

SUGGESTIONS FOR OBTAINING THE ASSENT OF CHILDREN

As of June 6, 1983, OPRR (Office for the Protection from Research Risks) adopted new federal regulations regarding the use of children as research subjects. In addition to protections afforded children under existing statutes, the new regulations require the HSIRB to determine that adequate provisions are made for soliciting the assent of the children.

The HSIRB recognizes that much of the research involving children poses no more than “minimal risk” for them. These suggestions are designed to assist researchers in drafting protocols for gaining children’s assent to participate in those research studies. Researchers whose procedures pose greater than minimal risk for their subjects can request additional assistance from the HSIRB in drafting protocols for assent.

What follows includes the definition of assent and guidelines for obtaining the assent of children of different ages. Because the ability of children to understand the elements of assent generally increases with age, researchers will likely provide less detailed explanations to younger children and more detailed explanations to older students. In addition, because there are individual differences in the development of children’s ability to understand the researcher’s requests, there is a necessary age overlap in the categories listed below.

Definition of Assent: “Assent” means a child’s affirmative agreement to participate in research. Mere failure to object should not be construed as assent.

Ages 2-7

For children between the ages of 2 and 7, the request for assent should be kept simple and direct. 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.

Ages 6-14

For children between the ages of 6 and 14, 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; (3) an assurance that the child’s participation is voluntary¹ 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.”

Ages 12-17

For children ages 12 through 17, the request for assent should include the elements of informed consent presented to adults, but this request should be presented in language appropriate to the child’s level of comprehension.

¹ Researchers working in educational and/or clinical settings should be sure the subjects know that the research is separate from any instruction or intervention.