Guidance Regarding Use of Children as Research Subjects

This guidance applies to researchers gathering data through either direct interaction/intervention with children, or when gathering data about children via third parties (e.g. parent or teacher reports of children's behavior).

1. **How are "children" defined for research purposes?**
   People under the age of 18 are considered children. When conducting research using children as subjects, special protections are required as children are not considered capable of providing legally binding informed consent.

2. **What categories of research involving children can the Butler University IRB approve?**
   Due to children's vulnerability, Butler University requires researchers to follow all regulatory procedures as outlined in section 45 CFR 46.407 of the Code of Federal Regulations, U.S. Department of Health and Human Services. The Butler IRB must determine the appropriate risk-benefit designation per research proposal. For non-exempt research, investigators are required to complete the "Children as research subjects form" available at: https://www.butler.edu/osp/irb.

   - Research not involving greater than minimal risk (45 CFR 46.404)*:
     - "Minimal risk" means 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 or during the performance or routine physical or psychological examinations or tests.

   - Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual participants will be approved by the IRB only if:
     - The risk is justified by the anticipated benefit to the subjects.
     - The relation of the anticipated benefits to the risk is at least as favorable to the subjects as that presented by available alternative approaches (45 CFR 46.405)*.

   - Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's condition will be approved only if:
     - The risk represents a minor increase over minimal risk.
     - 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 situations.
     - The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition, which is of vital importance for understanding the participant's condition [45 CFR 46.406]*.

3. **What is "assent?"**
   "Assent" is a child's affirmative agreement to participate in research. (45 CFR 46.402(b))*. When participants in non-exempt research are between the ages of 7-17, the IRB requires a participant assent process after parental consent has been granted.

4. How do children provide assent?

Assent can be presented in oral and/or written format, depending on the age, psychological state, and/or maturity of the child.

5. What are the age guidelines when obtaining assent?

- Seven and younger: Unless specifically required by the IRB during its protocol review and approval process, no formal assent process is required for children under seven years of age. As appropriate, the researcher may ask the child if he/she wishes to play a game or complete some other activity, but generally speaking, children this young exhibit their assent or refusal to participate through their behavior.
- Ages 7-13: A conversation in age-appropriate language should be used, and the child should affirmatively assent to participate in the research. If a written assent document is to be used, it should be written using language which can be understood by the youngest potential subjects.
- Ages 14-17: Informed consent documents should be written at an 8th grade level, allowing children ages 14-17 to understand content of consent documents. Study teams are encouraged to use the informed consent document when obtaining assent adolescents from ages 14 and up. If an informed consent document will be used for children ages 14-17 to obtain assent to participate, appropriate signature lines should be included for both the child and his/her parent(s)/guardian(s), and appropriate language (such as "you" or "your child") should be used throughout the informed consent form. The child may indicate assent by signing the informed consent document.

6. What do I do if parents provide consent for the children to participate, but the minor does not provide assent?

Failure of children to object does not equal assent. Sometimes parents and children may not agree on whether the children should participate in research. Some children may be unwilling to assent to participation in research, even after their parents have given consent. In these cases, the investigator is bound by the child's wishes. If a child refuses assent, the child cannot participate in the research unless the IRB has provided a waiver of assent. Even when subjects are capable of assent, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with the normal policies for waiver of informed consent.

7. What are requirements for parental/guardian consent in the context of research involving children?

- Adequate provisions must be made for soliciting the consent of each child's parent(s) or guardian(s).
- When parental or guardian consent is required, consent of one parent may be sufficient.
- When more than minimal risk is involved in research, both parents or guardians must give their consent, unless one is deceased, unknown, legally incompetent, not reasonably available, or when only one parent has the legal responsibility for the care and custody of the child.
- In situations during which consent is not a reasonable requirement (such as in the case of child abuse), consent from parents or guardians may be waived, as long as another appropriate mechanism for protecting the child is included.

Only parents and legal guardians have the legal authority and responsibility to provide consent. Consent from caregivers and/or service providers is not sufficient to legally conduct research involving minors. School principals, teachers, clinical personnel, etc. do not have the authority to give "blanket" consent for their students, patients, or clients to participate in research.

8. How should I deal with cases of child abuse and neglect?

Indiana law states that individuals who have reason to believe a child has been abused or neglected are required to report that suspicion to the individual in charge of their institution, facility, or agency, and to local law enforcement or child protection services. The following statement should appear under the confidentiality section of all informed consent documents involving research studies conducted with children: "*If the researchers learn that you or someone with whom you are involved is in serious danger of harm they will need to inform the appropriate agencies as required by Indiana law*." There may be instances where alternate language is appropriate.

Templates for Butler University's consent and assent forms can be found at: www.butler.edu/osp/irb.
* See Code of Federal Regulations, U.S. Department of Health and Human Services www.hhs.gov.