**Assent forms: Information and templates**

**Version Date: November 2024**

The Holland Bloorview REB strongly recommends that study teams use this template when creating assent forms for their study and that the order of items (headings) is maintained. Alterations to the structure of the headings must be justifiable. This document includes basic information about assent forms and two assent form templates. Template #1 is appropriate for simple studies or for a younger child. Template #2 is appropriate for more complex studies or for an older child. Note that unless there are multiple study groups, only one version of the assent form is required (i.e., only template #1 or template #2).

When preparing an assent form, keep in mind the following:

* Assent forms must be used when participants do not have the capacity to consent (e.g., children, individuals with cognitive disabilities or neurodevelopmental disorders, etc.). This means that some children will need to have the assent form read and explained to them.
* A capacity assessment should be performed for all studies (except if enrolling Healthy adults). Please ensure the capacity assessment document is submitted to the REB for review. A [Capacity Assessment Worksheet template](https://hollandbloorview.ca/research-education/research-ethics-board/research-ethics-board-forms#:~:text=informed%20assent%20process.-,Capacity%20Assessment%20Worksheet,-Assent%20Form%20Template) is available on the HB REB website.
* The target language should be a grade 2-3 reading level. Keep the language and concepts appropriately simple.
* Although there are very formal requirements for the elements that must be present in a consent form, no such requirements exist for assent forms. This means that the study team can propose assent content that they believe will best inform the participants about the study.The REB may askfor more or less information to be included.
* The length of the assent form should be proportional to the complexity of the study and the maturity of the participants.
* Only someone who is trained on obtaining consent/assent and who has been delegated this task may obtain assent.
* The assent form must be amended whenever important new information becomes available that may be relevant to the child’s assent and their willingness to continue to participate. Any revisions made to the approved assent form must be submitted to the REB for review and approval prior to use.
* If the study involves different methods of informed consent (e.g. e-consent, verbal consent), please refer to [Ethical Considerations for Remote Consent and Assent](https://hollandbloorview.ca/research-education/research-ethics-board/guidance-notes#:~:text=Ethical%20Consideration%20for%20Remote%20Consent%20and%20Assent) for additional guidance. Please ensure that the applicable appendix(es) is/are included in the main ICF document.

For more information about obtaining assent, consent, and capacity assessments, see [SOP-706](https://hollandbloorview.ca/research-education/research-ethics-board/standard-operating-procedures#:~:text=Informed%20Consent%20and%20Assent) Informed Consent/Assent Process and the “[All There is to Know About Consenting](https://hollandbloorview.ca/research-education/research-ethics-board/guidance-notes#:~:text=in%20Research%20Guidance-,Consent,-and%20Capacity%20Guidance)” guidance document.

**How to use this template:**

*GREY Highlighted text*: General instructions for the section

**BLUE text:** Guidance and example language.

**BLACK text:** Holland Bloorview approved template wording and/or examples that should not be altered without justification

Specific example language for your study may not be provided in this document. If there is no template language for your specific situation, please create your own.

**TEMPLATE 1: For simpler studies or younger children**

**Assent to Participate in a Research Study**

**Study Title:** Insert study title as written on the protocol.

**Short title:** *If the study title is long or complicated a simplified version of the title should be added. This shortened title may also be used in the footer for each page of the assent form.*

**Principal Investigator:**

*Include the name and contact information (i.e., telephone number) of the Holland Bloorview Principal Investigator. Indicate “Dr.” only for doctors licensed to practice in Canada (Restricted to physicians, psychologists, dentists, chiropractors and optometrists); indicate “Nurse” only for nurses licensed to practice in Canada. All other Investigators should be referred by their credentials and, if applicable, country of practice.*

**Example:**

Jane Smith, PhD, Bloorview Research Institute, Holland Bloorview Kids Rehabilitation Hospital Contact number 416.425.6220. ext.####

**Co-Investigator(s):**

*Include the name(s), affiliation and contact information of all Co-Investigators.*

*If the Co-Investigators are students, list the program of study, Bloorview Research Institute affiliation and academic affiliation.*

**Example:**

John Brown, PhD, Bloorview Research Institute, Holland Bloorview Kids Rehabilitation Hospital, Contact Number 416.425.6220. ext.####

Jane Dave, PhD candidate, Bloorview Research Institute, University of Toronto, Contact Number 416.425.6220. ext.####

**Research Contact:** *Include the name and telephone number of at least one research contact/study coordinator at Holland Bloorview*

**What is a research study?**

Research can help us learn new things. It can help us learn more about disabilities. In a research study we can test new ideas and ask new questions to try to find answers. This may help us make treatments and technology better for kids and youth.

