|  |  |  |
| --- | --- | --- |
| **Institutional Review Board (IRB)** |  | Consent Form |

Title of the Study: [Insert Study Title]

Study Number: [Insert Study Number once assigned by IRB]

Principal Investigator: [Insert PI’s name and department]

Co-Investigator(s): [Insert name and department for all co-investigators] [DELETE if none]

Faculty Advisor: [Insert FA’s name, department, and e-mail/phone] [DELETE if faculty/staff PI]

We are asking you to allow your child to take part in a research study. This consent form describes the research study and give you information you need to know before deciding whether to allow them to take part. You may freely choose whether or not to allow them take part in the study; participation is completely voluntary. At the end of the form we will ask you to confirm that you voluntarily agree to allow them to be part of this study.

# Overview of Key Information

* Goal is [one-line summary of purpose]
* Will take [duration]
* Your child will [brief 1-2 line summary of tasks (e.g., “complete a short survey”)]
* We will ask for information you or your child might not want other people to know. [DELETE if not asking for private or sensitive information.]
* We will [not] ask for information that could be used to tell who your child is.
* We will not share information about your child’s identity with anyone else. [OR 1-2 line summary of confidentiality] [DELETE if data are anonymous]
* [Statement of risks: “Risk are same as in everyday life”; “Small risk of ….”; etc.]
* [Brief 1-2 line statement of benefits to participants, if any]
* [Compensation, if any. For example, “Your child will be given a $10 gift card when finished”; etc.]
* [Brief 1-2 line statement of alternative procedures, if any]

# Why is this research study being done?

The goal of this research study is to [describe specific purpose and scope]. We plan to have approximately [sample size] people take part in this study.

# What are you being asked to do?

[Describe the procedures to be followed, clearly indicating the kinds of tasks that participants will be asked to perform, the duration of the tasks/study, the kinds of information they will be asked to provide, and the nature of any biological specimens that will be collected and how they will be obtained, as appropriate to your research project. Be sure to use language that is easy for the parents/guardians of participants to understand. Avoid jargon and technical terminology.]

[**If conducting interviews**, indicate whether the interview will be recorded, how it will be recorded, whether it will be transcribed, and how any tapes or transcriptions will be handled (including whether and when they will be destroyed). Then clearly describe how the results of the interview will be used (in thesis or dissertation work, publications, or other scholarly work) and whether the participant’s identity will be included in any publications/presentations.]

[**If using deception**, you either need to include a notice and prospective agreement such as “We may not tell you everything about the study up front, but we will explain more at the end of the study” or justify in your IRB application why deception or incomplete disclosure is required.]

# How will we use your private information/biological specimens?

In this study, we will ask your child to provide [private and/or sensitive] information that you or your child might not want other people to know.

[ONE OF THE FOLLOWING IS REQUIRED]

We will not ask for your child’s name or any other information that could be used to tell who they are. In other words, the information your child provides will be completely anonymous. [OR]

We will ask for [specify the kind of identifiable information]. This information could be used to tell who your child is.

[FOR RESEARCH INVOLVING BIOSPECIMENS]

Your child’s [fluid / blood / tissue] samples contain genes, which are made up of DNA that serves as the "instruction book" for the cells that make up our bodies. We [may / will / will not] analyze the genetic material in the samples they provide. This [may / will / will not] include a procedure known as genomic sequencing that can determine the exact order of the base pairs (chemical letters) in [the tissue or fluid being studied].

[IF DATA/SPECIMENS ARE IDENTIFIABLE, ONE OF THE FOLLOWING IS REQUIRED]

We may remove any information that could be used to tell who your child is. If we do so, then we may then use the [data/samples] for future research studies, and we may also share the [data/samples] with other researchers. [OR]

We will not use the [information/samples] for any other research projects. We will not share the [information/samples] with other researchers.

[State the extent, if any, to which confidentiality of records identifying the subject will be maintained. This section should explain how the researchers will minimize the risk of breach of confidentiality by discussing and data security measures to be taken (storage, coding, encryption, limited access to study records, etc.). Any regulatory or other agencies which may have access to the research records should also be noted. For example, “We will do the best we can to make sure that the information your child provides is kept confidential. We will store the recordings in a locked file cabinet in the principal investigator’s office. We will not use your child’s name or other information that could be used to tell who they are in any presentations or publications. ”]

In some cases we may need to share the information your child provides. The UNG Institutional Review Board makes sure that research with people is done ethically. They may review our records. The research sponsor, [funding agency or sponsor name], may review our records. State or federal laws or court orders may also require us to share information from the study records.

