ASSENT FORM TEMPLATE

GENERAL REMARKS

This assent form template is intended to assist investigators to write assent forms which meet the UBC CREB's requirements. This form is based off UBC C&W REB's current template.

PLEASE NOTE that this form template is primarily intended for children between the ages of 7 to 13 years who are not legally competent to consent on their own behalf but who have the capacity to assent. However, it is not expected that an assent form will necessarily be suitable for all children in this age-range. For example, if a 12 or 13 year old is capable of reading the adolescent assent form, s/he should be given that to read and should sign his/her assent at its conclusion. If a younger child (for example, 7 or 8 years old) is unable to read the assent form, it can be used as a guide for the researcher to review information with the prospective assenting participant. The age range of 7-13 is also not fixed. An assent form should be given to incompetent prospective participants who are 14 years and older and capable of assent, but who cannot read a full adolescent assent form. A particularly precocious child under 7 years old should also be provided with an assent form if s/he is capable of reading it.

This template can also be used for incompetent adult-aged participants who are capable of assent, but of course references to children in the template will have to be amended.

The template is a guide only. It is expected that some of the headings and related text may need to be changed or omitted depending on the nature of the study. Researchers should feel free to flag any issues or wording in a proposed assent form on which they would like REB input or advice.

Refer to UBC REB Guidance Note 15 (paying specific attention to notes 15.5.1 and 15.5.2) regarding REB requirements for the preparation of assent forms to accompany the consent forms of a study.

Aim for no more than two pages in length using a minimum 12 point font.

Write the assent in first person.

Use the provided section headings where they are relevant

[University of British Columbia (or Affiliated Institution) and/or Hospital Department Letterhead]

PARTICIPANT ASSENT FORM
Children aged 7-13 years

Short Study Title: Include a small, easily understood segment of the main study title or paraphrase the main study title briefly in easy to understand language (e.g. "Assent Form – Hematoblastoma Biology Study").

Invitation

Include an invitation to participate. The assent form must invite, not ask, the participant to participate in the study. Any phrases that may inadvertently coerce the participant (child) into the study (i.e. unduly influence their decision to assent) must be omitted. An example of such a statement is "The study doctors want me (need me) to help…"

Sample Wording:

"I am being invited to be part of a research study. A research study tries to find better treatments to help children like me. It is up to me if I want to be in this study. No one will make me be part of the study. Even if I agree now to be part of the study, I can change my mind later. No one will be mad at me if I choose not to be part of this study."

Why Are We Doing This Study?

This section must briefly explain in lay terms appropriate for those reading the assent what the study is about and why it is being done. All acronyms, drug, and disease names must be spelled out and explained in simple terms.

Sample wording:

"I have a disease called [_____]. This disease affects many other children. This study is trying to find out [anticipated results] so that scientists can [anticipated benefits of results]."

"This study will help us learn more about a drug called [name of drug]. [Name of drug] is being tested to find out if it helps children like me who have a medical condition called Attention-Deficit/Hyperactivity Disorder, or "ADHD." Children who have ADHD often have a hard time sitting still, playing or working quietly, finishing things they start, paying attention, waiting their turn, and not bothering others. I am being invited to be a part of this study because my doctor has decided that I have ADHD."

What Will Happen in This Study?
Explain summarily and accurately what the participant will have to go through, including:

- *A description, in simple and appropriate lay terms, of any therapies that will be administered to the participant, and how.*
- *For tissue sampling and banking: how much tissue will be taken and from where, how and when it will be taken; what will be done with it in the study; whether or not it will be stored and for how long (i.e.* "kept frozen for many years"*); and any future uses of the tissue. Explain the notion of a tissue bank in appropriate lay terms.*
- *The total amount of time that the participant will spend participating in the study and, if relevant, the total number of visits to the research site (hospital, clinic, etc.).*

Sample wording:
"If I agree to be in this study, I will go to see the doctors for one hour each week for 4 weeks (4 visits). The third time I go to see them (my third visit) they will give me medicine to take home and start taking the next morning. The medicine that I will take home will be [name of drug, description]. During my fourth (last) visit, the doctor will use a needle to take blood from my arm for some tests, and I will give a sample of urine (pee) for other tests. If it does not look like the medicine is helping me, or if it makes me feel bad, then they will ask me to stop taking the medicine."

Who Is Doing This Study?
Include mention of the name of the principal investigator and that s/he and her/his colleagues will be available to answer questions or deal with any problems that may arise. There is no need to mention the sponsor of the study.

