

# Special Considerations for the Protection of Children Participating in UT-Sponsored Research

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## Checklist for Protocols Involving Children as Participants

The information in this section is provided to clarify the Form B preparation and review process for researchers who plan to include children as participants in their research projects. This information is intended to facilitate the compliance approval process. If you have additional questions about your research project, please contact the Office of Research Compliance Officer at (865) 974-3466 for further information.

## General Information

Federal regulations [Title 45 CFR Part 46, Subpart D] require that the researchers explicitly address the measures taken to protect the welfare and rights of children participating in research projects. At the University of Tennessee, the adequacy of these measures is assessed by the Institutional Review Board (IRB) during the approval process. Because of the potential vulnerability of children, a higher standard of protection must be demonstrated for approval. **As a result, almost all research** involving children requires expedited or full-IRB review of Form B applications. The only exception to this rule (discussed in part 5 of this section) occurs when the research involves observation of public behavior. All other minimal risk projects that would normally be considered exempt from IRB review (Form A applications) are not exempt when children are involved.

**Please note that you may not initiate contact with potential child-participants, or begin data collection, before you have received final approval from the IRB.**

Although Form B applications take longer to prepare and review than Form A applications, most Form B applications are reviewed and approved within three weeks of

submission. However, the approval process sometimes takes longer than this, especially if significant revisions are required. Therefore, please give yourself adequate time to prepare and submit your application. Please understand that the complexity of your project and the initial quality of your application affect the time required for approval.

The following section addresses several significant areas of concern that commonly arise during IRB reviews of research involving children. When preparing your Form B application, follow the Form B Application Guidelines. Copies of the Form B Application Guidelines are also available from your Departmental Review Committee Chair. If you have additional questions about your specific research project or need further clarification, please contact the Office of Research Compliance Officer located at 1534 White Avenue or by calling (865) 974-3466.

## **1. Identifying and Recruiting Potential Child-Participants**

Clearly describe the methods used to identify and recruit potential child-participants. Describe the measures taken to prevent potential concerns about coercion or breaches of confidentiality in the identification and contact stages of your research project. Copies of notices or advertisements that will be used should be included in your application.

Only after permission from the appropriate authorities has been granted in writing may potential child-participants' identities be obtained from school classrooms, care-giving programs, or other agencies. For example, researchers wishing to study students in public school systems must obtain written permission from the school board or its authorized representative before students can be contacted. This approval cannot be used to require teachers or students to participate.

School board or institutional permission is often conditioned upon IRB approval of your project. If your project must receive approval prior to the granting of any institutional permission, please contact Research Compliance Services. This is a common complication that can be easily remedied without delaying the approval process.

## **2. Consent Procedures**

Federal law recommends the **assent** of the child and requires the **permission** of the parent(s), or guardian(s), in place of consent of the child before a child may be involved in a research project. Research involving "mature" or emancipated minors may not need parental permission, but full IRB committee approval must be obtained to waive the parental permission requirement.

Note: A **guardian** is an individual who is authorized under applicable state or local law to give permission for a child [45 CFR, 46.402(3)].

**Permission** is the explicit agreement of parent(s) or guardian to the participation of their child or ward in research. Failure to object or other forms of passive permission cannot be construed as permission [45 CFR, 46.402(c)].

Both parents must give their permission in any research that places the child-participant at greater than minimal risk [45 CFR, 46.406 and 46.607], unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child [45 CFR 46.408 (b)].

The permission of one parent is sufficient for any research that places that child-participant at no more than minimal risk [45 CFR 46.404]. The UT-IRB may consider that the permission of one parent is sufficient for research involving greater than minimal risk, if there is a clear prospect of direct benefit to the child-participant [45 CFR 46.408 (b)].

The requirement of parental permission may be waived in those cases where it is clear that the parents' interests do not adequately reflect the child's interests (e.g., research on child abuse or neglect). These cases require investigators to develop special procedures, which must be approved by the full IRB, that protect the rights and welfare of the children asked to participate.

When permission is required, the information contained in the permission procedure should include all the elements normally required in an informed consent. (The basic elements of informed consent can be found in the Human Subjects section of the Office of Research Forms web page.)

**Assent** is a child's affirmative agreement to participate in research. Assent is an ethical concept. However, failure to object cannot be construed as assent [45 CFR, 46.402(b)]. Researchers who include children in their research should be especially mindful of the rights of children participating in their research. Even when assent is not required, researchers are asked to demonstrate a good faith effort to enlist the cooperation of children who participate in their research.

It is the responsibility of the IRB to decide if researchers should seek a child's assent as part of a project's consent procedure. The determination of a child's capacity to provide assent is based on the nature of the research, and the child's age (typically the IRB requires assent from children age seven and older), maturity, and psychological state of the population of children from whom participants will be drawn. The decision to require assent depends on the capacity of the children to appreciate the nature, extent, and probable consequences of their participation in a research project.

Assent is especially important in cases where there is no direct benefit to the child-participants. When assent is required, the procedure should include an explanation of the proposed research in language that is appropriate for to the child's age and maturity. The investigator should indicate on their Form B what the children will be told about the research and how the information will be conveyed. The investigator should discuss how the information provided might vary with the age, maturity, and level of experience of the children involved in the study. The assent process should be free from coercion and unfair inducements. All children who are capable of providing assent must be informed

that they are free to withdraw from participation at any time. (A Sample Assent Form can be found in the Human Subjects section of the Office of Research Forms web page.)

