**INSTRUCTIONS TO INVESTIGATORS**

This template is for use when obtaining written documentation for research projects **that involve minors between the ages of 7 – 13 years of age** as research subjects.

Delete the **RED** text before submitting this form to the IRB.

**Guidelines for completing this assent template:**

* Student researchers must include their Faculty Sponsor’s contact information and credentials.
* Use simplified language that is understandable to your subjects and avoid technical terminology, acronyms, scientific jargon, and abbreviations.
* Avoid using first person language from the perspective of the participant (e.g, “I understand…” or “I agree to…”).
* Delete all instructions in ***RED*** text in the template and make the font and color of text the same throughout before submitting for review.
* Proofread your consent document for grammar and spelling errors prior to attaching it to your IRBNet package.
* Enter the version date of the consent & page numbers in the header before submitting for review.
* Be sure to include the generic DU logo in the heading or your specific department logo.

**For younger child participants, depending on their age, maturity, the psychological state of the child involved and the complexity of the study, it may be best to obtain verbal consent from the child. Refer to the verbal consent script template in IRBNet. Be sure to adequately describe the consenting process in the study submission materials and delete the RED text before submitting this form to the IRB.**

**Assent Form for Participation in Research**

 **Children – Ages 7 - 13**

**Title of Research Study:** *If the official title is technical and difficult to understand, a simplified non-technical title should be used in addition to the official title*

**IRBNet #:**

**Principal Investigator:** *Name and credentials*

**Faculty Sponsor:** *If student investigator, insert Faculty Sponsor’s name & credentials*

**Study Site:** *Location where study will take place (i.e., DU department or lab, school district, community center, etc.)*

We want to tell you about a research study that we are doing. A research study is a way to learn more about something. We would like to learn more about *[details regarding the study aim or goals of the investigation in very simple terms]*.You are being asked to join the study because *[insert name of condition or other reason(s) for inclusion].*

You do not have to be in this study. It is up to you. You can say okay now to be in the study and change your mind later. All you have to do is tell us when you want to stop. No one will be upset if you don’t want to be in the study or if you change your mind later.

If you agree to join this study, you will be asked to *[describe the procedures (e.g., answer questions, activities) in words a child would know and understand. Also include number of visits and time frame understood by a child].*

**If applicable.** We will want to record you during the study as you *[answer questions or complete the activities]*. If you do not want to be recorded, that is okay too. Just tell us if it makes you uncomfortable and we will stop.

**Use any of the following statements as appropriate to describe the possible risks, discomforts, and/or benefits of the study.**

We do not think that you will be hurt or upset during the study.

We think that *[procedure or activity (e.g., blood draws, physical activities, answering questions)]*may *[hurt a little, be uncomfortable, or hard to do]*.

We do not know if being in this study may help you.

We think the study will help you by *[describe how in simple terms.]*.

We may learn something that will help other children with *[insert name of condition or topic under study]*someday. **[We strongly recommend that you include the following statements in your consent, to inform participants that you may share de-identified data you collect from them. Certain sponsors now require researchers to make available their de-identified data to the research community, as do a growing number of journals in a variety of disciplines. If you choose not to include the following language and later wish to share de-identified data, you may not be able to do so without re-contacting participants to obtain consent.]** *Also, other researchers may want to use the information that we learn to help more children. We may allow them to use the information that we learned to help them with their study.*

Your parent or guardian will know that you are in this study. You do not have to be in this study even if your parent or guardian thinks it is a good idea. It is up to you.

We will not tell anyone else that you are in this study. You do not have to tell anyone about the study or *[the activities, your answers to the questions, etc.]*

Do you have any questions about this study? If you say okay to the study, you can ask questions at any time. Just tell the researcher or your parent/guardian that you have a question. Your parents/guardians have the researchers’ phone number to call any time.

If you agree to participate in this research study, please sign below.

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Participant Signature Date