

Assent Process

In order to grant approval of research involving children, the IRB must determine that adequate provisions are made for obtaining the assent of the children when, in the judgment of the IRB, the children are capable of providing assent. The IRB must also ensure that adequate provisions are made for soliciting the permission of each child's parents or guardian; depending upon the type of research conducted, the IRB must determine if one or two parental signatures are required.

DHHS and FDA regulations define a "child" as a person who has not attained the legal age for consent to treatments or procedures involved in research or clinical investigations in the jurisdiction in which the study will be conducted. For research conducted in the state of Iowa, the term "minor" is used and, under Iowa Code, is defined as "an unmarried person under the age of eighteen years." (Iowa Code 600A.2[12])

For research subject to review by the ISU IRB but conducted outside of the state of Iowa, the ISU IRB will consult University Counsel regarding the applicability of other state, national, or international laws. In general, the IRB will apply the law of the state in which the research is being conducted.

To obtain assent, a child's affirmative agreement to participate should be obtained prior to his or her enrollment in a study and before any data collection may begin. If a child refuses participation in a study, he or she should not be enrolled even if the parent or legally authorized representative gives permission. Alternatively, if the child agrees (i.e., affirmatively agrees) to participate but parental consent has not been granted, the child may not be enrolled in the research. In rare circumstances, depending on the nature of the study and the age and circumstances of the child, the IRB may waive the requirement for parental or legally authorized representative permission.

In general, the IRB recommends that children, age seven and older, and most cognitively impaired adults be given the opportunity to give assent to participation.

Document History

Created/Approved: 12/6/2007

Revised: 11/25/2008

Revised: 5/10/2010