### **3. Risk and Benefit Assessment**

#### **Risk Assessment:**

Federal regulations require IRBs to classify research involving children into one of four categories and to document their discussions of the risks and benefits of the proposed research study. **The four categories of research involving children that may be approved by the UT-IRB, based on degree of risk and benefit to individual participants are as follows:**

1) Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.404].

Examples of research in this category might include: research on children's attitudes about food preferences, surveys about play activities, etc.

2) Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual participant. Research in this category is approvable provided: (a) the risk is justified by the anticipated benefit to the participant; and (b) the relationship of risk to benefit is at least favorable as any available alternative approach [45 CFR 46.405].

Examples of research in this category might include: research on the coping strategies of children living in foster care, or research on the effectiveness of drug-use intervention programs for children testing positive for drug use.

3) Research involving greater than minimal risk, with no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition is approvable provided: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings; and (c) the intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition that is of vital importance for the understanding or amelioration of the participant's disorder or condition [45 CFR 46.406].

Examples of research in this category might include: research using abused children that is designed to identify early warning signs of potential abuse in the general population of school-aged children; or research on the effectiveness of corporal punishment.

4) Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of

children. Research that is not approvable under 45 CFR 46.604, 46.405, or 46.606 may be conducted or funded by DHHS provided that the IRB, and the Secretary, after consultation with a panel of experts, finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health or welfare of children. The panel of experts must also find that the research will be conducted in accordance with sound ethical principles [45 CFR 46.407].

No examples of research in this category are provided because projects in this category are unique and require federal approval.

Assessing probable risks is a central consideration of the IRB's approval process. The assessment of the probability and magnitude of the risk may differ depending on conditions child-participants may have. The issue of what is considered "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations" may vary depending on the circumstances or conditions of the population from which the children are drawn. The IRB considers the extent to which research procedures would be a burden to a child. Behavioral interventions likely to cause psychological stress may be considered to exceed minimal risk.

#### **Benefit Assessment:**

Carefully identify and describe all reasonably anticipated benefits that may be received by child-participants. As noted in the risk assessment subsection, anticipated benefits to child-participants must exceed anticipated risks when research procedures expose child-participants to greater than minimal risk.

#### **4. Use of Educational Records**

Federal law [34 CFR 99, 99.03 through 99.37] governs the privacy and access to elementary and secondary school records. The primary rights of access to these records are given to parents, guardians, and to students (once they have reached 18 years of age). Except for administrative purposes, schools must withhold access to personally identifiable information from educational records except with the written permission of the students' parents, or students once they have reached 18 years of age. To be valid, a written consent for disclosure of educational records must include three items: a specification of the records to be disclosed, the purpose(s) of the disclosure, and the party or class of parties to whom the disclosure will be made.

The requirement for written permission applies to all research, except that conducted by or for educational agencies or institutions developing, validating, or administering predictive tests, administering student aid, or improving instruction (provided such studies will not permit the identification of individual students and that personally identifying data will be destroyed upon completion of the study).

#### **5. Exempt Research Involving Children**

At this time, the only research procedure involving child-participants exempt from IRB review (Form A is the appropriate application form) is observation of public behavior. The definition of observation of public behavior requires that researchers not interact in anyway with the children, record their identities (this includes the use of audio- and videotaping procedures), or place the children at risk.

### **Examples of Cases When the IRB Exemption Involving Children Does Not Apply**

The observation of public behavior exemption does **not** apply when a) the child-participants have a reasonable expectation of privacy (e.g., a private conversation in a public park); b) survey instruments are used (this would constitute an interaction, even if conducted by an independent third-party, such as a teacher); and c) the researcher rearranges or changes the setting/environment in which the public observation takes place.

### **Quick Checklist for Protocols Involving Children as Participants**

If you have questions as you prepare your Form B, please contact the Office of Research Compliance Officer located at 1534 White Avenue or by calling (865) 974-3466.

1. Are you preparing a Form B application?
  - 2a. If your project involves greater than minimal risk to children who participate in your project, then your Form B application will require a full IRB committee review. Allow sufficient time for the preparation and review of your Form B.
  - 2b. If your project involves less than minimal risk to children who participate in your project, then your Form B application may receive an expedited review.
3. Have you adequately described your methodology and procedures using nontechnical language?
4. Have you clearly identified your methods for identifying and recruiting children?
5. Do you intend to recruit children through schools, or conduct your research at schools? If so, your Form B should include written permission to approach children and teachers from the school board and principals in the schools you are targeting.
6. Have you described your parental consent procedures and included a copy of the parental/guardian's informed consent form in your Form B? If a waiver of parental permission is requested, provide justification.
7. Have you described your child assent procedures? Assent should be sought from children seven years-old and older. If a waiver of children's assent is requested, provide justification.

8. Have you included an assessment of the probable risks and benefits anticipated in your research?

9. Are you planning to use information from school records? If so, have you included a written consent for disclosure of educational records that specifies the records to be disclosed, the purpose(s) of the disclosure, and the party or class of parties to whom the disclosure will be made.