*[This template is designed to help you create an ASSENT document to facilitate obtaining assent from minors, defined by the State of Georgia as persons younger than 18 years of age. Written assent is usually obtained from children ages 11 through17, with their maturity, capacity to give assent, and psychological and physical condition being considered. The assent document should state, in very simple terms, the purpose of the study, what is expected of the child, the risks and benefits of the study, the right to leave the study at any time, and who the child can talk to if they have questions about the study. Instructions are included in brackets, and examples are bulleted in some sections.]*

**ASSENT DOCUMENT FOR ENROLLING MINORS**

**IN A RESEARCH STUDY**

Georgia Institute of Technology

Project Title:

Investigators: *[List the Principal Investigator (John Doe, Ph.D.)]*

Protocol and Consent Title: *[Include version number and date (Main 00/00/00v1)]*

*[The following sentence, including the word RESEARCH*, *is required.]*

You are being asked to be in a research study. Your parent/guardian/caregiver knows about the study, but you can decide if you want to be in it or not.

**Purpose:**

*[This section is required. Give a simple description of the study’s purpose that is age appropriate.*

* *[An example of an Assent Purpose Statement follows:]* “We are trying to help children who have an amputation to walk better with a new type of prosthetic leg. ”

**What Will Be Done:**

*[This section is required and must include a simple description, sufficient for the child to know what is to be expected during the study.]*

* *[An example of a Assent Procedures Statement follows:]* “If you decide to be in this study, your parent/guardian/caregiver will bring you to our lab two times. Your parent/guardian/caregiver will be here in the room with you the whole time. We will let you try on a special prosthetic boot. You will walk in it on the first day for a few minutes. On the second day, you will climb a few steps while wearing the special boot. Somebody will always stand nearby to keep you from falling. We will ask you about the boot and whether it helped you walk and climb steps. We will videotape your lower body, but not your face. You may stop at any time.”

**Risks/Discomforts:**

*[This section is required and should be written so that the child can decide whether to take the risk or experience the possible discomfort.]*

* *[An example of a Assent Risks/Discomforts Section follows:]* “The boot might rub your residual limb. Be sure to tell us if it rubs or hurts at all, and we will try to make it more comfortable. If you want to stop, that’s OK and nobody will be angry or disappointed.”
* *[An example of a Assent Risks/Discomforts Section when no risks or discomforts are associated with participation follows:*] “We don’t think you will be uncomfortable or hurt at all while being in the study. If you want to stop, that’s OK and nobody will be angry or disappointed.”

**Benefits:**

*[This section is required and must include a description of any benefits expected for the participants or for society. It is okay NOT to expect the participant to benefit; in such a case, you should describe possible eventual benefits of this research to society. Note that compensation is not a benefit of being in the study.]*

* *[An example of an Assent Benefits Section follows:]* “We don’t think that being in this study will help you at all with your prosthetic leg. We hope to learn how to help other children walk more safely with a prosthetic leg.”

**To Thank You :**

*[This section is required and should specify what payment or reward the child will receive for being in the study. Compensation should be age appropriate and not coercive. Children are easily tempted by being offered electronic games or other highly popular toys, so the IRB generally prefers that those not be offered. Compensation should also not be so great that a parent/guardian/caregiver might be influenced to enroll their child simply to secure the payment.]*

* *[An example of an Assent Compensation to You Section follows:]* “We want to thank you for being in our study. We will give you a $10 gift card for McDonald’s both times you come to the lab.”

**Confidentiality:**

*[This section is required and should describe the extent, if any, to which confidentiality of records identifying the participant will be maintained.]*

* *[An example of an Assent Confidentiality statement follows:]* “We won’t tell your friends or teachers or anyone besides your parent/guardian/caregiver that you are in this study. The videotape will not show your face, and we will not let anyone besides the researchers see the videotape.”

**In Case of Injury/Harm:**

*[This section is mandatory, even for minimal risk studies, and must inform participants whom to inform if they are injured due to being in the study.]*

* *[An example of an Assent In Case of Injury Statement follows:]* If you get hurt as a result of being in this study, your parent/guardian/caregiver has been told what to do.”

**If This Is A Clinical Trial:**

*[Per 21 CFR 50.25(c), the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials:*

*“A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”*

*Additional guidance, including the definition of applicable clinical trials, may be found at* [*https://researchintegrity.gatech.edu/clinical-trials*](https://researchintegrity.gatech.edu/clinical-trials)*.]*

**Participant Rights:**

*[This section is mandatory and must include the following language:]*

* You don’t have to be in this study if you don’t want to be.
* You can stop being in the study any time.
* Nobody will be angry or disappointed if you decide not to be in the study or if you decide to quit.
* You will still get the $10 gift card even if you decide to quit.

**Questions:**

*[This section is mandatory and must include information about whom the child can talk to if the child has questions about the study.]*

* *[An example of an Assent Questions Statement follows:]* “You can ask Dr. Principal Investigator about the study. You can email the Georgia Tech Office of Research Integrity Assurance at [IRB@gatech.edu](mailto:IRB@gatech.edu) if you have questions.”

*[Finally, include the following signature language. If this study is clinical, participants must write in the date AND TIME of their signature. If you are using electronic signatures, verbal consent, or electronic consent, please see the instructions at the end of the document.]*

If you want to be in the study, please sign on the line below. Remember, you can quit being in the study any time.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Name (printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

*[ELECTRONIC SIGNATURES: If the assent process will take place online and you intend to obtain electronic signatures, then a Waiver of Documentation is not needed. You will need to keep the signature section in this document and state in your IRB Wise submission what software will be used to obtain the electronic signature. Currently, only DocuSign is approved by OIT to obtain electronic signatures. Additionally, please state in the IRB Wise submission which survey software will be used to obtain consent. Please see the* [*OIT website*](https://gatech.service-now.com/continuity?id=kb_article_view&sysparm_article=KB0023604) *for more information about which programs/software are approved.]*

*[CONSENT WITHOUT SIGNATURES: If the assent process will take place online or verbally and the study qualifies for a Waiver of Documentation of Consent; you may simply remove the signature section and replace that language with either “Agree” and “Disagree” buttons or the following statement listed below. Additionally, please state in the IRB Wise submission which survey software or teleconference tool will be used to obtain consent. Please see the* [*OIT website*](https://gatech.service-now.com/continuity?id=kb_article_view&sysparm_article=KB0023604) *for more information about which programs/software are approved.]*

* “By completing the online survey, you indicate your assent to be in the study.”

*[Before uploading the Assent document, be sure to delete all of the bracketed instruction language from the document. Assent documents will be returned without review if instruction language is not removed.]*