are probably limited when adolescents have been granted the right to privacy in certain matters by state law.

3. Could the study practicably be conducted without the waiver?

- ▶ **Answer:** No. If the minors needed to get permission from their parents they would have to reveal that they are sexually active and that they have contracted a venereal disease. While some parents might be aware of their child's health status, the researchers are familiar enough with the community in which the research is taking place to know that this is not likely.

4. Is debriefing possible and will it be conducted?

- ▶ **Answer:** No demographics will be collected for any follow-up. The purpose of the study will be explained in the consent process. Notifying parents after participation would not be helpful and would jeopardize the minors' privacy.

Based on the answers to these questions, an IRB might conclude that parental permission could be waived under the regulations. IRBs could come to different conclusions, based on institutional policy, community standards, and state law. IRBs could require that additional procedures be put in place to protect the

subjects. For example, an IRB could request that a research project have a child advocate who could assess whether an adolescent should participate. This would be someone not associated with the research team and with whom an adolescent could discuss his or her involvement.



6.0 Documentation of Parental Permission and Child Assent

Documentation of parental or guardian permission for children to become research subjects is required in most research. Documentation of child assent is not required by the federal regulations for protecting research subjects. Institutional Review Boards have the discretion to determine the appropriate manner, if any, of documenting child assent.

If adolescents are involved in research where a consent form would have been used if the subjects were adults, it would generally be appropriate to use a similar form to document an adolescent's assent.

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. Thus, such waivers may be permitted under the following two conditions:

1. The documentation of consent 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.
2. The research involves procedures for which consent is not normally required outside the research environment.

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

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Footnote

1. "Minimal risk means that 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." Daily life refers to the daily life of normal children.