

BRANDMAN UNIVERSITY INSTITUTIONAL REVIEW BOARD

Children's Assent to Participate in Research

In March of 1983 the Department of Health and Human Services issued the most recent human subject regulation, i.e., "Additional Protection for Children Involved as Subjects in Research" (45 CFR 46-Subpart).

These regulations governing children in research situations decree that investigators need to take into consideration age, maturity, and psychological state of the participating children and include them in the consent form, and soliciting the assent of younger children. The regulation defines "assent" as the child's affirmative agreement to participate. "Mere failure to object should not, absent affirmative agreement, be construed as assent."

The following items should be addressed in an assent procedure*, utilizing language appropriate to the child's age and/or developmental level:

- a) Why the child is asked to participate.
- b) What is going to take place from the child's point of view.
- c) The risk to the child.
- d) The benefit to the child.
- e) Identification of the researcher by name and telephone number in case questions should arise.
- f) In non-therapeutic research, a statement that the child has a choice to participate or to withdraw at any time without negative consequences.
- g) A statement that the child may retain a copy of the assent form.
- h) Date and signature lines for the researcher and, if appropriate, for the child.

** Represented by an assent form, or by a prepared script of the explanation to be tendered.*

Brandman University
16355 Laguna Canyon Road
Irvine, CA 92618

ASSENT RESEARCH FORM FOR MINORS

[Title of Study]

You have been invited to participate in a research study conducted by *researcher's name*, a doctoral candidate at Brandman University under the supervision of *Chair name*. Your participation is voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether to participate. If you decide to participate, you will be asked to sign this form prior to [completing the survey, participating in the interview, being observed, etc.]. You will be given a copy of this form.

Responsible investigator: *Your name, degree title*

Purpose of the study:

Include your study's purpose. Do not need to elaborate with explanation narrative.

What will happen if I take part in this research:

- *[Provide separate descriptions for what the minor will be asked to do.]*
- *[List and describe the procedures/tests/activities and their frequency chronologically using simple language, short sentences and short paragraphs.]*
- *[Use bullets or number the paragraphs as appropriate.]*
- *[Either describe or attach survey/interview.]*
- *[Specify the location of study activities.]*

Benefits of this Study:

Brief statement of potential benefits.

Potential risks or discomforts:

Below is an example only! Researcher will develop this narrative to reflect the study.

There is minimal risks or discomforts associated with the survey and/or interview. If you feel uncomfortable with a question, you can skip that question or withdraw from the study altogether. If you decide to quit at any time before you have finished the questionnaire or interview, your answers will NOT be recorded.

Confidentiality:

Below is an example only! Researcher will develop this narrative to reflect the study.

Responses will be kept completely confidential. Your name will not be used in this research and

you will not be identified when the research is published or discussed.

Decision to quit at any time:

Below is an example only! Researcher will develop this narrative to reflect the study.

Participation is voluntary; you are free to withdraw their participation from this study at any time. You also may choose to skip any questions you do not wish to answer.

How the findings will be used:

Below is an example only! Researcher will develop this narrative to reflect the study.

The results of the study will be used for scholarly purposes only. The results from the study may be presented in educational settings and at professional conferences. The results may be published in a professional journal.

Contact information:

If you have concerns or questions about this study, please contact *researcher name* at *researcher email*. You may also contact *name of chair* at *Chair email*.

SIGNATURE OF PARTICIPANT

I have read the information provided above. I have been given a chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in the study.

Name of Participant (Minor)

Signature

Date