

GUIDELINES FOR ASSENT DISCLOSURES

ASSENT is the term used to describe a child's affirmative agreement to participate in research. Researchers should seek assent and parental consent when a child does not have the capacity to consent.

ASSENT DISCLOSURES are the means researchers use to share the key elements of a research study with children. Disclosures may include assent forms, infographics, videos, PowerPoint presentations, and other media used to help children to make or contribute to an informed decision about research participation.

What 7 elements MUST be in all assent disclosures?

1. a statement that the child is being invited to participate in a research study
2. what the research purpose is
3. an explanation of what the child will be asked to do
4. all foreseeable risks and any potential benefits
5. a statement indicating that participation is voluntary
6. a statement indicating that the child has the right to withdraw at any time, how to withdraw, and assurance that no one will be upset with the decision
7. how the research results will be shared

What other elements SHOULD be in assent disclosures?

There are other **COMMONLY REQUIRED** elements that may be included in an assent disclosure depending on developmental level of children approached. These include:

- assurance that the child will be told about new information that may affect their decision to continue to take part
- when it may be impossible to withdraw from a study (e.g. anonymized data/samples)
- when a researcher may need to withdraw the child from the study
- how their identity will be protected
- when the researcher has a duty to tell others if worried about their well-being
- information about receiving compensation for participation as it relates to covering expenses, the value of a thank you gift, and prorated value for partial participation
- name, phone number, and email address of the researcher who can answer questions about the study
- name, phone number, and email address of the person in the REB office who the child can contact if unsure or worried about doing the study

Researchers **MUST** justify to the REB why they are **NOT** including these additional elements. Researchers should propose flexible strategies to include these when inviting participants whose level of comprehension may be different within the same study (e.g., young children and adolescents).

CLINICAL TRIALS and research involving the use of **HUMAN BIOLOGICAL MATERIAL** have additional commonly required elements. See REB-704 for a list of these other elements.

IT IS IMPORTANT THAT ASSENT DISCLOSURES...

1. Use accessible language, avoid technical terms, and be culturally and cognitively appropriate.
2. Include a signature page that lets the child sign and date to confirm that the researcher explained what the study involves, that the child's questions were answered, and the child agrees to participate. Researchers should offer but not *require* children to sign the form.
3. Include a section on the signature page for the researcher to sign and date, confirm discussing the elements of assent with the child, verify answering the child's questions, and indicate that the child agreed to participate.

See REB-704 (Elements of Informed Assent) and REB-705 (Process for Informed Assent) for further details:

<http://research.hollandbloorview.ca/researchethicsboard/standardoperatingprocedures>