# *Assent (Children Age 13-17)*

**Instructions (DO NOT INCLUDE THIS INFORMATION IN YOUR ASSENT):**

* **If your study does not include all ages from 12-18 [e.g., you include only subjects ages 15-18], please use age appropriate to the protocol.**
* **Font must be Times New Roman and at least at 12 point.**
* **Must be paginated.**
* **Bottom margin must be at least 1 inch.**
* **All footer information must be either on the left side of the page or the middle.**
* **A version number and date must be included in the footer of the document**
* **If the text below is in blue, this language must be used exactly as written.**
* **Use language that the average person is likely to understand (no higher than sixth grade-level). Define any technical terms and/or acronyms. For guidance, see IRB Document 118.9, “**[**Glossary of Lay Terms for Use in Preparing Consent Forms**](http://www.creighton.edu/fileadmin/user/ResearchCompliance/IRB/Policies_and_Procedures/118_9_Glossary_of_Lay_Terms_for_Use_in_Preparing_Consent_Forms.pdf)**.”**
* **Write using second person (i.e., subject addressed as “you” and clinical investigators as “I/we”).**

# *Assent to Participate in a Research Study (Minor Age 13-17)*

**TITLE OF RESEARCH:**

**IRB NUMBER:**

**SPONSOR PROTOCOL NUMBER:**

**INVESTIGATOR NAME:**

**INVESTIGATOR ADDRESS:**

**INVESTIGATOR PHONE:**

**SPONSOR:**

**………………………………………………………………………………….**

**INTRODUCTION**

You are being asked to be in a research study of [*insert general statement about study*].

You were selected as a possible participant because [*explain how subject was identified, include any exclusionary criteria*].

We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

**PURPOSE OF STUDY**

The purpose of the study is [*explain research question and purpose in lay language*].

Ultimately, this research may be [*published as part of a book on…, presented as a paper, etc.*].

This study will use [*insert investigational product or device name]*

**DESCRIPTION OF STUDY PROCEDURES**

If you agree to be in this study, you will be asked to do the following things: [*explain procedures and tasks; identify any procedures that are experimental; describe length of time for participation, frequency and duration of procedures; etc*.]

**ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT**

**\***[*If applicable, explain any alternative procedures or courses of treatment available to the subject*.]

**RISKS/DISCOMFORTS OF BEING IN THIS STUDY**

The study has the following risks.

First, [*explain first risk, including the likelihood of the risk*].

Second, [*explain second risk, including the likelihood of the risk*].

Third,

[*If there are no foreseeable risks, state as such*] There are no reasonable foreseeable (or expected) risks. **There may be unknown risks.**

**BENEFITS OF BEING IN THE STUDY**

The benefits of participation are [*explain benefits of participation that will be gained by the participants and/or other. If a benefit is not likely to occur to each participant do not include*.

[*If there are no expected benefits, state as such.*]

**CONFIDENTIALITY** [*choose a or b as applicable*]

1. This study is anonymous. We will not be collecting or retaining any information about your identity.
2. The records of this study will be kept strictly confidential. Research records will be kept in a locked file, and all electronic information will be coded and secured using a password protected file. [*If audio or video tape recordings are made, explain specifically who will have access to them, if they will be used for educational purposes, and when they will be erased/destroyed and indicate how they will be destroyed or erased.*]

**We will not include any information in any report we may publish that would make it possible to identify you.**

**PAYMENTS**

You will receive the following payment/reimbursement: [*explain amount of payment or other reimbursement information (e.g., class points, tokens, donations, etc.), as well as when payment and/or reimbursement will occur and in what cases payment will not occur if any.* *If there will be no payment, state this.*] [If the study will use the Greenphire payment system, ask CIIACC staff for the standard CHRISTUS informed consent language regarding this setup.]

**RIGHT TO REFUSE OR WITHDRAW**

The decision to participate in this study is entirely up to you.You may refuse to take part in the study *at any time* without affecting your relationship with the investigators of this study. Your decision will not result in any loss of benefits to which you are otherwise entitled. Youhave the right not to answer any single question. You also have the right to withdraw completely from the interview at any point during the process. You have the right to request that the interviewer not use any of your interview material.

**RIGHT TO ASK QUESTIONS AND REPORT CONCERNS**

You have the right to ask questions about this research study and to have those questions answered by research staff or study investigator before, during, or after the research. If you have any further questions about the study, at any time feel free to contact *(Principal Investigator)* at (*Email address)* or by telephone at *(Phone Number).* If you would like a summary of the results of the study, they will be sent to you.If you have any other concerns about your rights as a research participant that have not been answered by the investigators, you may contact the CHRISTUS Health Institutional Review Board at (469) 282-2686 or christus.irb@christushealth.org. If you have any problems or concerns that occur as a result of your participation, you can report them to *(name of the principal investigator)* or the CHRISTUS Health IRB at the numbers above.

**CONSENT**

Your signature below indicates that you have decided to volunteer as a research participant for this study and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study investigators.

Name of Participant (Print) Date of Birth

Signature of Participant Date

Name(s) of Parent(s)/Legal Guardian(s) (Print) Relationship to Child

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Signature of Parent Date

For the Research Investigator—I have discussed with this subject, and the parents/guardians of the subject the procedure(s) described above and the risks involved; I believe he/she understands the contents of the assent document.

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**Signature of Principal Investigator Printed Name Date**

**Or Person Obtaining Consent**

**Witness to Assent\***

I was present during the explanation of the research to be performed under Protocol **(INSERT PROTOCOL NUMBER HERE)**.

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**Witness Signature Printed Name Date**