PARENTAL CONSENT FOR RESEARCH WITH MINORS

TEMPLATE AND INSTRUCTIONS

The following page contains a template for creating appropriate parental permission (informed consent) documents for your research 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 edited Parental Consent document into the Portal where prompted, either in the “assent” question or in the “documents” tab.

Additional Notes

1. 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>).

The Code of Federal Regulations for human participant’s research provides guidance on the required elements of informed consent. For further information, see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>

This template document was created primarily to provide a general structure for researchers to address these elements. Further modifications to the template pertaining to your particular project are necessary. Please check your constructed parental consent form against the Federal Code above.

For research involving children, also note that assent by children is needed when children are mature enough to understand instruction and are capable of providing such assent (generally ages 7-17).

1. Obtaining parental consent and permission 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 parents/guardians of participants.
2. This form is for parental permission and consent of minor participants only; templates for minor assent and for written adult consent are available separately on the Portal homepage.
3. Please email irb@gcsu.edu for additional questions or clarification if needed.

PARENTAL PERMISSION/CONSENT

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

Dear Parent/Guardian:

I am/we are from the Department of {insert department} at Georgia College & State University. My/our contact information is located at the bottom of this letter.

We are conducting a research study on {insert a general statement regarding your research purpose}. We would like to include your child in our research study. Your child was selected as a possible participant because {explain how participant was identified}. The study will take place in {study location/building and room}. If your child takes part in this project, it should take approximately {state the amount of time required of participants per session and for the total duration of the research} to complete the research study.

If your child takes part in this project, he/she will be asked to do the following activities:
{List all procedures, preferably in chronological order, which will be used in the research. Explain all procedures using language that is appropriate for the expected reading level of the parents/guardians.}

This research has the following risks: First, {explain first risk, including the likelihood of the risk and any measures that will be used to minimize the risks. Continue providing the risks, as necessary}.

The research has the following benefits: {explain benefits of participation that will be gained, either by the child, society, or to the body of knowledge (Note: monetary compensation is not considered a benefit of being in the study)}.

Your child will receive the following payment/reimbursement: {Explain the amount of payment or other reimbursement information (i.e., class credits), as well as when payment and/or reimbursement will occur. If applicable, indicate other ways participants can earn the same amount of credit or compensation. Delete this section if it is not applicable}.

The information in this research will be kept confidential. {State how the data will be coded}. Research data will be stored in a secure location. {State why the location is secure. (e.g., locked filing cabinet/room with limited access}. The data will be made available only to the persons conducting the research. No reference will be made in oral or written reports that could link your child to the research.

Your child's participation in this project is completely voluntary. Your decision whether or not to allow our child to participate will not affect your or your child’s relationship with {name agency, school, etc.  where subject was recruited}. In addition to your permission, your child will also be asked if he or she would like to take part in this project. Only those children who have parental permission and who want to participate will do so, and any child may stop taking part at any time. You are free to withdraw your permission for your child's participation at any time and for any reason without penalty.

You may keep a copy of this document for your records.

If you have any questions about this project, please contact us using the information below. If you have any questions about your or your child’s rights as a participant, contact the Georgia College IRB (contact information at the bottom of the page).

Sincerely,

(signature)

Principal Investigator’s Name

Phone Number

email@bobcats.gcsu.edu / email@gcsu.edu

{Include contact information for all investigators involved in the project, and if PI is a student, be sure to include Supervisor’s contact information as well}.

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**I DO / DO NOT (circle one) give permission for my child**

 **(name of child)**

**to participate in the research project described above.**

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(Print) Parent’s name

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Parent’s signature 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 Dr. Whitney Heppner, GC IRB Chair, CBX 090, GC, email: irb@gcsu.edu; phone: (478) 445-0870.