Columbia University Medical Center

Assent Form for Children (ages 7-12) to be Part of a Research Study Involving Whole Exome or Whole Genome Sequencing

For children ages 7-12 to be part of a research study involving whole exome sequencing (WES) or Whole Genome Sequencing (WGS), the child must indicate that they agree to participate in the study by signing this Assent Form.

Additionally, his/her parent or legal guardian must sign a Consent Form on his/her behalf (either for individuals with a medical condition or for individuals without a medical condition).

***Note that children ages 13-17 who are capable of understanding may provide assent by reading and signing the appropriate individual Consent Form that the parent or legal guardian also signs.**

There are additional consent templates for (1) individuals without a medical condition, (2) individuals with one or more medical condition(s)/symptom(s), (3) parents of children with one or more medical conditions, and (4) parents of children without a medical condition. Research involving trios (i.e., children with one or more medical conditions and their biological parents) would utilize both of the applicable adult and parental consent forms. This template does not apply to protocols that propose the analysis of data from previously conducted sequencing or involve the collection of biological samples and storage for future undefined sequencing of those samples.]

Instructions for Assent Form Preparer:
Fill in the information requested in italics or delete as applicable. Include a version date in the footer. If your study has more than one consent form, clearly identify the individual forms in the footer. Please also ensure that a minimum 1" space is left in the lower right hand corner for the IRB approval stamp.

This template uses large font size and icons to improve comprehension.

If assent is not waived by the IRB, children in this age group should be fully informed of the research using language suitable for their age, maturity and psychological state and assent should be obtained from those deemed capable of making a meaningful decision. Assent should be solicited in the presence of parent or guardian. When assent will be verbal only, the parental permission should include an acknowledgment by the person obtaining consent/assent/permission and parent or guardian. The assent script could also include an acknowledgment by the person obtaining assent that verbal assent was obtained (see acknowledgment of verbal assent in section 7 of this form).
If assent is not solicited, the reason for not soliciting assent should be noted in the research record for the subject.

While it is important for all consent/assent processes that information be presented verbally, it is particularly important that the information in this form is presented verbally because the children to be enrolled are very young. Do not rely on the child's ability to read this form.

For this age group, assent may be obtained verbally. Unless required by the IRB, signature of the child is optional (see the signature section).

Study Title: *[This is the only section where medical/scientific terminology may be used. The title should conform to the title of any grant application/protocol.]*
Study Number: **IRB-*[insert IRB protocol number]***
Study Doctor:

Research Assent Form

What is a research study?

Research studies help us learn new things and test new ideas. First, we ask a question. Then we try to find the answer.

This paper talks about the research we are doing and tells you about what you will do if you want to be in this study. ***We want you to ask us any questions that you have. You can ask questions any time.***

Important things to know:

- You get to choose if you want to be in this study
- You can say "No" or "Yes"
- If you say "Yes" now but then change your mind, you can always say "No" later
- You will still get to see your doctor even if you don't want to be in this study

Why are we doing this research?

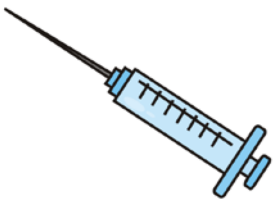
We want to find out more about [*add the medical condition(s), symptom(s) being studied]*.

What will happen if I say "Yes" I want to be in this study?

[*Include a brief description of the study procedures associated with the protocol. Examples of common study procedures associated with WES/WGS sequencing are noted below for your reference.*]

If you decide to be in the research, you will:

- **Give Blood**: We will poke you with a needle so we can take some of your blood. We will try to get blood without poking two times. We will do some tests on your blood *[select as appropriate: to find out more about your medical condition(s), symptom(s) [OR] to compare your blood to other people's (or family member's blood)].* The tests will look at your DNA



seq

uence. Most of the tiny cells that make up your body contain DNA. The DNA gives our body the instructions it needs about how to develop and function.

- **Answer Questions**: As part of the study, we will ask you to read and answer questions about you and your health on a piece of paper. We will ask you about whether you have been sick or hurt. **[OR]**

- **Medical Records**: We will look at notes from your past doctor visits to learn more about you and your health.

Could bad things happen if I am a part of this study?

The needle poke to test your blood is a little bit painful and uncomfortable. Sometimes the needle can leave a bruise on the skin.

You can say "No" **at any time** to what we ask you to do for the research and we will stop.

Could the research help me?

[*Choose the most appropriate selection:*]
Yes, being in this research may help you because [*provide brief description to explain the prospect of direct benefit*].

No, this research will not help you. But we hope that we learn something about the new things and ideas that we will test. Someday we hope that this research will help other kids who have *[enter condition or symptom]* like you.

What else should I know about this research?

- Remember, if you don't want to be in this study you can say "No." You will not get in trouble if you decide not to be in the study.
- You can say "yes" now and change your mind to "no" later. If you change your mind, just tell your parents and the study doctor that you don't want to be in the study anymore. This will take you out of the study.
- To thank you for being in this study, we would like to give you [e*nter amount or token gift*]. (or)You will not be given anything to participate in this study.
- You can ask questions at any time. If you want to talk to someone about this research, you can talk to [*enter research contact*].

Is there anything else?

If you want to be in the research study, please write your name below. We will write our name too. This shows we talked about the research and that you want to take part.

If you don't want to be in the study, don't write your name.

Child Name _____ Date _____

Person Obtaining Assent (Print Name)_____ Date _____

Person Obtaining Assent (Signature) _____ Date _____

[This text box only applies if you will obtain the assent verbally, in which case the signature lines that appear later in the form should be deleted.

If you will obtain the child's signature, the "Acknowledgment of verbal assent" text box should be deleted and the signature lines should be retained.]

Acknowledgment of verbal assent

Print name of Child: _____

Print name of parent(s)/guardian(s) present: _____

Do you want to be in this study?

Child's response: ☐ Yes ☐ No

_____ _____
Signature of Person conducting the assent process Date

_____
Print name of Person conducting the assent process

_____ _____
Signature of Witness Date

_____
Print name of witness

The signature of a witness is only required when obtaining assent from:

- a Non-English Speaking Research participant using the short form process, or
- a person who is physically not able to read, talk or write.