**HRP-502b: TEMPLATE – Assent**

## ****Assent Instructions****

## Assent:

## Assent is generally an agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. An assent is typically paired with permission from a parent or guardian, and together they comprise the informed consent to participate.

*Minors:*

## Children (minors) are a vulnerable research population and, as such, require additional protections when they are potential research subjects. Subpart D of both 45 CFR 46 (DHHS), and 21 CFR 50 (FDA) require certain additional protections for children involved as subjects in research. The requirements of Subpart D apply to all non-exempt research involving children conducted under the auspices of George Mason University. The regulations require that adequate provisions be made for soliciting the assent of all children involved in research, when the children are capable of providing assent. In determining whether children are capable of assenting, the ages, maturity and psychological state of the children should be taken into account. In general, children should be given developmentally appropriate information about a research study in a language and manner that is understandable to them, given their age, maturity, and cognitive abilities.

## For children aged 12-17 years: Children in this age group should be fully informed about the research, using language appropriate to their age and maturity, and written assent should be obtained. Oral assent can obtained for individuals or populations in which written assent is not appropriate. Assent must be obtained in addition to the consent of a parent or guardian.

## For children aged 7-11 years: This age group should be fully informed about the research, using language appropriate to their age and maturity, and documented assent should be obtained from those deemed capable of making a meaningful decision. Oral assent should be obtained for individuals or populations in which written assent is not appropriate. Assent must be obtained in addition to consent of a parent or guardian.

## For children under the age of 7: Typically, minors under 7 years old should provide oral assent. The oral assent script should be conversational and stated in such a way that is understandable and age-appropriate. Please use the guide below to create the script.

## Assent must be obtained in addition to the consent of a parent or guardian.

## ****Assent Template Language****

## <TITLE OF RESEARCH STUDY>

### ASSENT SCRIPT (Children Under Age 7)

My name is (Insert name of person who is assenting) and I am from \_\_\_\_\_\_\_\_\_ (Insert Institution/Department).

I want to talk to you about a research project I am doing. I am trying to learn more about (state purpose of research in simple language) \_\_\_\_\_ and I would like for you to participate. Your parents have already agreed to allow you to talk to us, but you can talk with them about it at any time.

If you would like to help me with my project, you will be asked to (include information on what they will be expected to do and the duration of the activities. All procedures should be described in simple terms).

**Will anything bad happen?**
Explain any possible risks, using simple terms, including any painful or uncomfortable procedures. Explain that they should let the PI and their parents know if they feel sick or pain from the study.

**Will anything good happen?**
Only describe KNOWN benefits to the child. If there are no known benefits, state so.

**What if I do not want to do this?**

You do not have to be in this study. It is up to you. You can say “no” now, or you can change your mind later. All you have to do is tell us. You will not be in trouble for saying “no” or changing your mind.

**Who can I talk to about this study?**

If you have questions about the study or have any problems, please let me or your parents know, and they can get in touch with us.

**Would you like to participate?**

If you would like to participate in our project, please say “yes”.

If you would not like to participate, please say “no” at this time.

## <TITLE OF RESEARCH STUDY>

### ASSENT FORM (Children Aged 7-11)

My name is (Insert name of person who is assenting) and I am from \_\_\_\_\_\_\_\_\_ (Insert Institution/Department).

I want to talk to you about a research study I am doing. Research studies help us to learn new things. In our study, we want to learn more about (state purpose of research in simple language) \_\_\_\_\_.Your parents have already agreed that you may take part in the study, so feel free to talk with them about it before you decide whether you want to join the study.

**What will happen to me in the study?**

We would like you to participate because (Include reasons for inclusion)\_\_\_\_\_. If it is ok with you and you would like to join the study, you will be asked to (include information on what they will be expected to do and the duration of the activities. All procedures should be described in simple terms).

**Will anything bad happen?**
Explain any possible risks, using simple terms, including any painful or uncomfortable procedures. Explain that they should let the PI and their parents know if they feel sick or pain from the study.

**Will anything good happen?**
Only describe KNOWN benefits to the child. If there are no known benefits, state so.

**Will anyone know that I am in the study?** (Confidentiality)

Explain simply what information you will be collecting and what information may be shared with others.

**Will I receive anything for being in the study?**

Describe any compensation provided to children.

**What if I do not want to do this?**

You do not have to be in this study. It is up to you. You can say “no” now, or you can change your mind later. All you have to do is tell us. You will not be in trouble for saying “no” or changing your mind.

**Who can I talk to about this study?**

If you have questions about the study or have any problems, you can talk to you parents, or call (insert name and phone number of PI) \_\_\_\_\_\_\_\_, the Principal Investigator for this study. If you have questions about the study but want to talk to someone else who is not a part of the study, you can call the Institutional Review Board office at George Mason University at 703-993-4121.

This study has been explained to me and I am willing to be in it.

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

Child’s Name (printed) and Signature Date

Check which applies below *[to be completed by the person administering the assent].*

[ ]  The child is capable of reading and understanding the assent form and has signed above as documentation of assent to take part in this study.

[ ]  The child is not capable of reading the assent form, but the information was verbally explained to him/her. The child signed above as documentation of assent to take part in this study.

## <TITLE OF RESEARCH STUDY>

### ASSENT FORM (Children Aged 12-17)

My name is \_\_\_\_\_\_\_\_\_ (Insert the name of individual assenting) and I am from \_\_\_\_\_\_\_\_\_ (Insert institution, department).

I want to talk to you about a research study I am doing. In our study, we want to learn more about (state purpose of research in simple language) \_\_\_\_\_.Your parents have already agreed that you may take part in the study, so feel free to talk with them about it before you decide whether you want to join the study.

**What will happen to me in the study?**

We would like you to participate because (Include reasons for inclusion)\_\_\_\_\_. If you would like to participate in the study, you will be asked to (include information on what they will be expected to do and the duration of the activities. All procedures should be described in simple terms).

**What are the risks?**
Explain any possible risks, using simple terms, including any painful or uncomfortable procedures.

**What are the benefits?**
Only describe KNOWN benefits to the child. If there are no known benefits, state so.

**Will anyone know that I am in the study?** (Confidentiality)

Explain simply what information you will be collecting and what information may be shared with others.

**What if I do not want to participate or decide later to withdraw?**

Being in this study is voluntary. You don’t have to be in this study if you don’t want to or you can stop being in the study at any time.

**Will I receive anything for being in the study?**

Describe any compensation provided to children.

**Who can I talk to about this study?**

If you have questions about the study or have any problems, you can talk to you parents, or call (insert name and phone number of PI)\_\_\_\_\_\_\_\_, the Principal Investigator for this study. If you have questions about the study but want to talk to someone else who is not a part of the study, you can call the Institutional Review Board office at George Mason University at 703-993-4121.

Your signature below means that you have read the above information about the study, have had a chance to ask questions to help you understand what you will do in this study, and you are willing to be in the study. Your signature also means that you have been told that you can change your mind later if you want to.

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

Child’s Name (printed) and Signature Date