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Piedmont Healthcare
Assent / Information Sheet to Participate in a Clinical Study
(ages 7-12 years)

*See right column for instructions / explanations.*

*Use lay terminology whenever possible and complete or delete blanks as appropriate.*

*This document is to be accompanied by the corresponding parental permission form.*

Title:

Principal Investigator (The Study Doctor):

**What is a research study?**

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

**What this document is.**

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.

**Why this clinical study is being done.**

We are doing this research to find out more about \_\_\_\_

**What will happen to me during this study?**

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

**Could bad things happen if I join this research?**

Some of the tests might make you uncomfortable or the questions might be hard to answer. We will try to make sure that no bad things happen.

**Could this research help me?**

We think being in this research may help you because \_\_\_\_\_

OR

This research will not help you. We do hope to learn something from this research though. Als someday we hope it will help other kids who have \_\_\_\_\_ like you do.

**Do I have to participate?**

• 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.

Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the study.

Taking part in a study is separate from medical care. The decision to join or not join the study will not affect your status as a patient here at Piedmont Healthcare.

**How long will I be in the study?**

It is expected that your participation will last \_\_\_\_.

**What else should I know?**

You would not be paid to be in the study.

OR

To thank you for being in the study, we would give you \_\_\_\_. You should talk with your parents about how you would like to use this.

OBTAIN ASSENT

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 This child is 7 to 12 years old and has given verbal consent (**signature not required**). I attest that the child is able to provide assent and demonstrates sufficient understanding of the research.

 This information sheet has been offered to the child and parent for reference.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent Date

 Time (hh:mm)