WRITTEN MINOR ASSENT (FOR CHILDREN AGED 7 – 17)

TEMPLATE AND INSTRUCTIONS

The following page contains a template for creating appropriate minor assent documents for your research studies at Georgia College (GC).

Instructions

1. Download and save this template file to your computer.

2. Edit the document on the next page as appropriate for your study replacing all bracketed, highlighted areas with information that is pertinent to your specific study.

3. Review and modify all non-bracketed/highlighted text to ensure that it is also appropriate for your study.

4. Delete this instructions page, and save your edited document to your local computer/disk.

5. Upload the final version of your assent document into the Portal where prompted (either in the “assent” question or in the “documents” tab).

Additional Notes

1. Assent by children (ages 7-17) is needed when children are mature enough to understand instruction and are capable to provide assent. This template document is created primarily to provide a general structure for researchers to accomplish the assent process. Further modifications to the template pertaining to your particular project are necessary.

Also, note that the Code of Federal Regulations for human subjects research requires first obtaining the permission (i.e., informed consent) of parental or legally authorized representative(s) when minors (younger than 18 years of age) are included (see guidance in [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.408](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html%2346.408)). (See also: parental consent document template in GC IRB Portal).

1. Obtaining assent is an integral part of conducting human subjects research ethically when minors are involved. Therefore, this document is an integral part of the ethical review of such research applications. Please construct it carefully and provide all information needed to would-be participants.
2. This form is for written minor assent with children/adolescents; templates for obtaining parental consent and adult written consent are available on the GC IRB Portal homepage.
3. Age appropriate language is advised when this form (e.g., descriptions of study procedures, risks/benefits, etc.) is further revised by using the simplest language for younger children and more adult-like language for older adolescents.
4. Please email irb@gcsu.edu for additional questions or clarification if needed.

MINOR WRITTEN ASSENT

*(Sample: please substitute your project information where appropriate)*

**Project Title:** {insert your study title here}

**Investigator and contact information:** {insert your (and any supervisors’) contact information here}

**1. What is this study about? What will I do in this study?**

We are doing a research study about {purpose in simple language}. A research study is a way to learn more about people. If you decide that you want to be part of this study, you will be asked to {simple description of what they will be asked to do, including time involved}.

**2. Could anything bad happen to me?**

{Include here any potential risks or discomforts associated with your study – procedures they will need to do, things that will take a long time, things that they may not enjoy, other risks or discomforts, etc.}.

{Describe simply and briefly how you will mitigate any of these potential risks or discomforts – e.g., “Your teacher will be here the whole time,” “You can take as many breaks as you want,” etc.}.

You can also stop any part of the study after we start.

**3. Can anything good happen to me?**

We think this study has some benefits. A benefit means that something good happens to you.  We think these benefits might be {simple description of the benefits of the study}.

{If no anticipated benefits, state “There are no known benefits to you for helping with this study.”}

**4. Do I have other choices?**

{Applicable only to some studies that offer interventions or treatments: “If you do not want to be in this research study, we will tell you what other kinds of treatments/programs there are for you.”}

{If not applicable, omit this section}

**5. Will anyone know I am in the study?**

{Sample text: “When we are finished with this study we will write a report about what was learned.  This report will not include your name or that you were in the study.”}

**6. What if I don’t want to be in the study?**

You do not have to be in this study if you do not want to be.  If you decide to stop after we begin, that’s okay too.  Your parents know about the study, too.

**If you decide you DO want to be in this study, please write and sign your name in the blank below.**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, want to be in this research study.

               (Write your name here)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_              \_\_\_\_\_\_
               (Sign your name here)                                   (Date)

Research at Georgia College involving human participants is carried out under the oversight of the Institutional Review Board. Address questions or problems regarding these activities to the GC IRB Chair, email: irb@gcsu.edu.