There are pending regulatory changes that have a general compliance date of 21 January 2019. This module will be updated in January 2019 to reflect these changes. We invite you to review the **CITI Program's Final Rule Resources** for information on the changes to the Common Rule.

RESEARCH WITH CHILDREN - SBE

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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. 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 United States (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 from state to 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 will have to rely on community standards and practices to determine whether subjects are considered children or adults.

REGULATIONS THAT APPLY TO RESEARCH WITH CHILDREN

1. The basic federal regulations for protecting research subjects known as the Common Rule: U.S. Department of Health and Human Services (HHS) Regulations, Subpart A, 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 the 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.

   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 also may be governed by institutional policies.

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.

The exemption categories that may be used with children are:

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, providing the researcher does not participate in the activities being observed
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 researcher 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 activities when children are the research subjects:

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

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 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

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 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 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 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

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.

Most research in the social and behavioral sciences will fall in two of the four

categories. The first is research with no more than minimal risk. 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. 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 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 (Protection of Human Subjects 2009). "Daily life" refers to the daily life of normal children.

The remaining two categories 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 that may provide an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

WAIVERS OF PARENTAL PERMISSION AND CHILD ASSENT

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

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.

3. The research meets the same criteria as those for waivers or alterations of informed consent for adults, as described in the Common Rule. The criteria are:
   a. The research involves no more than minimal risk to subjects.
   b. The waiver will not adversely affect the rights and welfare of the subjects.
   c. The research could not practicably be carried out without the waiver.
   d. Whenever appropriate, the subjects will be debriefed after the study.

The same criteria may be used for waivers of the requirement to secure parental permission. In addition to permitting waivers of parental permission and child assent in accordance with the Common Rule, Subpart D includes 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, provided that an appropriate mechanism is in place to protect the children, and provided that the waiver is not inconsistent 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.

CASE STUDY: WAIVER OF PARENTAL PERMISSION

Prevention of Sexually Transmitted Diseases (STDs) in Adolescents

Researchers 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 interview teenagers who, based on full disclosure of the study's goals, are willing to take part in the research. 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. No identifiers will be collected.

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?**
    - **Considerations:** The researchers want to interview teenagers who have already sought treatment. The research does not involve medical treatment, but is limited to an interview. The teenagers will be fully informed about the research goals and the kinds of questions they will be asked. Identifiers 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 or routine physical or psychological exams; that is, that the research involves no more than minimal risk.
2. **Would the waiver affect the rights and welfare of the subjects?**
    - **Considerations:** 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 may be 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?**

- **Considerations:** 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, the answer to the question would probably be "no". 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?**

    - **Considerations:** 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.

DOCUMENTATION OF 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, as described below.

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 two conditions:

- 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.
- 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 researcher to present each subject (or parent or guardian) with a written statement regarding the research.

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 45 CFR 46.409, before wards can be included in research that is greater than minimal risk and approved by an IRB pursuant to 45 CFR 46.406 or 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.

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 (2009).

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