

Assent form template for clinical research

This form has been developed by KidsCAN Trials in collaboration with researchers and ethics board members from the University of Alberta, University of Calgary, University of Manitoba, University of Western Ontario, and the Children's Hospital of Eastern Ontario. Thank-you to the parents from the TRanslating Emergency Knowledge for Kids (TREKK) network for their review of this template.

Instructions for use

An assent form should be used for studies in children who are not legally competent to consent on their own behalf but have the capacity to understand the process of a research study.

Remove instructions page from the form before submitting for ethics board review

*Instructions and example text are in **blue font** and italicized.*

The footer should contain page numbers (e.g. Page 1 of 3) with an updated version number and date. Institutional or project team logos may be added as appropriate.

Use at least size 12 font.

If assent is obtained verbally, the child's signature is not required.

Language should be clear and no greater than a grade 4 reading level.

The child is not required to initial each page.

A copy of the assent form should be given to the child, and the original maintained with the study documents.

If, for a particular project, it is necessary to significantly deviate from this template, please provide the justification for doing so in a letter to the Research Ethics Board.

Study Title

Principal Investigator(s):

Phone Number:

Study Coordinator:

Phone Number:

This research study is sponsored by: if applicable

What is a research study?

A research study is a way to find out new information about something. Children do not need to be in a research study if they don't want to.

Why am I being asked to be in this study?

You are being asked to take part in this research study because we are trying to learn more about *(condition being studied)*. 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 to me?

We want to tell you about some things that will happen to you if you are in this study.

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
- There will be around *XXX* other children in this research study over the next *(duration of recruitment)* years.
- 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/other]* can be present in this *[location]*.
- We will ask you to sit with us and *(talk about some things/look at some pictures)*. It will take about *XXX* to do this
- We will ask you to answer some questions about *XXX*.

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)*

Will the study help me? *(Describe any benefits to the child from participation in the research or if there are none omit this section).*

Will the study help others? *(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.

What do I get for being in the study?

You *(and your parents)* will get *(enter amount or item)* for *(each visit/entire study)*. There will not be any tests or marks on your school report card if you decide to be in the study.

Can I say no?

Yes of course, you do not have to be in the study. It's up to you. No one will be upset if you don't want to do this study. You can tell your parents, grandparents, guardian or your doctor if you do not want to be in the study. If you do join the study, you can change your mind and stop being part of it at any time.

What choices do I have if I say no to this study?

There are other ways to help your *(insert name of condition being studied)* if you don't want to be in this study.

Who will know I am in this study?

This study was explained to your parents and they said that we could ask you about the study. Your parents can help you decide if you want to be in this study.

Who will see information about me?

The information collected about you during this study will be kept safe. Your name will not be kept with this information, so no one will know except the people doing the research. The study information about you *(will, will not)* be given to your parents *(or teachers)*. The researchers will not tell your friends or anyone else if you decide to join the study or not. *(For secondary data use – Other people doing studies in the future would have to ask special permission to look at your information and they would not be allowed to share this information with anyone else.)*

Are there any questions?

What if I have more questions later?

If you have any question about this study that you didn't think of now, either you can call or have your parents call *(insert study telephone number)*.

You will be given a copy of this paper to keep.

Would you like to take part in this study?

- Yes, I will be in this research study.** **No, I don't want to do this.**

Child's name Signature Date

Assent was obtained verbally Age at the time of assent: _____

Person obtaining Assent Signature Date