

Appendix M: Sample Assent Form

Revised Date: 12/01/20

Note to Investigators: If minor children (according to age of majority of the state in which the child lives) will be included in the study it is necessary to document the child's affirmative agreement to participate in research. An assent form is a written document used to inform the child of the study using age-appropriate language so he/she can determine whether or not to participate in the research. An assent form is generally presented to children over six years of age. If the child is not yet able to read, procedures may be used to present the information verbally to obtain verbal assent.

Note: Parents (or legal guardians or legally authorized officials) must sign separate consent forms permitting the minor to participate in research. Any project involving minors requires a signed consent form from either the child's parents or legal guardians before approaching the child for assent.

The following is a template for use in creating an assent form. Use language that targets the child's age and maturity level.

1. Introduce yourself and others who may interact with the child. **My name is _____.**
2. Describe the study purpose. We are asking you to take part in a research study. **We are trying to learn more about _____.**
3. Describe what the child will be asked to do. **If you agree to be in this study, you will be asked to: [Describe what will happen using language appropriate to the age-group targeted. If many tasks are involved, use a bullet format to list the tasks. Include the amount of time and number of sessions that are involved.]**
4. Describe risks (if any) associated with participation and how the risks are managed. **[e.g., Will the study hurt? The stick from the needle will hurt but the hurt will go away after a while.]**
5. Describe any benefits (if any) that the child may experience from participation. **[e.g., This study won't make me feel better or get well, but the doctors might find out something that will help other children like me later.]**
6. Make sure the child has discussed his/her participation with his/her parents. **[e.g., Please talk to your parents about this study before you decide whether to participate. We will ask your parents if it is all right with them for you to take part in this study. If your parents say that you can be in the study, you can still decide not to participate.]**
7. Invite questions about the study. **[e.g., You can ask me any questions that you have about this study, and I will try to answer them for you. If you have questions that you think of later, you can call me at _____.]**
8. Discuss Voluntary Participation. **[Taking part in this study is up to you. You do not have to be in the study. If you want to be in the study, you can say yes. If you say yes, but change your mind later, you can stop at any time.]**

Please mark one of the choices below to tell us what you want to do:

- No, I do not want to be in this study. Yes, I want to be in this study.

Write your name here: _____ Date: _____