University of South Alabama
Institutional Review Board

- Determine the study risk level by identifying what permissible categ
meets in order to approve the research. Permissible categ
from the Subpart D regulations.
- How are study procedures different from standard of care for the subjects?
- What are consent (e.g., parental permission and assent) requirements for t

Submission Requirements:

IRB Review of Research Involving Children– Determinations:

Federal regulations classify permissible research involving minors into four categories, based on degree of risk and type of prospective benefit. These categories are described in terms of "minimal risk".

> Minimal risk is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life

> Greater than minimal risk is a term used in defining Category 2 [45 CFR 46.405] and Category 3 [45 CFR 46.406]. The regulations do not provide any further definition regarding the level of risk. Therefore, the investigator's assessment, based on the study risks

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Federal regulations and institutional policies do not prohibit children who are “wards of the state or any other agency, institution, or entity” from research participation. However, permission must be obtained from the legal guardian which is usually the agency or court, not a foster .004 Tc l-2 (-6 (ga)4 (l)

1. In most cases, parental consent must be obtained if the research involves minors under the age of 19. The requirement for parental consent may be inappropriate in some cases such as research on child abuse.

2. Minors 6 years of age or younger, verbal or written assent is typically not required. Consent is based on the permission of the parent(s)/guardian(s) and no assent is required. A brief verbal explanation of the research procedure should be explained to the child.

3. Minors 7 years or older should be involved in the decision to participate in a research projects unless: a) the subject is not capable or mentally/emotionally, of being consulted, b) the IRB specifically waives the requirement.

4. It is highly encouraged that a separate written assent form be used for children 7 years -12 years old to document assent. In general, it should briefly explain in basic terms:
   - they are being asked to participate in a research study;
   - the purpose of the study;
   - an estimate of how much time is involved in participating;
   - what will happen to them if they agree to participate (e.g., 'draw some blood');
   - foreseeable risks/discomfort and any benefits they may experience;
   - they should ask their parents and doctor/researcher any questions they have about participation;
   - participation is voluntary and they can withdraw at any time

5. Typically, adolescents 13-18 years old should be fully informed about a study and give assent to their own participation in the research. In the instance, both the adolescent and the parents(s)/guardian(s) sign the form, with a signature line for the adolescent first. The signature line for parental consent/permission should follow.

6. NOTE: Assent expires when a child becomes a adult. At that time the subject must sign the IRB approved adult consent for the research study.

Federal regulations do not provide specific information on parental permission/child assent. However, they do provide parental permission requirements. In addition, they also charge that "adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent in taking into account the ages, maturity, and psychological state of the children involved" [45 CFR 46.408]

Request for Waiver of Assent (45 CFR 46.408 and 46.116, Subpart A)

There are three circumstances in which the IRB may waive assent for children to be enrolled in a research study. This judgment may be made for all children participating in the study, or for each child, as the IRB deems appropriate. The investigator must [(e95 (gat)3 ()-1 (t)-2 (ud)-10 (y)20 (, or)9)]TJ

When it is evident that the intervention/procedure involved in the research shows a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research.

When the intervention/procedure involved in the research shows a prospect of direct benefit to the child and the protocol has a risk level similar to standard treatment.