**Why do you want to talk to me?**

We want to tell you about a research study we are doing. We would like to find out more about [insert topic and describe goals in simple language]*.*You are being asked to join the study because [insert name of condition or other reason(s) for inclusion].

**If I join the study, what will I be asked to do?**

If you agree to join this study, you will be asked to[describe procedures, (e.g., questionnaires, activities) in words a child would know and understand. Also include number of visits and time frame in words easily understood by a child].

**Will any part of the study hurt?**

*Describe risks and discomforts using terms a child would know and understand; take into account a child’s fears (e.g. frustrating, tiring), communication style (e.g. visual vs verbal); provide examples.*

There are a few things that might happen if you decide to take part in this study:

* During [describe procedure], you might [describe risk, e.g. feel a bit tired or frustrated, feel anxious] similar to how you might feel when [insert similar situations that might elicit a similar risk]. [Describe what can be done, for example: If this happens, you can tell us to stop the activity at any time].

*Example for interventional:*

* When taking this drug, some people have noticed feeling lightheaded or dizzy. Let us know right away if you feel any of these things.
* We don’t expect any other risks, but since this is a new type of drug, there may be some risks we don’t know about at this time. If you feel something different, please tell us right away.

**Will the study help me?**

*Describe any benefits to the child from participation in the research.*

*Use any of the following statements that are appropriate:*

We don’t know if being in this study will help you.

We think that the study might help you by [describe how].

We may learn something that will help other children with [insert name of condition or topic under investigation]someday.

This study will help us learn more about [topic under investigation].

**Do I have to join the study?**

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell us you want to stop. No one will be mad at you if you don’t want to be in the study or if you join the study and change your mind later and stop. We are talking to your parents/guardians about the study and you should talk to them about it too.

**What if I have questions?**

Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

If you have any questions about this study please feel free to ask [Insert Study Contact name and contact #].

I, \_\_\_\_\_\_\_\_\_\_\_\_ (name of participant) have been explained this study and agree (assent) to participate.

Participant Name Signature Date (DD/MMM/YYYY)

**Assent (for the study team to complete):**

I have discussed this research study with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ using language which is understandable and appropriate for the participant. I believe that I have fully informed him/her of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assented to participate in this study.

Person obtaining Assent Signature Date (DD/MMM/YYYY)

If Interpretation services will/may be used for the assent discussion, please include the following:

The person signing below acted as an interpreter, and attests that the study as set out in the assent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

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Print Name of Interpreter Signature & Date (DD/MMM/YYYY)

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Language

**TEMPLATE 2: For complex studies or older children**

**Assent to Participate in a Research Study**

**Study Title:** Insert study title as written on the protocol.

**Short title:** *If the study title is long or complicated simplified version of the title should be added. This shortened title may also be used in the footer for each page of the assent form.*

**Principal Investigator:**

*Include the name and contact information (i.e., telephone number) of the Holland Bloorview Principal Investigator. Indicate “Dr.” only for doctors licensed to practice in Canada (Restricted to physicians, psychologists, dentists, chiropractors and optometrists); indicate “Nurse” only for nurses licensed to practice in Canada. All other Investigators should be referred by their credentials and, if applicable, country of practice.*

**Example:**

Jane Smith, PhD, Bloorview Research Institute, Holland Bloorview Kids Rehabilitation Hospital Contact number 416.425.6220. ext.####

**Co-Investigator(s):**

*Include the name(s), affiliation and contact information of all Holland Bloorview Co-Investigators.*

*If the Co-Investigators are students, list the program of study, Bloorview Research Institute affiliation and academic affiliation.*

**Example:**

John Brown, PhD, Bloorview Research Institute, Holland Bloorview Kids Rehabilitation Hospital, Contact Number 416.425.6220. ext.####

Jane Dave, PhD candidate, Bloorview Research Institute, University of Toronto, Contact Number 416.425.6220. ext.####

**Research Contact:** *Include the name and telephone number of at least one research contact/study coordinator at Holland Bloorview*

**What is a research study?**

Research can help us learn new things. It can help us learn more about disabilities. In a research study we can test new ideas and ask new questions to try to find answers. This may help us make treatments and technology better for kids and youth.

