

NYCHP Template for Child Assent

Read this entire instructional page prior to beginning your assent form.

Who can use this template?

This template is intended for studies that meet **all** of the following criteria:

- 1. Will enroll children under the age of 13 who are unable to provide consent.
- 2. Where consent is provided by a Parent/Guardian.

NOTE: The child participant must be assented using this form and a Parent/Guardian must provide their consent by signing the Parent/Guardian Consent Form.

Instructions for completing Child Assent Form Template

- Read all instructions prior to drafting your Informed Assent Form.
- All instructional text is in RED or is Yellow Highlighted.
- RED text in brackets [] should be replaced with information pertinent to your study, e.g., [your name here]. All text should be changed to black before submitting.
- Yellow Highlighted text provides instructions regarding the inclusion or deletion of sections, along with helpful information for completing the section.
- Some sections may need to be revised in order to meet the needs of your research study (i.e. replacing template language where necessary, deleting sections that do not pertain to your study). Contact your Research Director for guidance if you feel certain section do not pertain to your study.
- Assent form needs to be written in laymen terms with around an 3rd or 4th grade reading level when tested against the Flesch-Kincaid (FK) grade level readability test. Review the <u>NYCHP IRB Readability Level of Consent Documents</u> guidance sheet for more information.
- **Do not** copy/paste directly from your research protocol, proposal, grant application, etc.
- **Do not** alter the letterhead, header/footer, side margins, font size (12 point), or font style (Arial) of this template.

Before you attach the Assent Form to your IRB submission, you MUST:

- Delete this instructions page, all Yellow Highlighted instructional text, and any RED text not relevant to your study.
- Change to BLACK all RED text you replaced with your study information.
- Remove all Comments, Notes, and/or Track Changes.



Child Assent Form NYCHP Assent to be in a Research Study Entitled

[Title of Study (in Italics): must match title listed on New Protocol Submission xForm]

What is a research study?

We are asking you to be in a research study. Research helps us learn new things. Only people who decided they want to help will be in the study. We will tell you about the study and then you should take time to make your decision. You should talk to your parent or guardian before you decide.

Who is doing this research study?

This person doing this study is [Name of Principal Investigator] with [List the academic department under which you are conducting this research study. If you are in a sub-department, list both College and Department/Academic Sub-Unit]. They will be helped by [Names of Faculty Advisor/Dissertation Chair and Co-Investigators].

Why is this study being done?

This study is to find out [Explain reason for the research study].

What will happen to me in this study?

If you want to be in this research study, [Describe in simple terms, what the child is expected to do and which parts of the study are experimental.]

How long will I be in the study?

[Describe time commitment for child in simple terms.]

What are the good things about being in this study?

If there are direct diagnostic benefits or direct therapeutic benefits, insert:
There are good things that might happen. [Describe only known benefits to the child].

OR if there are no direct benefits, insert:

There are no benefits to you but we hope what we learn from this study will [Describe any indirect benefits child will receive or how it will help others with conditions similar to theirs.]

Will being in this study hurt me?



We do not think you will be hurt by helping us with this study.

If there are minor risks or discomforts:

You may [Describe any risks or discomfort to child participants.]

<u>Do I have other choices?</u> If there are no alternative treatments other than this study, delete this section.

Yes, you can decide not be in this study and [Describe alternative procedures for child that may be available other than this study.]

Will people know I am in the study?

The people doing the study will know that you are in the study along with [List any other people who will know child is in the study]. They will not tell anyone else. If they talk about the study or write about it, they will not use your name.

Is it ok if I say "No, I do not want to be in the study"?

You do not have to be in this study if you do not want to. No one will be mad or upset with you if you change your mind. You can decide at any time to stop being in the study.

Who can I talk to about the study?

If you have questions now, feel free to ask us. Remember, you should talk with your parents or guardian about this study.

If later you have more questions about the study, you can contact [Insert name] can be reached at [provide telephone number(s), with area code, that will be readily available during and after normal work hours].

Research Participants Rights

For questions/concerns regarding your research rights, please contact:

Institutional Review Board New York College of Health Professions (516) 000-000 / Toll Free: 1-800-922-7337 IRB@nycollege.edu

You may also visit the NYCHP IRB website at https://nycollege.edu for further information regarding your rights as a research participant.

All space below was intentionally left blank.

Please include the above statement if there is significant blank space left at the end of this document before the signature page, otherwise delete.



This section <u>must</u> be on a separate page from rest of consent document. Do you understand and do you want to be in the study?

ere answered.	
ly.	
this research study.	
Signature of Child	Date
Signature of Person Explaining the Study	Date
	this research study. Signature of Child