**Assent Template for Children Ages 11-13 (version 1/29/2019): To be used for subjects who are children ages 11-13 and who are enrolled in research studies that require expedited or full committee review. Children in this age group require an assent document with more simplified language than older children, but can include more detailed information than children ages 7-10. Assent for children ages 11-13 is usually a written document, unless the requirement for documentation is waived. Children in younger age groups may need even further simplified assent documents or text. Please refer to our other assent templates for ages 14-17 and ages 7-10 for children outside this age group 11-13).**

**Children *are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.***

***Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.***

***Remove this text, the instruction text below, or instructions imbedded in the document from the final document submitted to the IRB and used for subjects. If you are submitting the research for an exemption determination, then you should use the template for the Information Sheet for Exempt Studies to obtain the child’s agreement to be in the study, not this template.***

***The IRB will require that the format (below) be used and that the document is printed on normal paper, not letterhead. The IRB plans to use the electronic approval stamp in this template. The document will be converted to a PDF and sent back to the Principal Investigator (PI) for use in the research.* The PI must use the stamped approved copy of the assent document with subjects.**

***General instructions:***

1. ***The revised Federal regulations that became effective January 21, 2019 introduce several new elements of consent, which are included below in the template. If you are not familiar with the new consent requirements, please review the*** *“*Instructions for Completing the Assent Templates” ***for a summary of the current requirements.***
2. ***The information should be provided to subjects in language that they will understand, meaning lay language at a reading level appropriate for the age, maturity level, and reading capabilities of the child (subject target population) being recruited for the research. For younger children we have different assent templates in which the language level is simplified further.***
3. ***The assent document should provide enough information about the study to the child so that he/she can decide whether or not to participate in the research.***
4. ***Remove the brackets for inserting text from the final document. Remove any information that does not apply to your research. Convert all text to black print.***
5. ***Be sure to complete the title for the research. The title should match the one on the application, unless there is a specific reason for an altered title (i.e. deception will be used in the research).***
6. ***If you are conducting research in a foreign country or with non-English speaking subjects, you should consider what will be the best method for a subject to contact you, especially as most research questions will arise during the actual conduct of the research (e.g. when you are in that foreign location). Considerations may include presence of technology in that area of the world, the economic cost of making an international phone call, or what is affordable for your target population. For phone numbers, be sure to include the international code.***
7. ***The document submitted to the IRB should have a running footer (present on all pages), which contains a version date and page numbers in the X of Y format. If the document is revised, it should be given a new version date. Ensure that the auto-update function for dates is turned off in the document so that it will not change to the current date every time you open the document. If you will be using multiple versions on a document, note the version after the date (e.g., “Version 7/22/13 – Interview”; “Version 7/22/13 – Survey”).***
8. ***If you are requesting a waiver of documentation of consent or an alteration of consent involving a verbal assent process, the signature lines should be removed from this document. In general, assent for children ages 11-13 is usually written.***
9. ***In accordance with the DePaul Editorial Style Guide and current practices in the field of human subjects, please do not use the prefix Dr. for persons with a PhD degree in the body of the consent document. To the general public, Dr. means a medical doctor and particularly when a research study might involve some biomedical aspects, a prospective subject could misinterpret the Dr. as meaning you have medical knowledge and can provide medical advice.***

**ASSENT FOR CHILDREN TO PARTICIPATE IN RESEARCH**

**AGES 11-13**

**[TITLE OF STUDY]**

**Principal Investigator:** [Insert the PI’s name and if desired degree and title (i.e., Associate Professor). If the PI is a student, indicate undergraduate student or graduate student]

**Institution:** DePaul University, Chicago, Illinois, USA

**[Department, School, College- delete the ones that do not apply]:** [List the name, i.e., Nursing, Psychology, LAS, etc.]

[For students, research assistants, or fellows] **Faculty Advisor:** [Insert faculty sponsor’s name, Degree and Department, School, or College]

[If applicable, include. If not applicable, delete] **Collaborators:** [Insert names and affiliations (i.e., organization or institution) of collaborating investigators]

***What is research?***

We want to talk to you about a research study we are doing and see if you want to be in our research study. Research is a way for us to test new ideas and helps us learn more about new things. [*Edit this statement to fit the type of research you are conducting.* Research is one of the ways we find out if a new therapy is safe and will work, if a new type of teaching method is as good or better than an old one, what children like you think about XYZ.]

