

Columbia University Medical Center

Assent Form to participate in a Research Study

Minor (Ages 12-17)

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 consent or assent form, clearly identify the individual forms in the footer, for example "screening consent form" or "assent form".

[All yellow high-lighted 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 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. Stand-alone charts or other visuals aids may be helpful for the child to have.

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 documented. You can choose between developing an assent form or having the adolescents co-sign the parental permission form, so long as in either case, the form is written in age-appropriate language and has appropriate signature lines.

While it is important for all consent/assent processes to include verbal presentation of information, it is particularly important when the participants are minors. Do not rely on the minor's ability to read this form.

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]*

Sponsor/Supporter: *[insert names of funding agencies if any]*

2. Researchers' contact information

Principal Investigator: *[name and degree(s) of the Researcher conducting the study]*

Phone Number(s):

Co-Investigators: *[name(s) and degree(s) if applicable]*

Phone Number(s):

Study Coordinator: *[name(s) and degree(s) if applicable]*

Phone Number(s):

3. Why are we interested in talking with you?

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

Before agreeing to participate in this study, it is important that you read this form and talk with the research staff. You should only take part in this study if you want to. This form will explain why we are doing the research and what will happen to you if you are in this research study. We would like to discuss the study and review this form with you. You can ask questions at any time before, during or after our discussion. You will also have time to read this form and ask any questions about the research study. At the end, we will ask you to sign this form if you agree to participate.

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 any time you think of a question.

4. What is this research study about?

In this research study, we want to *[find out/learn more about—i.e. provide a simplified explanation of the how or why you are doing the research. Use simple language]*.

There will be about *[insert number]* participants in this study.

5. What will happen if you agree to be in the study?

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

The following will be asked of you, if you decide to be in this research study: *[List the procedures that are required in this research. Use a bullet or numbering format]*.

[Choose as appropriate:]

- 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]*.
- This research will take *[insert how long total]*.

[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 will take *[insert number of visits]* visits that each last about *[insert duration of visit(s)]*. You will have to come back to the office *[insert total number of times or visits or revise accordingly to briefly indicate what is required of the child in terms of time]*.

6. Are there any consequences if you participate in this study?

[Choose as appropriate to describe the risks [physical, social, financial, psychological, privacy, or other] and possible discomforts.]

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 participate 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.
- 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]*.

7. Will you benefit from being in this study?

[Choose as appropriate to describe the benefits:]

You will 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]

Taking part in this study may help you feel better or may make your *[Insert medical condition]* go away, but we do not know this for sure.

8. 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. If you have any questions about this study you can call *[insert PI name]* at telephone # *[insert phone number]*.

If you have any questions about your rights when you are in a research study, you may contact the Institutional Review Board by mail, telephone, or email at:

Institutional Review Board
Columbia University
154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883
Email: irboffice@columbia.edu

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

9. What about your privacy?

To protect you, the information collected in this study will not be shared with anyone unless required by law. *[Be sure this is accurate, e.g., if parents will have access, it should be so noted.]*

The researchers in this study will need to talk about you and the study *[Insert as relevant: with your parent/guardian and with other researchers]* but will not talk about you with anyone else except the people working on the study. If the researcher(s) need(s) to talk to anyone else about you he/she/they will ask you and your parent/guardian if it is okay to do so.

10. What will it cost you to be in this study?

There is *[choose one: some/no cost]* to you or your parents for being in this research study.

Add one of the following statements:

You will not get paid to participate in this study.

[or]

You will receive *[add amount of gift cards]* for your participation in this study.

11. Do you have to be in this study?

No, you do not have to be in this study. We are asking you if you would like to be in the study but if you say **no**, no one will be upset with you. You can also say yes now and if you change your mind later, you can quit the study at any time.

[Add, if this is an intervention study:] If you choose not to be in this study, you can: *[List alternatives to participation, e.g., alternative treatments, if any].*

Please talk this over with your parents/guardians before you decide whether or not to participate. Even though your parents/guardians have said it is all right with them if you want to be in the study, you can still say **no**. If you do agree to be in the study but later decide you would rather not be in the study, you may stop your participation at any time. Your decision will not affect your care or that of your parents or family members in any way.

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 Minor

Date

Print name of minor

Signature of Person Obtaining Assent

Date

Print name of person obtaining assent

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.