**UNIVERSITY OF GEORGIA**

**CONSENT FORM**

**[TITLE OF THE STUDY]**

***Instructions:*** *Instructions appear in italicized red font. Recommended language appears in black font. This template must be modified to fit your study. Remove italicized directions/guidance and red font when drafting your consent document. To ensure comprehension, avoid academic phrasing and technical terminology; aim for a readability level no higher than 8th grade.*

**Researcher’s Statement**

You are being asked to take part in a research study. The information in this form will help you decide if you want to be in the study. Please ask the researcher(s) below if there is anything that is not clear or if you need more information.

**Principal Investigator:** *Name*

*Department*

*Contact Information*

*Provide the key information someone might consider to decide if they want to participate. This key information should fit within the first page to page-and-a-half of the document. At a minimum, include the following:*

* *Summarize the purpose(s) of the research in lay language;*
* *The fact that consent is being sought for research and that participation is voluntary;* Your involvement in the study is voluntary, and you may choose not to participate or to stop at any time without penalty or loss of benefits to which you are otherwise entitled.
* *The expected duration of the prospective participant’s participation;*
* *In simple, non-scientific or academic language, the key procedures to be followed in the research;*
* *The reasonably foreseeable major risks or discomforts to the prospective participant;*
* *The primary benefits to the prospective participant and/or to others that may reasonably be expected from the research; and*
* *Appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the prospective participant.*

*You can also describe here why the individual is being asked to participate [i.e., based on inclusion/exclusion criteria.]*

If you are interested in participating in the study, please read the additional information on the following pages, and feel free to ask questions at any point.

**Study Procedures and Time Commitment**

*Describe the participant's time commitment for participation and/or length of study. If more than one, indicate how many separate visits are required. Provide details of visits/sessions. If procedures and timelines are complicated, consider a table or providing additional materials (brochures/instructions) as addendums.*

*Identify experimental procedures (e.g., interventions, manipulations, treatments.)*

*Include the use of photographs, audio, or video recordings.*

**Risks and discomforts**

*In simple language, describe any reasonably foreseeable psychological, social and economic, legal, or physical risks or discomforts.*

* *Psychological risks (e.g., feelings of stress/discomfort, sadness, guilt or anxiety, loss of self-esteem, etc.)*
* *Social and economic risks (e.g., privacy concerns, breach of confidentiality that may result in embarrassment or stigmatization within one’s business or social group; effects to financial or social standing, employability, or insurability)*
* *Legal risks (e.g., possibility of discovering illegal activities that may require reporting to authorities)*
* *Physical risks (e.g., temporary dizziness, nausea, muscle aches, rashes, infection, bruising, etc.)*

**Benefits**

*Describe the probable benefits of participation in the research for the participants. If there are none, state so.*

*Describe the expected benefits to society/humankind or to scientific knowledge.*

*Note: Compensation, financial or non-financial incentives, and earning extra credit for being a research participant are not benefits and should be listed under a separate heading (see Additional or Optional Sections).*

**Confidentiality of records**

*If the information/specimens collected includes information that identifies participants directly (e.g., name, e-mail address) or indirectly (use of codes), describe who will have access to the identifiable records or link to the participant and indicate when the identifiable information will be deleted. For example, “We will only keep information that could identify you long enough to match your responses with your medical records. We do not plan to share this information with anyone who is not connected to this research study.”*

*Include one of the following:*

*If the information will be used or shared after the identifiers have been removed, for example with other researchers and/or for future studies without additional consent, describe this possibility.*

*OR*

*If the information will not be used or distributed for future research, state this.*

*\*If the project is funded by a federal agency (e.g., NIH, EPA), indicate that the Office for Human Research Protections and departments at the University of Georgia responsible for regulatory and research oversight may access the records.*

*\*If the project is FDA regulated, indicate that the Food and Drug Administration and departments at the University of Georgia responsible for regulatory and research oversight may access the records.*

*\*If applicable to this study, describe the conditions under which the investigator will break confidentiality (e.g., mandated reporting of child abuse or neglect or indication of suicide ideation.)* *If there are none, you may state, “Researchers will not release identifiable results of the study to anyone other than individuals working on the project without your written consent unless required by law".*

**Research Injuries or Illnesses** *(Include this section if the project involves more than minimal risk to participants or is FDA regulated.)*

In the event that any research-related activities result in an injury or illness, the sole responsibility of the researchers will be to arrange for your transportation to an appropriate health care facility *(OR, describe any available medical treatments, what they consist of, and where further information may be obtained)*. If you think that you have suffered a research-related injury, you should seek immediate medical attention and then contact *[PI name]* right away at *[insert phone number].* Medical expenses will be your responsibility or that of your third-party payer (insurance). However, you cannot be prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

**Participant rights**

*Identify the IRB as the office to contact with questions about research participant rights.* If you have any questions or concerns regarding your rights as a research participant in this study, you may contact the Institutional Review Board (IRB) Chairperson at 706.542.3199 or irb@uga.edu.

***ADDITIONAL SECTIONS – Most studies will require one or more additional sections. Please refer to the ‘Consent Additional or Optional Sections’ document for further guidance.***

If you agree to participate in this research study, please sign below:

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Name of Researcher Signature Date

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Name of Participant Signature Date

**Please keep one copy and return the signed copy to the researcher.**