**Child or Adults Lacking Capacity to Assent Template with Guidance – 2.4.2025**

**Instructions**

* Designed for children 11 to 17 years of age.
* Write at an elementary grade reading level.
* The [Plain Language Medical Dictionary](https://www.uvm.edu/rpo/irb-educational-resources#dictionary) is available to help.
* Please delete instructional text/red highlights (including any non-applicable text as directed by the instructions) and this instruction page before submitting to the IRB.

**Using the Research Assent Form**

* After describing participation and obtaining assent, the researcher leading the assent should have the adolescent write their name. The researcher should then print their own name and sign the consent. A copy of the completed form should be given to the family. Save the original form in the research file along with the parental consent form.

# Title of Research Protocol: title

**Principal Investigator:** name

**Why are we Doing this Research?**

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer. This form talks about our research and the choice you have to take part in it. We want you to ask us any questions at any time.

**Important things to know…**

* You get to decide if you want to be in the study.
* You can say ‘No’ or you can say ‘Yes’.
* No one will be upset if you say ‘No’.
* If you say ‘Yes’, you can always say ‘No’ later.
* You can say ‘No’ at any time.
* We would still take good care of you no matter what you decide.

We are doing this research to find out more about[explaining how/why the child qualifies or may qualify for the study].

**What will happen to me in this study?**

If you want to be in the study, this is what will happen: [list all study procedures, where they will occur and how long it will take, bullet the list]

**Can anything bad happen to me?**

**[**Can I get hurt?]

Some of the tests might make you uncomfortable or the questions might be hard to answer. We will try to make sure that no bad things happen.

[You may want to add simple and general terms to explain any specific risks and what you will do to decrease them, if this is appropriate for the study population]

**Could the research help me?**

[If no direct benefit, include the following information:]

You may not feel better from this study. We hope to learn something that could help other children in the future.

[If treatment or intervention with possible benefit, include the following information:]

Taking part in this study may help you feel better, but we do not know this for sure. We also hope to learn something that could help other children in the future.

**Do I have other choices?**

[If applicable, describe the alternatives open to the child, otherwise include the following statement:]

You do not have to be in this study if you don't want to. It is also OK to say yes and change your mind later. You can stop being in the study at any time. If you want to stop, please tell the study doctors.

**Will I receive any payment or gifts if I am in this study?**

[This section should be included when appropriate to clarify if the adolescents will be compensated for their time, inconvenience; discomfort, etc... include the form of the compensation, such as gift cards]

To thank you for being in the study, we will give you      . You should talk with your parents about how you would like to use this.

Or

You will not be paid to be in the study.

**Will anyone know I am in the study?**

We will do everything we can to make sure that any private information about you is kept private.

[Describe what will happen (mandatory reporting requirements) should child reveal harm to self or others.]

**What if I have questions?**

You can ask questions whenever you have them. You can ask the researcher or other people working with them on the study (insert PI name and study team contact information). We have also explained this study to your parents, so you can ask them questions as well. However, if you do not want to be in the study, that is okay.

If you want to be in this study, please sign your name. You will be given a copy of this form to keep so that you can look at it again later.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Minor Providing Assent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Minor Providing Assent Printed

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Researcher or Designee Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Researcher or Designee Printed

Name of Principal Investigator:

Address:

Telephone Number:

Name of Faculty Sponsor:

Address:

Telephone Number: