Columbia University Medical Center

Assent Form to participate in a Research study

Minor (Ages 7-11)

Instructions for Consent 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 assent form, clearly identify the individual forms in the footer, e.g., "screening consent form" or "assent form".

[All yellow high-light areas should be deleted when you are done.]

When developing your assent form, you may want to use certain fonts, such as Arial and Times New Roman, and font size 12 or 14, that are more appropriate for younger aged children.

If possible, the form should be limited to a few pages. If appropriate, illustrations may be used in addition to words to assist in the child's 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 participant.

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 section 7).

1. Title of research study and general information

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]*

2. Researchers' contact information

Principal Investigator: *[name and degree(s) of the Researcher conducting the study]*
Phone Number(s):
Co-Investigator(s): *[name(s) and degree(s) if applicable]*
Phone Number(s):

LEAVE SPACE (minimum 1") FOR IRB STAMP

3. Why are we interested in talking with you?

We want to tell you about a research study we are doing. Research is a way to learn more about something. *[Add the following as appropriate:]* This is the way we find out if medicine or other treatments are safe and if they work.

We are asking you and other children to be in this research study because *[insert simple/layperson name of medical condition or other reasons for inclusion. **Use very simple language**]*.

We are working to *[find out/learn more about—i.e. provide a simplified explanation of the how or why you are doing the research. **Use very simple language**]*.

It is okay to ask questions about what we are telling you. If you do not understand something, just ask us. We want you to ask anytime you think of a question.

4. What will happen to you if you are in the study?

[Description of what will take place from the child's point of view.

Choose as appropriate:]

If you want to be in this study, this is what will happen:

- We will ask you to *[insert specifics, e.g., answer some questions]*.
- We will have you do *[insert specifics]*.
- We will look at your *[insert specifics, e.g., doctor's records]*.

[Indicate the approximate total length of the participant's expected participation by the number of days, months or years (from screening to final completion). If the study has different stages, explain how long each will last.]

This research will take *[insert how long total]*.
It will take *[insert number of visits]* visits that each last about *[insert amount of time of visit(s)]*.

[Choose as appropriate:]

You may not benefit directly from this study. We hope to learn something that could help other children in the future *[add, if applicable:]* who have *[Insert medical condition]*.

[OR]

We don't know if being in this study will help you. Some of the ways you could be helped are:

- You could *[insert specifics, e.g., get better]*.
- Some kids feel *[insert specifics, e.g., less pain].*
- Feel good about helping other kids.

5. Will it hurt?

Choose as appropriate:
There is a chance that during the study you could feel uncomfortable, afraid, lonely, or hurt. We will help you with these feelings and you can **stop** at any time if you want. If you are in the study you could experience any of the following:

- You could *[insert specifics, e.g., get a bruise]*.
- You may feel *[insert specifics]*.
- You may feel *[embarrassed/sad/uncomfortable]* by the questions we ask.
- Someone might be able to see the things you tell us but we will try our best to keep this a secret.
- The *[insert specifics, e.g., blood sample]* may hurt.
- The study *[drug/device/treatment]* could make you feel *[insert specifics, e.g., dizzy, have an upset stomach]*.

6. What if you have questions?

You may ask questions at any time. You can ask now or later. You may talk to the researcher or someone else. Your parents/guardians have the information on who to call if you have questions after you go home.

7. Do you have to be in this study?

No, you do not have to be in this study. No one will be mad at you if you say **no**. You can also say yes now and change your mind later. Just tell the doctor or your parent/guardian that you want to stop.

If you say yes, you can ask as many questions as you want, at any time. No one else will know what you tell us *[insert as relevant:]* besides your parents/guardian.

Please talk this over with your parents before you decide if you want to be in the research study. Your parents have said that it is ok with them if you are in the research study. You can still say **no** even if your parents said that it is ok with them if you are in this research study.

[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

If you sign this paper, it means that you want to be in this study. **If you do not want to be in the study, do not sign this paper.**

Signatures

[Omit signature lines that do not apply to your study. If the signature line remains, the expectation is that it will be used at the time of each enrollment.]

_____

Signature of Child Date

_____

Print name of Child

_____

Signature of Person Obtaining Assent Date

_____

Print name of person obtaining Assent

LEAVE SPACE (minimum 1") FOR IRB STAMP

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.