Baylor University

**[(Department name(s)]**

Assent Form for Research

PROTOCOL TITLE: **(title should match protocol and grant)**

PRINCIPAL INVESTIGATOR: **[name]**

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| **INSTRUCTIONS:**  Information in the consent document must be organized to facilitate comprehension. Assent documents should be written in plain language and be easily understood by your target population taking into consideration the age and circumstances of the minor population. Many sections of this document include brief instructions and wording suggestions **in bracketed bold font** to provide investigators with a general overview of information required in the section. **Before you submit your document, delete all instructional language, brackets, and boxes and unbold your additions.**  Please note that not all of the information in this form will apply to your study. Please delete any sections that do not apply to your study and add any information that applies to your study but is not included in this template. This is only a template and should be used as a guide.  **Depending on the age of participants**, you may need more than one assent form with language appropriate for the different age groups (e.g., 7-12, 13-17). |

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| **What is a Research Study?** |

We want to tell you about a research study we are doing. Research studies help us to learn new things and test new ideas. People who work on research studies are called researchers. During research studies, the researchers collect a lot of information so that they can learn more about something.

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| **What is this study about?** |

We are doing this study because we would like to learn more about **[describe topic or condition]**. We are asking you join this study because **[add reason for inclusion]**.

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| **What will I do if I am in this research study?** |

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| **INSTRUCTIONS:** List all types of research activities that participants will be asked to do in words easily understood by a child. Use a bulleted list if the study includes multiple tasks/tests in order to facilitate understanding.  **If subjects will be audio or video taped**, add the following information:  We would like to make **a/an** **audio/video** recording of you during this study. **Audio/video** recordingis **required/optional** for this study**. (If required)** If you do not want to be recorded, you should not be in this study. **(If optional)** If you do not want to be recorded, you can still be in the study. Just tell the researcher that you don’t want to be recorded. |

If you decide to be in this study, we will ask you to: **[use simple language to explain tasks and procedures including details about procedures, questionnaires, activities, tests, etc.]**

This study will take **[insert length of time for participation, frequency of procedures or any other applicable information]** and there will be **[insert number of study participants]** in this study.

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| **Can anything bad happen to me while I am in this study?** |

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| **INSTRUCTIONS:** The information in this section should be limited to the risks and discomforts **related** to the procedures done for research purposes, and should not include those related to a research subject’s routine care, unless it would aid the subject’s understanding of the study.  Describe the reasonable foreseeable risks, side effects, and discomforts of each study procedure, drug/supplements, device, etc. **in language that a child will understand**. Include physical, psychological, social, and legal risks. If something might be painful, state this.  Many studies at Baylor involve the use of similar instruments, measures, devices, etc. The ORC maintains a library of standard/sample language that conveys these risks to participants. See G-07 Standard Consent Language guidance located on the Guidance Page for sample language and definitions.  **If the research presents more than minimal risk to the participant, include the following statement:** This study may involve risks that are currently unforeseeable. |

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| **Will being in this research study help me?** |

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| **INSTRUCTIONS:** Choose a statement(s) below and/or modify accordingly. **Do not include payment as a benefit.** |

We expect this study to help you by **[insert details]**.

**[OR]**

This study won’t help you, but we will learn more about **[describe condition/topic under investigation]**

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| **What else should I know?** |

You do not have to be in this study. It is up to you. You can say “yes” now and change your mind later. No one will be upset if you do not want to do this. All you have to do is tell us you want to stop.

We will limit the use of your information that we collect to people who have a need to review this information. We cannot promise to keep everything a secret, but we will work to keep your name and other information private. Your responses may be used for a future study by us or we may share your responses with other researchers.

If you tell us that someone is hurting you, the law says that we have to let other people know so they can help you. If you tell us you might hurt yourself or someone else, then we will have to let people know.

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| **Will I get anything to participate?** |

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| If you are paying for participation or giving small gifts, be specific about the amount given and how it will be paid.  For example:  You will get a $5 amazon.com gift card each time you participate in an interview.  You will get to choose a small gift, such as a book or keychain for your participation today.  **Delete this section if participants will not receive compensation.** |

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| **Who do I talk to if I have questions?** |

You can ask any questions at any time. You can ask now or later. Just tell the researcher when you see them, or ask your parent or another adult to contact:

[Name of PI]

Phone:

Email:

Or

[Name of secondary contact person(s)]

Phone:

Email:

**Statement of Assent**

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

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Signature of Subject Date

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| **For projects involving collecting verbal assent, remove the signature lines and include the following:** If you want to be in the study, let me know and we can get started. |