We are going to explain the research study to you and it is ok to ask us questions when we are talking with you. You can circle, highlight, or underline things in this paper that you do not understand or that you want to know more about. We want you to ask questions now and anytime you think of them. If you do not understand something, just ask us.

***Why are we doing this research study?***

We are working to find out more about [provide a simple explanation of the purpose of the study or what you are trying to learn.]

***Why are we asking you?***

You are being asked to be in the study because [insert a simplified version of your inclusion criteria so that the child understands why you are asking him/her to be in this particular study.]

We hope to have [X number] of children like you in this research.

***What happens if you are in the research?***

If you are in the research, this is what will happen:

[*Insert a very simplified explanation of what is involved in being in the research. Some sample language is provided:*

* We will have you…
* We will ask you…
* We will look at your school records and record your test scores….
* We will record what you say to us.

The research will take [x minutes, hours, days, months or X number of visits that each last x minutes, hours.]

***Are there possible good things that can happen?***

We [do not know for sure if you will be helped by being in this study, do not think you personally will be helped by being in this study.] But we could learn something [that will help other children, your teachers, or about X.]

***What are the possible risks or bad things that can happen?***

The risks or bad things that may happen are:

[*Some sample statements are provided, but these are to be adapted to the actual risks to the research that you outline in the application.]*

* You could feel uncomfortable, afraid, lonely, or hurt. You can stop the study at any time you want to.
* Some kids feel….
* Sometimes the questions we ask can make you feel embarrassed or uncomfortable. You do not need to answer any questions you do not want to.
* You may get a bruise and feel some pain when we are drawing blood.

***Can you decide not to be in the research?***

Both you and your parent (guardian) must agree to you being in the study. It is your parent or guardian’s job to read all the information about the study and decide if it is ok for you to do it. But it is still up to you to say yes or no. Even if your parent or guardian says yes, you may still say no. You do not have to be in this study if you do not want to. Nobody will be mad at you if you don’t want to be in the study. Nothing bad will happen to you if you say no now or change your mind later after starting the study. You just need to tell us if you want to stop being in the study.

*[If the research takes place in a classroom setting or another type of setting in which the child’s normal activities are interrupted, explain to the child that if they are not in the study, what their options are.* For example: Instead of being in this study you may [insert a description of available alternatives, i.e., do your school work, play, leave and go home.]

If we learn anything new while we are doing the study, which might make you change your mind, we will tell you.

***Will I be paid or will it cost me anything?***

If you are in the study, you will be paid [insert and explanation of the payment plan]. It will not cost you or your parent (guardian) anything to be in the research.

***What happens to the information from the study?***

We will keep the information we collect for the study secure. We will not share information that has your name on it with people who are not part of the research team, unless we have to. [Insert if applicable, as every employee of DePaul is now a mandated reporter under state law:

Sometimes we have to tell other people your information because the law says we have to show your information to a court or to tell authorities if you report information about being abused or neglected or if you pose a danger to yourself or someone else.]

***What if you have questions, concerns, or complaints?***

If you have questions, suggestions, concerns, or complaints about the study or you want to get more information or provide input about this research, you can contact the researcher, [insert your name and phone number, and email, and if appropriate the faculty sponsor’s name and contact information].

This research has been reviewed and approved by the DePaul Institutional Review Board (IRB). If you have questions about your rights as a research subject you may contact Jessica Bloom in the Office of Research Services at 312-362-6168 or by email at jbloom8@depaul.edu.

You may also contact DePaul’s Office of Research Services if:

* Your questions, concerns, or complaints are not being answered by the research team.
* You cannot reach the research team.
* You want to talk to someone besides the research team.

***You will be given a copy of this information to keep for your records.***

**Statement of Assent from the Subject:**

I have read the above information. I have had all my questions and concerns answered. By signing below, I indicate my assent to be in the research.

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Age:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_