

Assent Form Template Instructions

(This template is for either clinical trials or clinical research)

Notes to Researchers:

1. Please note that this is a template to assist the Principal Investigator in the design of their assent form. It is important that Principal Investigators adapt their own assent to the outline and requirements of their particular study.
2. An assent form should be used for children 7 to 17 years of age.
3. An assent form should be written at a 2nd to 3rd grade reading level.
4. Delete the instruction page prior to IRB submission.
5. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the assent form that you develop and provide to participants in your research.
6. In this template:
 - square brackets indicate where specific information is to be inserted
 - bold lettering indicates sections or wording which should be included
 - standard lettering is used for explanations to researchers only and must **not** be included in your consent forms.
7. When writing the consent form, remember the following:
 - Use reader-friendly formatting so that your document *looks* easy to read (i.e. wide margins and bullet points).
 - Make sure that a version number and/or date is used

**UNIVERSITY OF SOUTH ALABAMA
ASSENT FORM FOR CLINICAL TRIALS**

[Insert title of the study]

[Name of Principal Investigator]

[Name of Organization]

[Address of Organization]

[Contact information of PI]

[Name of Sponsor]

WHAT IS A RESEARCH STUDY?

Explain the concept of research in simple terms.

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer.

This paper talks about our research and the choice that you have to take part in it. We want you to ask us any questions that you have. You can ask questions any time.

Important things to know...

- *You get to decide if you want to take part.*
- *You can say ‘No’ or you can say ‘Yes’.*
- *No one will be upset if you say ‘No’.*
- *If you say ‘Yes’, you can always say ‘No’ later.*
- *You can say ‘No’ at any time.*
- *We would still take good care of you no matter what you decide*

WHY ARE WE DOING THIS RESEARCH?

Simply explain the purpose of this study.

We want to find out how well your kind of cancer treatment is working. So we are getting information from lots of boys and girls like you.

In the whole study, there will be about 300 children who have brain tumors.

WHAT WOULD HAPPEN IF I JOIN THIS RESEARCH?

Simple explanation of procedures. Listing procedures often works well. Indicate the length of time of the individual participant’s active involvement. For younger children, provide a comprehensible measure of time. For example, the length of time of a TV show or movie.

If you decide to be in the research, we would ask you to do the following:

- *Blood draws: You may need a needle poke so we could test some of your blood. If possible, we will try to get blood without a new poke.*
- *Questions: We would ask you to read questions on a piece of paper. Then you would mark your answers on the paper.*

- *Talking: A person on the research team would ask you questions. Then you would say your answers out loud.*
- *Medical records: We will look at your past doctor visits and use information about your care.*

WILL THIS RESEARCH STUDY HURT?

Explain any risk that may occur during this study. If there are no known risks state this fact.

The stick from the needle to draw your blood will hurt, but the hurt will go away after a while. Some of the questions the doctor ask you may hurt your feelings. You do not have to answer any questions that make you feel bad. It will not hurt for the doctors to look at your medical records.

WILL YOU GET BETTER IF YOU ARE IN THIS RESEARCH?

Explain any benefits that may occur during this study. If there are no known benefits state this fact. Do not include payments or incentives in this section.

People may have good things happen to them because they are in research studies. These good things are called “benefits.” There is little chance of benefits to you from being in this research study. We hope to find benefits for people in the future.

WILL YOU GET ANY MONEY OR GIFTS FOR BEING IN THIS RESEARCH STUDY?

Describe any payment of gifts and how often they will receive it.

To thank you for being in the study, we would give you a \$100 Visa gift card. You should talk with your parents about how you would like to use this.

DO YOU HAVE ANY QUESTIONS?

Explain who they can contact if they have any questions.

You can ask questions any time. You can talk to [PI name and phone number]. Ask us any questions you have. Take the time you need to make your choice.

DO YOU HAVE TO BE IN THIS STUDY?

Explain that this study is voluntary and that they can stop at any time.

If you don’t want to be in the study, you don’t have to be. No one will be mad at you if you don’t want to do this. If you don’t want to be in this study, just tell us.

It is also OK to say yes and change your mind later. You can stop being in the research at any time. If you want to stop, please tell us.

If you want to be in the research after we talk, please write your name below. We will write our name too. This shows we talked about the research and that you want to take part.

Name of Participant _____
 (To be written by child/adolescent)

Printed Name of Researcher _____

Signature of Researcher _____

Date

Time