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| **SUNY DOWNSTATE HEALTH SCIENCES UNIVERSITY**  **& NYC Health + Hospitals, Kings County**  *(If not applicable, delete one of the above lines and the “&”)*  **BROOKLYN, NY 11203**  **CHILD ASSENT**  **(Age range: 7-12 years)** |
| Title:  Researcher(s):  Researcher Contact Information:  Sponsor: |

Instructions for Creating a Child Assent Form:

* This form provides suggestions for preparing assent forms. Studies vary significantly; deviations may be necessary.
* Instructions to investigators are in italicized type and should be deleted.
* Final text should be 14pt or larger. Each sentence or closely-related group of sentences should be a paragraph visibly separated from other paragraphs.
* Once instructions are deleted, the assent form for most studies should fit on one page.
* Items in italics are general instructions and should be deleted and substituted as indicated.
* To the extent possible, technical, medical, and scientific concepts should be explained in lay terms that are understandable to someone who is educated to the 4th grade level. Avoid long sentences and medical/technical jargon, and define any technical terms clearly whenever they are used. If the definitions of technical terms are lengthy, describe in separate sentences. The PI is encouraged to use readability resources, such as:
* [*Readability Formulas*](http://www.readabilityformulas.com/)
* [*MS Word -Test your document's readability*](https://support.office.com/en-us/article/test-your-document-s-readability-0adc0e9a-b3fb-4bde-85f4-c9e88926c6aa)
* *Add pictures, diagrams, tables, or charts if they will improve understanding.*

**I was told I can be in a research study. I can say yes or I can say no. I can ask as many questions as I like before I decide.**

**The study may help study doctors and others doing this research learn more about \_\_\_\_\_\_\_.**

*Describe the study topic in the simplest terms possible, e.g.*

* *for a study of immune function, add “how the body fights disease.”*
* *for a study of cancer, add “cancer.”*

**If I am in the study, the study doctors and others doing this research will\_\_\_\_\_\_\_\_\_\_\_.**

*Describe briefly the basic elements of the study from the perspective of the participant using short, subject-verb sentences. For many studies there will be only one sentence. For complicated clinical trials there should be at most 5-10 sentences, for example:.*

* *for a study involving only an additional blood draw, add “use a needle to take some blood from my arm.”*
* *for a randomized trial of two chemotherapeutic agents, add “give me one of two medicines. One medicine is a new medicine. The other is the regular medicine for people with my type of cancer. The medicine will be given for one hour through a needle in my arm. This will happen 2 times a week for 2 months.”*

***Risks***

*Describe the principal study related risk(s), e.g. for a study involving only an additional blood draw:*

*Drawing blood may hurt me where the needle goes in. The hurt will go away after a while.”*

*For a randomized trial of chemotherapeutic agents:*

*The medicines may make me feel sick. I may have a belly ache. I may have headaches. If I feel sick, I should tell my mom or dad.*

***Benefits***

*Describe the principal benefits of the study, e.g. for research not offering the prospect of direct medical benefit:*

Being in this study will not help me. What **the study doctors and others doing this research learn** may help children in the future.

*For research offering the prospect of direct medical benefit:*

Being in this study may help me with my\_\_\_\_\_\_\_ *[asthma, cancer, etc.].* What the researchers learn may also help children *[with asthma, cancer etc.]* in the future.

***Harms to unborn fetus***

*Include this section when enrolling individuals of childbearing potential, when individuals are screened for pregnancy test or when pregnant individuals are excluded or when pregnant individuals will be withdrawn from a study.*

The research study drug(s) (or indicate procedure) can harm an unborn fetus. Because of this, you should not become pregnant [If appropriate, include: or get someone pregnant] if you join this study.

Individuals who can get pregnant will have pregnancy test before enrolling and before certain procedures. If you join the study and have a positive pregnancy test, we will tell you about the test results. You must give your permission before we can share the results with a parent or guardian or anyone else. If you have a positive pregnancy test, we will ask you to leave the study. This means that even if we did not tell your parent or guardian, they might figure out you were pregnant. You will be referred to an adolescent healthcare provider who can discuss your options.

**I can say “no.” No one will be mad at me.**

**If I say “yes” now, I can change my mind later.**

**I can talk to my parents and the study doctors about the study.**

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| **Check your choice below:** | |
| *\_\_\_\_\_* | YES, I want to be in the study. |
| *\_\_\_\_\_* | NO, I do not want to be in the study. |

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Child**  **(7-12 years old)** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature** | \_\_\_\_\_\_\_\_\_\_  **Date** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Print Name of Investigator Obtaining Assent** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Signature** | \_\_\_\_\_\_\_\_\_\_  **Date** |