**Why am I being asked to be a part of this research study?**

You are being asked to take part in this research study because we are trying to learn more about [Insert name of what is studied here]. We are asking you to be in the study because [state why the child is being asked to participate].

**If I join the study what will happen?** *Describe what takes place from the child’s point of view*

If you decide to be in the study [describe study activities – examples below]

* You will be in the study for [insert duration of participation].
* We will use a needle to take some blood from your arm *(#)* times.
* We will need you to take [name of procedure] that will last [duration]. This is [a simple explanation of what will happen]. Your [mother/father/guardian] can be [location].
* We will ask you to sit with us and [talk about some your feelings/look at some pictures]. It will take about 1 hour to do this
* We will ask you to answer some questions about X.

*If your study is a randomized clinical trial, include a description of the trial interventions and describe how participants will be assigned to each intervention (e.g. by chance like flipping a coin). Include which interventions are standard of care and which are investigational. Also provide information on alternative procedures that may be available to a child.*

*Consider including additional sections, such as: “Could I get better by being in this study?”, “Are there any other treatments for me?”*

*If your study requires the collection of human biological material (blood, saliva, etc.), include the type and amount being taken as well as how it is being taken. Include the risks of collection and how the risk will be managed. Also include how long materials will be kept, how they will be stored, and how incidental findings will be dealt with.*

*Consider including additional sections, such as: “What will happen to my [blood/saliva/etc.]?”, “Will I learn anything new about me?”*

**Will any part of the study hurt?**

*Describe risks and discomforts using terms a child would know and understand; take into account a child’s fears (e.g. frustrating, tiring), communication style (e.g. visual vs verbal); provide examples.*

There are a few things that might happen if you decide to take part in this study:

* During [describe procedure], you might [describe risk, e.g. feel a bit tired or frustrated, feel anxious] similar to how you might feel when [insert similar situations that might elicit a similar risk]. [Describe what can be done, for example: If this happens, you can tell us to stop the activity at any time].

*Example for interventional:*

* When taking this drug, some people have noticed feeling lightheaded or dizzy. Let us know right away if you feel any of these things.
* We don’t expect any other risks, but since this is a new type of drug, there may be some risks we don’t know about at this time. If you feel something different, please tell us right away.

**Will the study help me?**

*Describe any benefits to the child from participation in the research.*

*If there are no expected benefits:* The study won’t help you **OR** We don’t know if the study will help you.

**Will the study help other people?**

*Describe any benefits to society from the research.*

This study might find out things that will help other children with [insert name of condition being studied]someday.

**Do I have to be in the study?**

You do not have to be in the study. It’s up to you. No one will be angry or upset if you don’t want to do this study. If you join the study, you can change your mind and stop being part of it at any time. All you have to do is tell us, nobody will be upset.

**What choices do I have if I say no to this study? [If applicable]**

There are other ways to help your [insert name of condition being studied] if you don’t want to be in this study. Examples are [insert alternatives].

This study is extra, so if you don’t want to do it [nothing else will change/there are no other choices].

**Do my parents/guardian know about this study?**

This study was explained to your parents/guardian and they said that we could ask you if you want to be in it. You can talk this over with them before you decide.

**Who will see the information collected about me?**

The information collected about you during this study will be kept safely locked up. The study information about you [will/will not] be given to your parents [or teachers].Nobody else will know it except the people doing the research. The researchers will not tell your friends or anyone else.

*If there is a possibility that the investigator may find out information that puts the child’s well-being into question, state:*

There is a chance that we may find out something that makes us worried about your safety. If this happens we will share this information with people who can help you.

**What if I have questions?**

You can ask any questions you want about the study. If you think of a question later, you can call or have your parents call [insert study telephone number].

I, \_\_\_\_\_\_\_\_\_\_\_\_ (name of participant) have been explained this study and agree (assent) to participate.

Participant Name Signature Date (DD/MMM/YYYY)

**Assent (for the study team to complete):**

I have discussed this research study with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ using language which is understandable and appropriate for the participant. I believe that I have fully informed him/her of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assented to participate in this study.

Person obtaining Assent Signature Date (DD/MMM/YYYY)

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Print Name of Interpreter Signature & Date (DD/MMM/YY)

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Language