Instructions for development of an assent script

ASSENT OF MINOR (AGES 7-11)

Children should be approached for assent <u>AFTER</u> the parent(s)/guardian have consented to their child's participation in the research study.

- Text that needs to be edited to be study specific is in RED and in *italics*; provide the correct text and remove the RED and *italics* before submitting your consent(s) to the IRB
- Delete all instructions before submitting your consent(s) to the IRB
- *Example text in RED and italics* should be edited by you as necessary and then *the Red and italics* removed
- *If your study involves multiple consent's (screening, randomization and then specific phases of the study) please only do one assent and summarize the study.*
- *Text in Blue is sample text, please remove before submission to the IRB*

If possible, the form should be limited to a few pages. Illustrations may be used instead of words if appropriate to assist in the child's comprehension.

The consent/assent processes, and the information in this form should be presented orally. Do not rely on the child's ability to read this form. In some cases, it may be appropriate for the child to provide an oral assent. If you encounter a child that can only provide oral assent, you should document this on the main informed consent document. If the child is able to assent they should sign the main informed consent document.

We have a glossary of terms that may be used to simplify the language used in your consent document. Click here to go to the glossary of terms.

STUDY TITLE: *Please write the entire title here*

PROTOCOL NUMBER: *Include this line, if applicable, otherwise delete*

CONSENT VERSION DATE: *This is the date the consent was developed or revised*

HOSPITAL OR INSTITUTION: *Where is the research taking place?*

INVESTIGATOR: *Principal Investigator submitting the application to the IRB*

SUBJECT'S NAME (printed):_____

Assent Script ages 7-12

WHY WE WOULD LIKE TO SPEAK WITH YOU:
We want to talk with you about being a part of something called a research study. A research study is when doctors collect information to learn more about a disease. Doctors who do research are also called researchers.

If you have any questions during our talk about this study, you can ask them. Don't worry about waiting until the person talking stops speaking to you. You can stop them at any time and ask your question.

We are doing this research study to learn more about children with *[insert disease type].* After we tell you about this research study, we will ask you if you'd like to be in this research study or not. If you decide to be in this research study, you will be asked to sign the same form your parent(s) signed. You may take a copy this form home and your parent(s) will be given a copy of the form that you both sign.

- It's okay to say 'NO' if you don't want to be in the study.
- It is also okay to be in the study now and leave it at any time.
- You should speak with your parent/guardian about your decision.

- We will still take good care of you no matter what you decide.

[*Include this paragraph if study is not about the treatment like a registry*]
This research study is not about getting treatment. You will have treatment for your illness, whether or not you agree to be part of this research study.

WHY ARE WE DOING THIS RESEARCH STUDY?
We want to find out *information on why the study is being completed and why the child is being asked to participate*

Example of what this language could look like: - more about Fibromatosis: this is the disease you have. When you have this disease cells in the body do not act normally. These cells grow faster than normal cells. They get in the way of how the body usually works. In this research study we will try to kill the bad acting cells with medicine, so that your body can work normally again.

We will be getting information from lots of boys and girls like you.
In this research study, there will be about *number* children who have *disease/condition*. You will have to come back to the office *number of times. Insert # of visit or revise accordingly to indicate what is required (in summary) of the child in terms of time.*

WHAT WILL HAPPEN IF I AM IN THE RESEARCH STUDY?
If you agree to be in the research study, this is what you will be asked to do:
Description of what will take place from the child's point of view.

Example of how this section could look. This section should emphasize what part of the research is done as EXTRA for the study.