Sample Wording:
*"**Dr Jane Smith*** (bold the PI's name) *and other doctors from _____ Hospital will be doing this study. They will answer any questions I have about the study. I can also call them at **555-555-5555*** (telephone in boldface)*, if I am having any problems or if there is an emergency and I cannot talk to my parents."* (No need to use the term "principal investigator".)

Can Anything Bad Happen to Me?
Explain in simple and appropriate lay terms any possible harm (i.e., side-effects or discomfort) that the participant might experience resulting from the study procedures. The specific frequency of the risk does not need to be included. Note: if the study is minimal risk, retain this section heading, but indicate that there is nothing in the study itself that should cause anything bad to happen to the participant.

Sample wording:
"Sometimes medicines make people sick or not feel very good. The doctors do not know very much about [name of drug] compared to many other drugs that people take. But they do know that some of the people who have taken [name of drug] in other studies have told them that they had headaches and stomach aches, or that they were dizzy, had a dry mouth, or had trouble falling asleep."

"Even though the medicine is being tested for the treatment of ADHD, I might not actually feel better during the study. It is possible I might feel worse. I should tell my parents right away if I feel worse."

What Should I Do If I Am Not Feeling Well?
Clearly indicate who should be contacted in the case of adverse effects, and list the telephone number(s).

Sample wording:
"If this medicine makes me feel bad or if I notice any strange or bad feelings during the study, I should tell my parents right away. I can also call the doctor who is treating me: [name of doctor and telephone number in boldface] or the study coordinator, [name of coordinator and phone number boldface] I can call at any time, day or night, to tell them about how I feel."

This section should be omitted for studies where there are no prospects of adverse effects.

Could I Get Better By Being in the Study?
Explain that no one knows whether the participant will feel any better during or after the study, and that they may even feel worse.

Sample wording:
"No one knows whether or not I will get better by being in this study, and I may get worse. The study doctors hope that I will get better, but they cannot tell me that I will get better."

This section should be omitted for a study with no prospect of direct therapeutic benefit.

Are There Any Other Treatments for Me?
If applicable, explain that the participant does not have to be a part of this study to be treated for their illness and that other treatments are available. Emphasize that they can ask their doctor or their parents about any other treatments and therapies.

This section should be omitted for a study with no prospect of direct therapeutic benefit.

Who Will Know I Am in the Study?

Instead of the UBC REB standard wording for confidentiality, use simpler wording but convey the core ideas. Explain that any information collected regarding the participant will be kept private and that nobody but their parents(s)/doctor(s)/study investigator(s) will know that they took part.

> Sample wording:
> *"Only my doctors and people who are involved in the study will know I am in it. When the study is finished, the doctors will write a report about what was learned. This report will not say my name or that I was in the study. My parents and I do not have to tell anyone I am in the study if we don't want to."*

When Do I Have To Decide?

Explain how long the prospective participant has to make a decision, and encourage him/her to discuss it with his/her parents.

> **Sample Wording:**
> *"I have as much time as I want to decide to be part of the study. I have also been asked to discuss my decision with my parents."*

Signatures:

- Include an assent statement that reads something like: *"If I put my name at the end of this form, it means that I agree to be in the study."*
- Include a line for the participant's printed name, signature, and date. (authorized third party and Principal Investigator are NOT required to sign this form because they have already signed the accompanying consent form).

Note: the person taking the assent must give a signed copy to the participant.

FORMAT GUIDELINES FOR ASSENT FORMS

Assent forms should be written at about a 9 year old's level of understanding.

1) Type size – no smaller than 12 point font

2) Use headings, small paragraphs and spaces between the paragraphs

3) Use simple lay language – explain medical terms and jargon, or omit entirely.

4) Use of DRUG TRADE NAMES in Assent Forms:

Exclusive use of drug trade names in assent forms is not allowed. Acceptable forms of designation of drug names are: "*generic name*" or "*generic name (Trade name)".* Where a drug product contains multiple ingredients, which makes use of their generic names impractical, the trade name for the combination product may be used.

5) Write out all acronyms the first time they appear in the assent form.

6) Number the pages in the following manner: "1 of 2", "2 of 2", etc.

7) Include a footer ON EACH PAGE with the version date and/or version number

8) All information required by the participant must be included in the assent form with the exception of ancillary drug information sheets, if applicable.

9) The assent form submitted for review should be in its final form (as it will be seen by the participant), including letterhead.

10) Spelling and grammar must be corrected before it is submitted for review.

11) Assent forms should, ideally, be a maximum of 2 pages in length.

12) Use "participant" throughout the consent form rather than "patient" or "volunteer". "Subject" may be used, but "participant" is preferred in TCPS2 (see chapter 2.A.). The chosen term must be used consistently throughout the document, including in the Title of Study.