**Instructions for Child/ Participant Assent Form**

**Assent** means a child's affirmative agreement to participate in research. Mere failure to object and absent affirmative agreement should not be construed as assent.

**Minor** refers to a person who is below 21 years of age and who has never been married. The term “Minor” and “Child” are used interchangeably.

In general ACMS IRB recommends that **assent** of a **minor** be sought when the child is 6 years of age or older, unless the child’s decision-making capacity is impaired.

For **children below 6 years** of age, written agreement of the child is not required.

For **children 6 to 12 years** of age, Child/ Participant Assent Form1 should be provided to document their agreement regarding participation.

NOTE (1):

If an investigator deems that the children age 6 to 12 years, has sufficient understanding and intelligence, Participant Information Sheet and Consent Form2 may be used instead. Their agreement regarding participation should be documented together with informed consent of their Legal Representative (e.g. Deputy, Adult Parent, Legal Guardian).

NOTE (2):

Information provided must be in a language understandable to children age 13 years. **ALL** consent documents should be written in simple language, at Primary 6 reading level or lower, which means short sentences, paragraphs and simple terms. Avoid medical/ scientific/ technical language or if they must be used, to include in brackets simple definitions or explanations for such terms.

For **children 13 to 20 years** of age, Participant Information Sheet and Consent Form2 should be provided to document their agreement regarding participation, together with the informed consent of their Legal Representative (e.g. Deputy, Adult Parent, Legal Guardian).

**Completing the template:**

* Language should be at a level appropriate to the child's age and development.
* Please note that parts in italics and/or yellow highlights should be modified for your specific research. Other parts may need to be modified as well depending on your research study.
* Please delete this page before submitting to ACMS IRB.

**CHILD/ PARTICIPANT ASSENT FORM**

|  |
| --- |
| **Protocol Title:** (Use the full protocol title as used in the ACMS IRB Application Form) |
| **Principal Investigator:** (Name)**Phone Number:** (Phone Number) |
| You are being asked to take part in a research study.This paper tells you about a research study we are doing. You can ask questions any time. |
| **What is this research study about?** |
| A research study is a way to learn information about something. We want to find out more about [*Describe the purpose of this research]. Example: This study will look at a new (experimental) [drug, device, etc.]. We want to see how well it works and if it is safe.*About *[Insert number]* children will be in this research study. |
| **Why am I asked to be in this research study?** |
| You are being asked to take part in this research study. This is because you have [*Indicate name of disease or condition/ other reason(s) for inclusion*]. |
| **What will happen if I take part in this research study?** |
| If you say yes to be in this research study, you will be asked to do certain things, like [*Describe the research procedure/ activities. Also include how much time is involved or number of visits*]. |
| **Will I feel any pain or discomfort if I take part?**  |
| *[Describe risks or discomforts using simple terms a child would know and understand; take into account a child’s fears].**Example: The study pills might make you feel […………]. Be sure and tell your parent if you feel any of these things.* |
| **Could the research study help me get better?** |
| The research study [*medicine, device, etc*.] may not help … you feel better … or … your [*disease or symptoms*]. *[Describe potential direct benefits to the child].* |
| **Do I have to be in this research study?** |
| You can choose if you want to be in this research study or not.* If you say ‘Yes’ now, you can always say ‘No’ later.
* If you say ‘No’, your doctor will still take good care of you.
 |
| **Do my parents know about this research study?** |
| Your parents know about this research study too.You can talk to your parents about this study before you tell us ‘Yes’ or ‘No’.*NOTE: Delete this section if the research is designed for conditions or for populations, which the parental or guardian permission is not a reasonable requirement to protect the participants (e.g. research involving child abuse or neglect).* |
| **What if I have questions?** |
| You can ask any questions you have, now or later.If you think of a question later, you can ask your parents or have them call the study doctor. |
| **Other information about this research study?** |
| If you want to understand more about this research study, please tell your doctor. You will be given a Participant Information Sheet and Consent Form. It is the same paper that we give to your parents when we tell them about this research study. |

**ASSENT**

This research study has been explained to me and I agree to be in this study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Child/ Participant Name for Assent Date

Check which applies (to be completed by person conducting assent discussion):

* The child/ participant is able to read and understand the assent form and has agreed to take part in this study.
* The child/ participant is not able to read the assent form, however, the information was explained verbally to the best of the child’s/ participant’s abilities to understand.

 \_\_\_\_\_\_\_\_\_

Name of Person Conducting Assent Discussion (Print)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Conducting Assent Discussion Date