

Berklee Institutional Review Board Consent Forms for Research Involving Minors

Assent is defined as “an agreement by an individual not competent to give legally valid informed consent (e.g. a child or cognitively impaired person) to participate in research.”

Berklee IRB Guidelines Regarding Obtaining Assent

Children under the age of 18 may not consent themselves. For children under the age of 6, there is no expectation that the child provides assent. The IRB does expect that assent will be requested from children who are 6 years or older (***sample assent form attached***). However, for children between the ages of 6 and 17, the appropriate method for obtaining assent will vary. The Berklee IRB recommends the following guidelines:

- **Age 6-10:** A simple oral description of the child’s involvement should be given to the potential participant and verbal assent requested. The level of complexity of the wording may vary slightly depending on the age of the child. If the IRB requires a witness for verbal assent due to the specific nature of the project, the procedure may be documented on a separate assent form by the presence of the signature witness, or there may be a section on the parental permission form where witness to assent can be documented. A parent or guardian may not be witness for a child’s verbal assent document.
- **Age 11 or older:** Written assent should be requested from the child, using age-appropriate 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. The Berklee IRB recognizes the need for flexibility in the methods for obtaining assent from children. Because a single method of obtaining assent may not be appropriate for all potential participants, investigators may need to be prepared to use different approaches with different participants. The primary concern always is that the potential participant is able to understand the explanation that is presented. The need for a witness to document verbal assent procedures is dependent upon the complexity of the research and the risks to the participant.

Child Assent Form
(Sample)

Title of Study:

Investigators(s):

(List Name, Department, Telephone number for each Investigator)

We are doing a study to learn _____

We are asking you to help because we don't know very much about _____

If you agree to be in our study, we will ask you _____

What we learn in this research may help other children with _____

If possible you will feel _____

You may ask us questions at any time.

You may ask to skip a question, or stop at any time.

The questions we ask are only about what you think. There are no right or wrong answers because this is not a test.

If you sign this paper it means you have read/have been told about our study and you want to be in it. If you don't want to be in the study, don't sign the paper. Being in the study is up to you and no one will be upset if you don't sign the paper, or if you change your mind later.

Child's Signature _____ Date _____

Investigator's Signature _____ Date _____