#### **ASSENT FORM**

For Children 7 – 17 years old [***or within this range as specified for your study, e.g., 7-12, or 13-17***]

*REMOVE ALL THE INSTRUCTIONS AND EXAMPLES BEFORE PRINTING*

* *Assent Forms should NOT include separate HIPAA language or a signature page.*
* *Assent Forms should be no longer than two pages.*
* *When submitting an Assent to IRB,* ***make sure the document contains ALL newly added information provided as tracked AND provide a clean copy****.*
* ***NOTE: For research that is not greater than minimal risk (e.g., online survey), check first to see if it is exempt. If it is not exempt (i.e., only if the identity of the child could not be linked to the data and other protections are in place), you may submit alterations to some sections, or a waiver of all sections, of this Assent template language. You can only do this when you have requested to make a waiver/alteration to the Assent in your application. The waiver/alteration requirements must still be met as stated in the application (e.g., alteration does not affect rights).***

**STUDY:** [***add study title***]

A research study is like a science project at school and it is a way to learn new things. We are doing a study to find out more about [***insert purpose of study in* *simple language***]. **[*State what is experimental in simple terms:*** The ***[drug/device]*** is not approved by the government to be used for ***[condition***], but doctors can still use it if they think it will help people**].** We are asking you to be in the study because you have [***state condition or simple inclusion***]. You do not have to be in this study if you do not want. It is up to you. You can even say okay now and you can change your mind later. All you have to do is tell us. No one will be mad at you if you change your mind. You can still get help with your [***condition***] if you are not in the study.

If you agree to be in this study, you will be asked to [***Describe procedures, (e.g., blood work, questionnaires, medication) in words a child would know and understand. Also include number of visits and time frame in words easily understood by a child]. For example: If you agree to be in this study, you will be asked to come to the study doctor’s office every week for four weeks. When you come in, you will have your blood drawn, and you will be given some questions to answer.***].

[***Describe possible risks, e.g., discomforts and/or side effects in simple language. For example: When you have your blood drawn, it might hurt. You might also have a bruise. This would be like any time you have your blood drawn. When you are given the questions to answer, some of the questions might make you feel upset. You do not have to answer any question that you do not want to answer.***].

[***For participants 13-17 years of age the following language must be included. If your study will only include children under the age of 13, then you can delete this section. If your study will include both children under 13 and 13 and up, then you may propose two assent forms, one with this section (13***

***and up) and one without this section 12 and under.***

If you are female and you are pregnant right now, you cannot be in this study. If you become pregnant, you will not be able to stay in the study. If you think you could be pregnant, please tell the study team that you do not want to be in this study. The study team is not allowed to tell your parents. You may be asked to have pregnancy tests for this study. If you are asked, then you have to have these tests in order to be in the study. The study doctor will talk to you and your parents about the results. If you do not want to have the tests, or you do not want the study doctor to talk to you and your parents about the test results, then you do not have to be in the study. If you are not okay with being in this study, then do not sign this form. If you sign this form, then you are saying that it is okay to do the pregnancy tests and to talk to you and your parents about the test results. You do not have to be in the study if you don’t want to. **]**

We do not know if you will be helped by being in this study. We may learn something that will help other children with [***insert name of medical condition or subject matter of study***].

This study was explained to your parents and they said that you could be in it. You can talk about this with them before you decide. Before you say yes to be in this study, we will answer any questions about the study that you may have. If you have other questions after you sign this form, you can ask us and we will answer them or get an answer for you. You can stop being in the study at any time.

If you turn 18 years old while you are in this study, then we will keep getting information about you until your next visit to the study doctor’s office. At that visit, you will be given the adult consent form to read and sign if you want to stay in the study. If you do not want to stay in the study you do not have to.

**Child’s Name** (print)**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Child’s Permission**

|  |
| --- |
| Signing below means:* You have read this form and that you choose to be in this study
* [***This bullet may be removed to be consistent with the decision above regarding age:*** If you are a female, signing this form means that you are okay with having pregnancy tests and with the study doctor talking to you and your parents about the test results **]**

If you don’t want to be in this study you do not have to sign. Being in this study is up to you, and no one will be mad at you if you don’t sign, or even if you change your mind later. If you want to be in this study, please sign your name. You will get a copy of this form in case you want to read it again.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Sign Your Name Date |

**Parental/LAR Attestation**

|  |
| --- |
| Where we say “parent” in this form, we mean a natural or adoptive parent, a legal custodian, or a legal guardian (collectively known as “Legally Authorized Representatives” or “LARs” for short)I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (print name of LAR) attest that I am one of the following individuals authorized to provide consent for the child named above as I am one of the following LARs (checkbox):[ ]  Natural or Adoptive Parent; [ ]  Legal Custodian; or [ ]  Legal GuardianI am signing below to confirm that the study has been explained to the child in my presence in a language that the child could understand. The child was told to ask questions and the questions were answered so the child could understand.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Sign Your Name Date |

**Investigator’s Certification [*if study is no greater than minimal risk, then this can be changed to* “Person Obtaining Consent”]**

|  |
| --- |
| **I certify that to the best of my knowledge the child understands the nature, demands, risks, and benefits involved in the participation of this study.** **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Investigator’s Printed Name Investigator’s Signature Date****[*if study is no greater than minimal risk, then the signature line can be changed to the following:*****Investigator or Designee’s Printed Name / Investigator or Designee’s Signature / Date]** |