**TEMPLATE WITH SUGGESTIONS FOR ASSENT FORMS FOR**

 **7 TO 13 YEAR OLD CHILDREN**

This assent template is meant to help investigators in preparing assent forms; the use of the template is not required. Please keep the following in mind as you develop the assent that is appropriate for your project:

1. Assent forms are typically used with children who are 7 to 13 years of age. Therefore, the target language level is a 4th grade reading level. This means that some very young children will need to have the assent form read to them. For these reasons the biggest challenge in writing assent forms is keeping the language and concepts appropriately simple.
2. Children 14 years of age and older are expected to give assent by signing the consent form used by their parents. Some IRB’s require a separate assent form for children 14 years of age and older. This is not the policy of the UHCMC IRB. However, if an investigator believes an assent form is better for this age group because of the complexity of the study or the nature of the study population, one may be used.
3. Without a waiver of assent, assent must be obtained from all children 7 years of age or older. If you do not believe assent is appropriate for some or all of the children eligible for your protocol, you must apply to the UHCMC IRB for a waiver of assent.
4. Although there are very formal requirements for the elements that must be present in a consent form, no such requirements exist for assents. This means that the investigator can propose assent content that he/she believes will best inform the 7 to 13 year old subjects about the study. **The assent template offers suggested headings and content; however, the investigator is encouraged to delete or add content as appropriate to the study. The length of the assent form should be proportional to the complexity of the study.** For most minimal risk studies, much of the information in the template can be deleted.
5. The IRB encourages the use of topic headings (those suggested in the template or others) with the belief that they improve readability. The sentences under each topic should be in a single paragraph.
6. The signature block only needs lines for the child to write his/her name and the person obtaining assent to sign his/her name. The person obtaining assent must be someone who is approved to obtain consent for the protocol. The UHCMC standard consent language is not needed.
7. If the child is not able to read the assent form, and verbal assent is obtained using the content in the assent form, the person obtaining assent should place in the chart or research record a statement with the following content. *I have discussed this clinical research study with \_\_\_\_\_ using language, which is understandable and appropriate. I believe I have fully informed him/her of the nature of the study and its possible risks and benefits. I believe the participant understood this explanation and assented to participate in this study.*

**What is a research study?**

A research study is a way to find out new information about something. Children do not need to be in a research study if they don’t want to.

**Why are you being asked to be part of this research study?**

You are being asked to take part in this research study because we are trying to learn more about [insert name of what is studied here]. [insert name of what is studied here] is a condition where [insert simple description of the condition/illness]. We are inviting you to be in the study because [state why the child is being asked to participate]. About [enter #] children will be in this study.

**Why is the study being done?**

The results of the study will help us to understand if [insert name of drug or treatment] will help children who have [insert name of medical condition].

**If you join the study what will happen to you?** [describe what will take place from the child’s point of view]

We want to tell you about some things that will happen to you if you are in this study.

You will be asked to come to see one of the doctors doing this study [insert how many] times and you will need to stay for about [ # ] hours.

You will have an equal chance of being given either [study drug] or an inactive pill and you will be asked to take it [insert # of times during the day] day for [insert # of weeks]weeks.

The study will last for [insert weeks/months/years].

We will ask you to give us some of your urine (pee) in a cup.

We will use a needle to take some blood from your arm [ # ] times.

We will leave a needle with a tube on it in your arm for [ # ] hours, so we can (get [ # ] blood samples)(give study medication).

**Will any part of the study hurt?** [describe risks and discomforts using terms a child would know and understand]

The medicines you take and the things that happen to you in this study may make you feel sick. If the medicine makes you feel too sick we may need to take you out of the study.

The study pills might make you feel […………]. Be sure and tell your parent if you feel any of these things.

We will draw blood from a vein in your arm [insert how many times]. You will feel a pinch when we use the needle to get the blood and this could leave a black and blue spot on the skin where the needle touched your skin.

**Will the study help you?** [describe any benefits to the child from participation in the research]

The pills in this study have helped adults with [insert name of medical condition], but it may or may not help you.

We do not know if your [insert name of medical condition] will get better because you take part in this study, although we hope this happens.

Some children may feel better because they are taking[insert the active medicine].

**Will the study help others?** [describe any benefits to society from the research]

This study might find out things that will help other children with [insert name of medical condition] some day.

**Do my parents know about this study?**

This study was explained to your parents and they said that we could ask you if you want to be in it. You can talk this over with them before you decide.

**Who will see the information collected about you?**

The information collected about you during this study will be kept safely locked up. Nobody will know it except the people doing the research.

The study information about you [will, will not] be given to your parents [or teachers].

If you are a girl you will have a pregnancy test if you join this study. The results of the pregnancy test would be given to your parents.

**What do you get for being in the study?**

You [and your parents] will get [enter amount or item] for [each visit/entire study].

**Will it cost anything to be in the study?** [cost statements are rarely needed in assent forms and are usually only in the parents’ consent form.]

It will not cost you or your parents any money if you join the study.

**Do you have to be in the study?**

You do not have to be in the study. No one will be upset if you don’t want to do this study. If you don’t want to be in this study, you just have to tell us. It's up to you.

You can also take more time to think about being in the study

**What if I have any questions?**

You can ask any questions that you have about the study. If you have a question later that you didn’t think of now, you can call [insert study telephone number]

You can also take more time to think about being in the study and also talk some more with your parents about being in the study.

**What choices do you have if you say no to this study?**

There are other ways to help your [insert name of medical condition] if you don’t want to be in this study. Examples are ………

This study is extra, so if you don’t want to do it (nothing else will change) (there are no other choices).

**Other information about the study.**

If you decide to be in the study, please write your name below.

You can change your mind and stop being part of it at any time. All you have to do is tell the person in charge.

You will be given a copy of this paper to keep.

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Write your name

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Witness Date

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Person Obtaining Assent Date