Research Involving Children

Research studies involving children or individuals from vulnerable populations should be submitted for full review so the IRB has sufficient information to determine risk/benefit.

The IRB will only approve research involving not greater than minimal risk to children that also satisfies all the conditions of additional protections for children.

Parents or guardians must give their permission (consent) for their children to participate in research.

Protocols for research involving children that use a passive parental consent procedure will not be approved.

Parental consent forms must not be unduly long, must be written in terms understandable to the general population, and must include all appropriate details about the research that are most relevant to the parent's decision to allow a child to participate in the study.

Children must give their agreement (assent) to participate in research.

When reviewing whether adequate provisions have been made for soliciting assent, the IRB will review the procedures and assent form taking into account the age, maturity and psychological state of the children involved (see guidelines below).

Guidelines for Obtaining Consent / Assent

Consent for involvement of a child in a research study is a two-stage process. The first stage is obtaining parental consent (throughout these guidelines "parent" also denotes "guardian"). Researchers must obtain and retain for each child involved in a study a signed parental consent form. This parental consent must be obtained before a researcher may approach a child to solicit the child's assent (stage two).

Parental Consent

A "passive" parental consent procedure, also called an "opt-out" procedure, typically involves distributing a letter to the child's parents describing the study and instructing them to return the form only if

they do not want their child to participate. Wenzhou-Kean University IRB will not approve protocols for research involving children that use a passive parental consent procedure.

The parental consent form must contain the same elements as a typical consent form (sample here) and be addressed to the parent(s). The wording of the parental consent document should be appropriate to the typical educational background of the research population.

Parents must be informed that participation in a research study is separate from instruction, and that refusal to allow their child to participate, or withdrawing their child from participation, will not in any way affect their child's grade, class standing, or participation in standard educational activities.

Assent

"Assent is a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent" [45 CFR 46.402(b)]

Researchers should solicit assent directly from children and in an environment/setting that minimizes influence, or the perception of influence, from parents or persons of authority.

Researchers may provide less detailed explanations to younger children and more detailed explanations to older children.

Assent forms should be written at a level of education and maturity appropriate to the youngest potential subjects in the age range, and the information delivered using suitable methods. In most cases, 7 years of age is a reasonable minimum for a child with normal cognitive development to be capable of participating in a meaningful written assent process. A researcher may need to be flexible in the approaches for obtaining assent; a single method of obtaining assent may not be appropriate for all potential subjects.

The means of obtaining assent from children must not only be age-appropriate but also must be developmentally-appropriate for the proposed population. "Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is

always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. Special provision may need to be made when comprehension is severely limited — for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disabled patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research."2

The age ranges below apply to typically-developing children.

Age of Child Participant	Written Assent Form	Parental Consent Form
Toddler – 6 years old	No – submit verbal script	Yes
School age 7 – 13	Yes – age appropriate	Yes
Adolescent 14 -17	Yes – similar to adult ICF	Yes
18 and older	Yes	No

Examples of Assent:

Very young children: Researchers should give explanations that match the level of understanding for children below school age (toddlers, preschoolers). A simple oral request for assent is sufficient, and assent may be oral. The protocol must include the procedure for documenting a "yes" or "no" response. The verbal script is considered the assent form and must be submitted as part of the protocol.

For example, the researcher might ask the child if he or she would join the researcher in the next room to look at pictures. If the child were to say "yes", that would imply assent for this age group. If the child were to say "no", the researcher should respect the child's wishes. It should be possible, however, to ask the child once again several minutes later.

Sometimes children may not communicate verbally their refusal to participate. For example, a child may begin working on another task unrelated to the research activity. The researcher should be aware of such a cue and end the activity. The researcher must use special

care to discontinue the participation of any child who appears to experience undue stress from the research procedure.

Sample Child Assent Script (ages 6 and younger) developed by Smith College IRB

Sample Assent Script with documentation of yes/no response (ages 6 and younger) adapted from Northwestern University IRB

Children ages 7-13: The request for assent should include: (1) a general description of the purpose of the child's participation; (2) a brief description of the experimental tasks/participation; (3) an assurance that the child's participation is voluntary and that he or she may withdraw from the study at any point; and (4) an offer to answer questions. A researcher studying reading comprehension might say the following: "I am studying how fourth grade students read. I am going to ask you to read a few stories for me and answer questions about the stories when you are finished. You don't have to read if you do not want to do so. If at any point you want to stop, that is fine; you may stop and go back to class." Written assent should be obtained.

Assent Form Template developed by Seattle Children's Hospital for children 7-13 years of age who can read

Sample Child Assent Form developed by Cornell University IRB

Sample Child Assent Form (ages 7-13) developed by Smith College IRB

Adolescents ages 14 -17: The request for assent should include the elements of informed consent presented to adults, but presented in language appropriate to the child's level of comprehension. Written assent should be obtained.

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1 Some of this material was developed by the Research Integrity Services staff, University of New Hampshire, and is used with permission.

2 The Belmont Report (1979). The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. www.hhs.gov/ohrp/humansubjects/guidance/belmont.html