Procedure for IRB Policy V

GUST Parental and Student/Child Consent.

The reading level of informed consent documents should be appropriate to the typical educational background of the research population. These documents should contain short sentences and everyday language.

Parental consent is one half of the consent process in the recruitment of children as human research participants. The child’s assent must also be obtained. The means followed to obtain this assent must be appropriate for the age ranges and levels of mental development found within the proposed participant pool. The National Commission for the Protection of Human Subjects of Biomedical and Social Science Research expects assent to be requested from children aged 6 years or older. For children aged 6–18, the appropriate method for obtaining assent will vary. The following guidelines may be followed:

- Ages 6–7: A simple oral description of the child's involvement is given to the participant and verbal assent is requested. This is documented via a witness signature on the informed consent form.
- Ages 8–13: A more complete oral description of the research (in layman's terminology) is given to the participant. Verbal assent is requested. This is documented via a witness signature on the informed consent form.
- Above age 13: Written assent should be requested from both parent and child, using age- and background-appropriate documents.
- Although age is used as the primary criterion in determining an appropriate means of obtaining assent, factors such as literacy and mental development must also be considered. Flexibility should be followed in obtaining children’s assent. Since one method may not be appropriate for all potential participants, investigators should be prepared to use different approaches with different participants. The primary goal is to ensure that the participant understands the explanation presented. The need for a witness to document verbal assent procedures depends upon the complexity of the research and risks to the participant.
- A parent or guardian may not be the witness for a child's verbal assent document.

The IRB is the sole body authorized to assess potential risks and benefits in each research proposal, and provisions for permission and assent, to determine if an activity satisfies the conditions for research involving children.