Pediatric Assent Form

(Child/adolescent to read aloud. If unable to read, the presenter should read to the child/adolescent.)

• I understand that my Mom or Dad has said that it is okay for me to take part in this project (study) about my illness called: (type of illness)

• I understand what this project (study) is about.

• I am going to be in this project (study) because I want to.

• I have been told that I can stop being a part of this project (study) anytime I want to. Nothing will happen to me if I want to stop. I will still be able to get treatment for my illness.

____________________  ______________________
Signature of Child    Date

____________________  ______________________
Signature of Presenter Date
SCHOOL AGE ASSENT SCRIPT (AGES 7-12)

Insert Study Title here

I. Introduction

• My name is_____________ and I am a (explain job role), and I work with Dr. ________________.

• Dr. _______________ has said that you have an illness called _____________. In order to learn more about your illness, Dr. ___________ with other doctors are doing a "project" (some people call it a study). I am here to give you more information about this project and to ask you if you would like to be a part of it.

II. Purpose of the project

(Describe the purpose in one sentence using age appropriate, concise, and concrete language. Verify the language with a pediatric professional who has expertise in child development.)

III. Treatment Plan and Side Effects

In this project, these things will happen: (concisely list the main procedures, which are different from standard of care and their most probable side effects. Describe using age appropriate, concise, and concrete language. Specify if the procedures involved include painful procedures, such as blood draws and lumbar punctures. If procedures such as these are involved, they should be described. Verify the language with a pediatric professional who has expertise in child development. Keep description to a minimum of 2-3 sentences).

IV. Benefits

• Being a part of the project may or may not help you and other children which have your same illness.

• Being a part of the project may help doctors learn more about your illness and its treatment.

V. Voluntary Participation and Right to Withdraw

• If you don't want to be in this project, you don't have to. No one will be mad at you.

• You can say yes now and change your mind later if you want to.
VI. Questions

- Do you have any questions about the project? You can ask questions at any time. You can talk to me, your parents, nurse, or doctor.

VII. Obtain Assent

- Use an IRB approved pediatric assent form to obtain assent.
- Read entire assent form to child.
- Ask the child if they understand the assent form.
- If the child says yes and they agree to participate, have them sign the signature line. If the child says no, review the part of the assent form they don't understand. If the child continues to say no, document their declination to participate and do not continue with enrollment of the subject in the study.
TEENAGE ASSENT SCRIPT (AGES 13-17)

Insert Study Title here

I. Introduction

- My name is________ and I am a (explain job role), and I work with Dr. ________________.
- Dr. ______________ has said that you have an illness called _____________. In order to learn more about your illness, Dr. __________ with other doctors are doing a "project" (some people call it a study). I am here to give you more information about this project and to ask you if you would like to be a part of it.

II. Purpose of the project

(Describe the purpose in one sentence using age appropriate, concise, and concrete language. Verify the language with a pediatric professional who has expertise in child development.)

III. Treatment Plan and Side Effects

- This research study will last for (length of treatment time).
- In this research study, these things will happen: (using age appropriate language, concisely list the main procedures that are different from standard of care and their most probable side effects. Specify if the procedures involved include painful procedures, such as blood draws and lumbar punctures. If procedures such as these are involved, they should be described. Verify the language with a pediatric professional who has expertise in child development. Keep description to a minimum of 2-3 sentences).
- (Include this section if applicable) After the treatment phase of the study is completed, the follow-up phase begins. This means (describe in detailed age appropriate language, the follow-up requirements).
- If you agree to participate in this study it is important you do not, or your partner does not, become pregnant. This is because the treatment effects on unborn babies are not known. If you need to discuss the best ways to prevent getting pregnant, let your nurse or doctor know.
- If you agree to participate in this study, it is important that you do not use recreational drugs or alcohol. They may interfere with the research study and can have negative effects on your body.
IV. Benefits

- Being part of the project may or may not help you and other children which have your same illness.

- Being a part of the project may help doctors learn more about your illness and its treatment.

- *(Include any additional benefits directly related to the study.)*

V. Voluntary Participation and Right to Withdraw

- If you don’t want to be in this study, you don’t have to participate. You can stop this study at any time and no one will be upset with you. If you want to stop this study, talk to your parents, nurses, or doctors.

- You can say yes now and change your mind later if you want to.

- *(If applicable) If you decide not to take part in this study, other treatment plans will be provided to you.*

VI. Confidentiality

- All information about you related to this study will be kept private except:
  - Some of your records may be shown to people who check that the study is being done correctly.
  - Reports on the results of the study may be printed but your name will not be used.

VII. Questions

- Do you have any questions about the project? You can ask questions at any time. You can talk to me, your parents, nurse, or doctor.

VIII. Obtain Assent

- Use an IRB approved pediatric assent form to obtain assent.
- Read entire assent form to child.
- Ask the child if they understand the assent form.
- If the child says yes and they agree to participate, have them sign the signature line. If the child says no, review the part of the assent form they don’t understand. If the child continues to say no, document their declination to participate and do not continue with enrollment of the subject in the study.