1. *Office Visits*
    a. *If you are in the study you will come back to this office every week.*
    b. *If you are not in the study you will only need to come back once a month. That means if you do the study you will see us three extra times a month.*
2. *Give Blood- You will give a small amount of blood. Explain how the blood will be drawn i.e. through a vein or a mediport.*
    a. *If you are in the study - This will happen at every visit.*

b. *If you are not in the study - You will have to give blood once a month. If you are in the research study you are only being asked to give blood three more times a month.*

3. *Medication*
   a. *If you are in the study - You will also have to take some medicine. The doctors want to find out if two medicines you take in your mouth and swallow will shrink your tumor and if these medicines will make you feel sick. You will take the medicine once a day.*
   b. *If you are not in the study – You will also need to take medication that may make you feel sick. You will take the medicine once a day.*
4. *After the therapy ends, the doctors will want to see you for many years to see how you are doing. We are interested to see if you develop any effects to you and your body as you grow up.*
5. *The doctors may want to do extra tests on the blood we take from you.*
   a. *The doctors will use the leftover blood that they already took from you.*
   b. *The test would allow the researchers to see how you respond to the medicine.*

If it is ok with you that the researchers do these extra tests, please check off yes and put your initials on the line.
Yes_____ No_____

WILL IT HURT?
The medicines used may hurt or make you feel sick. The doctors and nurses will help explain what may happen and how you may feel. It is very important to tell your parents and the doctors if you feel sick or hurt anywhere in your body. *This is where you will explain the risks to the child in lay terms. If medication will be given to lessen the side effects, please explain that here.*

CAN I DO SOMETHING ELSE INSTEAD?
Yes. Your doctor will tell you and your parents what other treatment(s) you may have instead.

DO I HAVE TO BE IN THIS RESEARCH STUDY?
No and no one will be upset with you if you don't want to be in this research study. If you don't want to be in this research study, just tell us.

If you want to be in the research study, tell us that. And, remember, you can say yes now and change your mind later. It's up to you.

Please talk this over with your parent(s) before you decide whether or not to be in the research study. Your parent(s) have said that it is okay with them if you want to be in the research study. Even though your parents have said it is okay with them, you can still say 'No'.

IF I JOIN THE STUDY WOULD IT HELP ME?
Choose statements below to include as applicable to the study:
We do not think being in this study would help you.
[OR]
We think being in this study may help you because:

- [explain]

We hope to learn something from this study. And someday we hope it will help other kids who have _____ like you do.

WHAT IF I HAVE QUESTIONS?
You may ask questions at any time. You can ask now or later. You may talk to the doctor or someone else. Your parents/guardians have the information on who you or they may call after you go home.
If you have any questions about your rights for being in a research study, you may call the Maine Medical Center Institutional Review Board (IRB) at (207) 396-8268. The IRB is a department at MMC that reviews research studies to make sure that the people participating in research studies are protected as much as possible.

WHAT ABOUT MY PRIVACY?
The doctor will talk about you and the research study with your parent/guardian, but will not talk about it with anyone else except the people working here. If the doctor needs to talk to anyone else about you he/she will ask you and your parent/guardian if it is OK.

Will this cost my family extra money?
Examples of language you can use:
Choose one of the following
There is no cost to you or your parents for being in this research study. **OR** There will be some costs related to your participation. We have discussed these costs

with your parents/guardians. We can discuss them with you if you like or you can discuss the costs with your parents/guardians.

Add one of the following statements: You will not get paid to participate in this research study. **OR** You will receive ---- for your participation in this research study.

CAN I REALLY SAY YES OR NO TO BEING IN THIS RESEARCH STUDY?
Yes, the choice is up to you. You can say yes or no.
If you say yes, remember:

- You can stop being in the study any time you want to
- You can call the doctor any time you have any questions
- Besides your parents/guardian, your information will only be shared with the doctor and nurses in this study

If you say no remember:

- No one will be angry with you
- We will still take good care of you

If you sign the form that was provided to your parent/guardian(s), it means that you have read this and you have talked with someone about it. It also means you have had all your questions for today answered and you want to be in the research study.

If you don't want to be in the study, don't sign the form that was provided to your parent/guardian(s).

Being in the study is up to you, and no one will be upset if you don't sign the form or if you change your mind later.