**Assent Form For Participating in Research**

# Age 7 – 17 Years

***Assent Template Version: January 2019.***

***This is a template – please replace all the text in blue with study specific information.***

**Protocol Title:** <use iRIS study alias>

**Principal Investigator:** <PI name, credentials; e.g. John Smith, MD>

**Study Contact:** <Contact Name and phone number>

###### Invitation to take part in a research study

Dr. <PI Name> is inviting you to take part in a research study. You need to know about the study so you can decide if you would like to join the study or not. If you enter the study you will be asked to sign this form. You may take this paper home to talk with your family and friends before making your decision.

Your parents have already agreed that we can talk to you about being in the study. If you want to be in this study, you will be asked to sign this form.

About <XXX> children will be in this study. This study will be done at about <XXX> centers throughout the United States.

###### Why is this study being done?

We are inviting you to take part in a research study because we are trying to learn more about <outline what the study is about in language that is appropriate to the child’s maturity and age>.

###### What will happen if you join the study?

If you agree to be in this study, the following things will happen:

<Describe what will take place from a child’s point of view in language that is appropriate to the child’s maturity and age>

You will come to the office for at least <XX> visits.

Your parent(s) or legal guardian will also be asked to give their permission for you to take part in this study. Please talk this over with your parent(s) or legal guardian before you decide whether or not to be in the study.

###### What about blood and or tissue samples that are collected for future research?

If you have agreed to allow for your <blood and/or tissue> sample to be collected and used for future research we will ask that you re-approve the use of your samples by signing an adult informed consent when you reach 18 years of age.

###### How long will this take?

<Please note that this time period is how much time subjects will be asked to devote to the study including follow-up visits>

You will be in the study for <XX months/weeks/years>. Each visit will take about <XX minutes/hours>.

###### What are the benefits to taking part in this study?

Taking part in this study may or may not help you. Information from this study might help researchers to come up with new tests or medications to help others in the future.

###### What are some of the risks and discomforts? What could happen that no one would like?

<Describe any risks or discomforts the child may experience as a result of their taking part in this research study>

These things are called side effects. Some side effects are not known yet. Some known side effects are <example: nausea, vomiting, headache>. If any of these things happen when you are on the study, or if other things happen that are not listed here, you should talk about them with the study doctor.

###### Can you stop being in this study?

Your parent(s) or legal guardian must give permission for you to take part in this study, but you can choose if you want to be in this study or not. You do not have to be in the study. No one will be mad at you if you do not want to do this. Your doctor will still take care of you like before. If you do not want to be in this study, just tell someone. You do not have to tell them a reason. If you decide to be in the study, you can stop at any time.

###### Is there a cost to be in the study?

The cost to take part in the study will be discussed with your parents.

You may receive a small gift for taking the time to take part in the study. You will not be paid to take part in the study.

###### Who will know you are in the study?

When researchers are working on a research project like this, everything you say and everything they write down is private. Researchers don’t talk or show the information to anyone who is not working on the study unless you are in danger and need help right away. When anything is written down about you, a special number is written instead of your name. The list and codes of names are kept in a secure locked file.

###### What if you have any questions?

You can ask questions any time. You can ask now or you can ask later. You can talk to the study doctor or you can talk to someone else. If you would like to contact the doctor, <he/she> can be contacted at <XXX-XXX-XXXX>.

Signatures

Sign this paper if you decide you want to volunteer for the study. It is not a promise or contract. It just means that you have read this and that you understand what we are asking. It also means that you would like to try it. Remember that you can always change your mind by just saying so to your parents or anyone working in this study. You understand everything that has been explained to you. You will get a copy of this assent form.

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Printed Name of Subject

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Signature of Subject Date Time

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Printed Name of Individual Obtaining Consent

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Signature of Individual Obtaining Consent Date Time

**CPHS STATEMENT:** This study (HSC-XX-XX-XXXX) has been reviewed by the Committee for the Protection of Human Subjects (CPHS) of the University of Texas Health Science Center at Houston. For any questions about research subject's rights, or to report a research-related injury, call the CPHS at 713-500-7943.