**UNIVERSITY OF NORTH CAROLINA AT GREENSBORO**

THIS IS A TEMPLATE FOR THE LONG FORM FOR OBTAINING INFORMED CONSENT FROM A PARENT/GUARDIAN FOR A CHILD’S PARTICIPATION IN RESEARCH. IT MUST BE ADAPTED TO INCLUDE ALL OF THE INFORMATION REQUIRED (**RED TEXT INDICATES REQUIRED LANGUAGE**) FOR INFORMED CONSENT. IF AN ITEM IS NOT APPROPRIATE FOR THE STUDY, PLEASE DELETE IT FROM THE FORM.

PLEASE NOTE THAT ALTERATIONS TO TEMPLATE LANGUAGE ARE ALLOWED WITH JUSTIFICATION.

**CONSENT FOR A MINOR TO ACT AS A HUMAN PARTICIPANT: Long Form**

Project Title:

Principal Investigator and Faculty Advisor (if Faculty Advisor is applicable):

Participant's Name:

**What are some general things you should know about research studies?**
Your child is being asked to take part in a research study.  Your child’s participation in the study is voluntary. You may choose for your child not to join, or you may withdraw your consent for him/her to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future.   There may not be any direct benefit to your child for being in the research study. There also may be risks to being in research studies. If you choose for your child not to be in the study or you choose for your child to leave the study before it is done, it will not affect your relationship or your child’s relationship with the researcher or the University of North Carolina at Greensboro.

Details about this study are discussed in this consent form.  It is important that you understand this information so that you can make an informed choice about your child being in this research study.

You will be given a copy of this consent form.  If you have any questions about this study at any time, you should ask the researchers named in this consent form. Their contact information is below.

**What is the study about?**

This is a research project. Your child’s participation in this project is voluntary. This section should include a statement that the study involves research, the purpose of the study, and how their child will be involved.

**Why are you asking my child?**

The reason for selecting their child; inclusion/exclusion criteria

**What will you ask my child to do if I agree to let him or her be in the study?**

The procedures to be used and identification of any procedures which are experimental, the expected duration (time) of the child’s participation, and any anticipated follow-up should be discussed. Any procedure which is likely to cause stress, pain (physical, psychological, or emotional), or any other unpleasant reaction should be described so that the parent/guardian understands fully to what they are consenting.

**\*\*FOR RESEARCH INVOLVING BIOSPECIMENS ONLY: How will my biospecimens be used?**

Please include a brief description of how biospecimens will be used and where they will be stored. If they will be sent to an outside lab for analysis, please state and include whether they will be sent in an identifiable or de-identified state.

Please include the following elements WHEN APPROPRIATE for your study:

* A statement that the participant’s biospecimens (even if identifiers are removed) may be used for commercial profit an whether the subject will or will not shar in the commercial profit
* A statement regarding whether clinically relevant research results, including individual research results will be disclosed to subjects an if so, under what conditions
* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (ie sequencing of human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

**Is there any audio/video recording of my child?**

This section should describe any plans to use audio/video recording if it is applicable to the project proposed (section should be omitted if there will be no audio/video recording). It should include the statement “Because your child’s voice will be potentially identifiable by anyone who hears the tape, confidentiality for things said on the tape cannot be guaranteed although the researcher will try to limit access to the tape as described below.”

**What are the dangers to my child?**

Please include the following statement: “The Institutional Review Board at the University of North Carolina at Greensboro has determined that participation in this study poses minimal risk to participants.” If there are minimal risks or more than minimal risks, describe the risks. Research involving more than minimal risk must also include an explanation as to whether compensation, medical, psychological or other types of treatments are available if injury or a stressful situation occurs.

If you have questions, want more information or have suggestions, please contact (name of principal investigator AND faculty advisor, if applicable) who may be reached at (333) 333-3333 (you can also include your email address if you like).

If you have any concerns about your rights, how you are being treated, concerns or complaints about this project or benefits or risks associated with being in this study please contact the Office of Research Integrity at UNCG toll-free at (855)-251-2351.

**Are there any benefits to society as a result of my child taking part in this research?**

Describe any benefits to society that may result from this study. Be sure that your language does not guarantee any benefits (use the word “may”).

**Are there any benefits to *my child* as a result of participation in this research study?**

Parents should be informed about direct or indirect potential benefits to their children or the absence of benefits. Be sure that your language does not guarantee any benefits (use the word “may”). Payment and incentives are not considered “benefits” to a participant and should be discussed within this section. If there are no direct benefits, state “There are no direct benefits to participants in this study.”

**Will my child get paid for being in the study? Will it cost me anything for my kid to be in this study?**

Costs and payments/incentives should be described explicitly, including conditions under which payments will not be given if that is the case. Describe how payments will be made if the participant elects to discontinue participation part way through the study. If there are no costs or payments involved, you may state, “There are no costs to you or payments to you or your child as a result of participation in this study.”

**How will my child’s information be kept confidential?**

Describe how information will be kept confidential. For example: stored in a locked file cabinet, password protection, encryption, not identifying participants by name when data are disseminated, anonymous data collection procedures. Include a statement that reads "all information obtained in this study is strictly confidential unless disclosure is required by law." If applicable, the researcher must add a description of any legal duty to report abuse that might supersede these confidentiality promises. For **Internet Research**, include this wording: “**Absolute confidentiality of data provided through the Internet cannot be guaranteed due to the limited protections of Internet access.** **Please be sure to close your browser when finished so no one will be able to see what you have been doing."Alternatively, add security statement from commercial survey tool used for the study.**

**Will my child’s de-identified data be used in future studies? – THIS SECTION IS ONLY TO BE USED IF USING DATA FOR FUTURE STUDIES**

**If the PI plans to use the participant’s de-identified data data for future studies, please state:** “Your child’s de-identified data will be kept indefinitely and may be used for future research without your additional consent or your child’s additional consent.”

**If the PI does NOT plan to use the participant’s de-identified data data for future studies, please state:** “Your child’s data will be destroyed at \_\_\_\_\_\_\_\_\_\_(state when data will be destroyed). Your child’s de-identified data will not be stored and will not be used in future research projects.

**What if my child wants to leave the study or I want him/her to leave the study?**

“You have the right to refuse to allow your child to participate or to withdraw him or her at any time, without penalty. If your child does withdraw, it will not affect you or your child in any way. If you or your child chooses to withdraw, you may request that any data which has been collected be destroyed unless it is in a de-identifiable state. The investigators also have the right to stop your child’s participation at any time. This could be because your child has had an unexpected reaction, has failed to follow instructions, or because the entire study has been stopped.”

**What about new information/changes in the study?**

“If significant new information relating to the study becomes available which may relate to your willingness allow your child to continue to participate, this information will be provided to you.”

**Voluntary Consent by Participant:**

By signing this consent form, you are agreeing that you have read it or it has been read to you, you fully understand the contents of this document and consent to your child taking part in this study. All of your questions concerning this study have been answered. By signing this form, you are agreeing that you are the legal parent or guardian of the child who wishes to participate in this study described to you by      .

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Participant's Parent/Legal Guardian’s Signature