# What are the risks?

There are risks and discomforts that can occur in any research study. If you allow your child to take part in this study, they might experience ….

[Describe the risks in terms that the subjects can understand. For research in which there are no more than minimal risks, you may simply state something like, “The possibility of harm or discomfort in this research study is the same as when your child gets a routine physical exam/does normal physical tasks/takes routine psychological tests/etc.” (select the most relevant example).]

# What happens if you are injured because you took part in this research study?

[If there is more than minimal risk or if asking for sensitive information that could have a negative impact on the participant (e.g., depression, suicidal thoughts), describe the resources participants may access in case of harm or discomfort (e.g., a counseling center, hotline, or clinic) and provide contact information for those resources.]

If your child is hurt or injured during this research project, please contact [name of designated research team member], [title], at [business phone and/or email address].

[State who will be responsible for the costs of procedures, follow-up tests, office visits, treatment of adverse events, etc. relating to research activities, if applicable.]

# What are the benefits of being in this research study?

Your child [may/may not/will not] benefit from this research study. [Explain possible benefits that participants may get due to their participation. If the research results could be clinically relevant, be sure to include a statement informing participants whether any results, including individual results, will be disclosed to them, and if so, under what conditions.]

[Society / other people with… / other people who…] may benefit in the future because of what the researchers learn from this study. [Explain the social/future benefits, if any.]

# What other options are there?

[For studies that include a biomedical or therapeutic intervention. Describe any appropriate alternative procedures or courses of treatment that might be advantageous to the subject.]

# What will we pay or give you in exchange for being in this study?

Your child [will / will not] be paid for taking part in this study. [Identify and explain any compensation participants will receive in exchange for participating, including monetary compensation, opportunities to win a prize (e.g., though a drawing), and/or partial course credit or extra credit.]

[IF COLLECTING BIOSPECIMENS]

The information and biological samples from this research [may / will not] be used to create a process or product that could be sold to make a profit. You and your child will not receive money or other compensation for the use of the [fluid / blood / tissue] samples your child provides other than what is described above.

# Who can you contact if you have questions?

For questions about this study, you can call or email the principal investigator, [name of PI], at [business phone and/or email address] or the faculty advisor, [name of FA], at [business phone and/or email address].

For questions about being a research participant, please contact the chair of the Institutional Review Board (irbchair@ung.edu) or the Assistant Director for Research Integrity, Dr. Troy Smith, 3820 Mundy Mill Road, Oakwood, GA 30566, 678-717-3670, [troy.smith@ung.edu](mailto:troy.smith@ung.edu).

# What are your rights as a research study volunteer?

Your child’s participation in this study is voluntary. You may choose not to allow your child to take part in this study. There is no penalty if you decide not to let them take part. You may withdraw your child from the study at any time.

[Explain the consequences of a parent/guardian's decision to withdraw their child from the research and procedures for orderly termination of participation by the subject. If collecting identifiable private information or biospecimens, be sure to discuss the process parent/guardian's should use to have their child’s info/specimens removed from the research records, destroyed, returned to them, etc., as appropriate.]

The researcher will notify you if they discover anything during the research project that could affect your decision to allow your child to take part in this study.

The researcher may take your child out of the study. [Describe any anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent]

# Please confirm that you understand

I have read this consent document. I have been able to ask any questions I have about the study. I have been able to tell the researcher about my concerns. The researcher has answered my questions and responded to my concerns. I believe that I understand the research study, the potential risks, and the potential benefits. I agree to allow my child to take part in this study.

--------------------------------------

Printed Name of Participant

----------------------------------------- ------------------------------------------------ ------------------

Printed Name of Parent/Guardian Parent/Guardian’s Signature Date

----------------------------------------- ------------------------------------------------ ------------------

Printed Name of Parent/Guardian Parent/Guardian’s Signature Date

# FOR THE RESEARCHER

I have explained the nature and purpose of the research study, the possible risks, and the possible benefits to the person named above. I have answered any questions and have responded to any concerns that have been raised. I have given a copy of this signed consent document to the parents/guardians of the research participant.

-------------------------------------- ------------------------------------------------ ------------------

Printed Name of Consenting Signature of Consenting Date

Research Team Member Research Team Member