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|  | Institutional Review Board  Human Research Protections  1 Park Avenue | 6th Floor | New York, NY 10016 |

**ASSENT OF MINOR (AGES 7-11 Biomedical)**

* Mandatory text that needs to be edited by you is shaded in green; provide the correct text and remove the green shading before submitting your consent(s) to the IRB
* Instructions (like these) are red text shaded in yellow; delete all instructions before submitting your consent(s) to the IRB
* *Example text in blue italic font* should be edited by you as necessary and then turned non-italic and black

When developing your assent form, you may want to use a larger font size. Certain fonts and font sizes are more appropriate for younger aged children. This form uses Comic Sans 12 point.

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.

As all consent/assent processes, the information in this form must 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 must advise the IRB.

# NYU Langone Health - ASSENT FORM

**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 this paper and you can take a copy of it home with you.

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.

[*Include this paragraph if study is not about the treatment*]

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?**

Description of what will take place from the child’s point of view

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 go 'haywire'. These 'haywire' 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 'haywire' 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 of the child in terms of time

**What will happen to you if you are in the research study?**

Description of *what will take place from the child’s point of view*]

If you agree to be in the research study, this is what you will be asked to do:

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

1. *Come back to this office every week.*
2. *You will give a small amount of blood. The blood will be taken from your arm. A needle will be used to draw the blood from your arm. This will happen at twice at every visit. You will have to give blood one time if you are not in this research study. If you are in the research study you are only being asked to give blood one more time at each visit.*
3. *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.*
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. 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.

**Can you do something else instead?**

Yes. Your doctor will tell you and your parents what other treatment(s) you may have instead.

**Do you 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 parents before you decide whether or not to be in the research study. Your parents 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'.

**What if you 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.

**What about your 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.

**Saying Yes or No to being in this research study**

You can say yes or no. If you say yes, remember:

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

If you sign this paper, 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 this paper.**

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

*Signature of Child Date*

*Signature of Person Obtaining Assent/Consent Date*