COOK COUNTY HEALTH

Office of Research & Regulatory Affairs

**Assent to Participate in Research – Instructions**

***Please remove instructions pages prior to submitting your informed consent document for IRB review.***

This assent document template is designed to help you draft an assent document which is compliant with institutional expectations. Assent documents provide information to research subjects to ensure they can understand the research and make an informed, voluntary decision whether to participate. Office of Research & Regulatory Affairs (ORRA) staff and IRB members will carefully review the assent document you submit to ensure that this requirement is met.

**Important notes**

* The templates and the suggested language within are suggestions only (in most cases), meant to provide a guideline for language which might be acceptable.
* Templates and language should be customized carefully for each individual study to facilitate subjects’ clear understanding of the research.
* In determining whether children are capable of providing assent consider age, maturity, and psychological state of the children involved. Generally children **ages 7-12** should be able to sign this simplified assent form.
* Studies which already have a template assent form provided by a sponsor or funding agency are welcome and encouraged to utilize those templates

**Using the template**

* Instructions to you are in brackets and are highlighted in gray. Be sure to address each highlighted item and to remove all bracketed/highlighted template instructions before submission.
* Be sure that formatting and grammar are consistent throughout the document. **Font size should be at least 12 pt**., please be sure font and size are consistent throughout. Be careful not to use font in specific sections to over or underemphasize the information provided. For example, don’t use bold or larger font in the payment section, or smaller font in the risks section.
* Leave a **1.5” x 2” space on each page** of your informed consent form for the approval stamp.
* The assent must be on **CCH letterhead**.
* If a section does not apply to your study, please remove it.
* Where the suggested language does not adequately address your study, please customize the language.
* Review your final version carefully for consistency with other study documents.

**Comprehensibility**

* Use simple language that is appropriate to the specific subject population. You can edit the suggested language to improve readability.
* Consider the environment and context in which the assent is presented to a potential research subject.
* As much as possible, avoid the use of or replace complicated or medical/technical language with lay language to ease subject comprehension.
* Write in second person so as to not be interpreted as suggestive or coercive.
* Define any abbreviations and acronyms.
* Use short, simple and direct sentences.

The following resources are publicly available for suggested lay terms and testing the readability of consent forms:

1. CDC Plain language Thesaurus <http://www.plainlanguage.gov/populartopics/health_literacy/thesaurus_v-10.doc>
2. CDC Everyday Words for Public Health Communication <https://www.cdc.gov/other/pdf/everydaywords-060216-final.pdf>
3. Glossary of Clinical Trials Terms - <https://clinicaltrials.gov/ct2/info/glossary>
4. Federal Plain Language Guidance <http://www.plainlanguage.gov/howto/quickreference/quicktips.cfm>
5. Document Checklist for Plain Language - <http://www.plainlanguage.gov/howto/quickreference/checklist.cfm>
6. Readability calculator - <https://www.online-utility.org/english/readability_test_and_improve.jsp>

 **ASSENT TO PARTICIPATE IN RESEARCH**

***Assent forms MUST use the most current version of CCH letterhead***

**[Insert Protocol Title]**

**[Insert Sponsor Name and Sponsor Protocol Number and IRB Number]**

If you want, you can be a part of this research study. Scientists do research to try to find answers to important questions.

**What is this research study about?**

We are asking you to take part in a research study because we are trying to learn more about [explain the reason for the research]. You are being asked to join the study because [explain why the child is being invited to participate].

**What will happen during the study?**

If you agree to be in this study, you will be asked to: [Explain where the study will take place, how long the study will last, and what procedures are involved. Make sure to use simple language to describe any medical terms]. If audio or video recordings will be made of the child, include the following:

\_\_ It is OK to record me during study

\_\_ It is NOT OK to record me during this study

**When you are in a research study, sometimes good things and bad things can happen.**

**Can anything good happen during the study?**

Things that happen to children in research studies that are good are called “benefits.” Some of the good things for this research study could be: [Explain the benefits that might result from participation. If there are no known benefits, include a statement regarding this fact. Benefits to others in the future may be included. Do NOT include any payments or incentives as a benefit].

**Can anything bad happen during this study?**

Things that happen to children in research studies that make them feel bad are called “risks.” Some of the bad things for this research study could be: [Explain the risks that might result from participation. If there are no known risks, include a statement regarding this fact. Explain that not all of the risks may happen to all participants and that some things may happen that the researchers do not yet know about. Explain the importance of letting the researchers or the child’s parents know if they feel sick, in pain, or do not like any aspect of the study].

**What other choices are there besides being in this study?**

[Explain appropriate alternatives to participation. If there are no alternative treatments or procedures, this section may be omitted].

**Will I get paid for being in this study?**

[Indicate if the child directly receives any payment for being in the research. If there is no payment or no direct payment to the child, this section may be omitted].

**Who will know you are in the study?**

We will do everything possible to keep your information private. [Explain how the child’s participation in the study will be kept secret. Clearly state who will have access to the information that is collected during the study. Describe what information will be given to parents, if applicable].

**What if you have questions?**

You can ask questions now or anytime during the study. If you have questions later, you can call [study personnel] at [phone number] or [study personnel] at [phone number]. If you have questions about the study but want to talk to someone else who is not a part of the study, you can call the Cook County Health Institutional Review Board (CCH IRB) at (312) 864-4821.

**What if you do not want to be in the study?**

You do not have to be in the study if you do not want to. Nobody will be upset or angry with you if you say no. You can even say yes now and change your mind later. Your parent must also give permission for you to be in this study. Please talk to your parents before you decide whether or not to be in this study. Even if your parent says “yes”, you can still decide not to be in the study. [Delete the previous sentence if it is not applicable under therapeutic protocols]. Your doctor will still take care of you even if you do not want to be in the study. [Delete the previous sentence if the researcher does not provide clinical care to the child].

Signing your name below means that you agree to take part in the study. You can change your mind at any time for any reason. You will be given a copy of this form to keep.

**Child’s Printed Name:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Child’s Signature**: \_\_\_\_\_\_\_ **Date**: \_\_\_\_\_\_

**Printed Name of Person Obtaining Consent:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of Person Obtaining Consent**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­ \_\_\_\_\_\_\_ **Date**: \_\_\_ \_\_\_\_\_\_\_