**UNIVERSITY OF NORTH CAROLINA AT GREENSBORO**

THIS IS A TEMPLATE FOR OBTAINING INFORMED CONSENT FOR 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. SEE THE ORI WEBPAGE FOR OTHER EXAMPLES/TEMPLATES.

PLEASE NOTE THAT ALTERATIONS TO TEMPLATE LANGUAGE ARE ALLOWED WITH JUSTIFICATION. PLEASE MAKE SURE FONT SIZE IS CONSISTENT AND IN BLACK.

\*\***FOR FDA REGULATED RESEARCH (INVESTIGATIONAL DEVICES/DRUGS):** PLEASE USE THE WORD “INVESTIATIONAL” WHEN REFERRING TO THE DEVICE / DRUG

**CONSENT TO ACT AS A HUMAN PARTICIPANT**

Project Title:

Principal Investigator and Faculty Advisor (if applicable):

Participant's Name:

**What are some general things you should know about research studies?**   
You are being asked to take part in a research study.  Your participation in the study is voluntary. You may choose not to join, or you may withdraw your consent 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 you for being in the research study. There also may be risks to being in research studies. If you choose not to be in the study or leave the study before it is done, it will not affect your 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 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 participation is voluntary. This section should include a statement that the study involves research and the purpose of the study.

**Why are you asking me?**

The reason for selecting the participant; inclusion/exclusion criteria

**What will you ask me to do if I agree to be in the study?**

The activities involved and identification of any procedures which are experimental, the expected duration (time) of the participant’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 also be described (but risks will need to be placed in risks section below), and a number with a contact person answer questions so that the person understands fully to what they are consenting.

**\*\*FOR RESEARCH INVOLVING BIOSPECIMENS ONLY. DO NOT INCLUDE THIS SECTION IF YOU ARE NOT USING BIOSPECIMENS:**

**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?**

This section should describe any plans to use audio/video recording if it is applicable to the project proposed. **If audio / video recording will take place, please include the statement,** “Because your voice will be potentially identifiable by anyone who hears the recording, your confidentiality for things you say on the recording cannot be guaranteed although the researcher will try to limit access to the recording as described below.”

**What are the risks to me?**

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 there is only low to minimal risk, please simply state “minimal risk”

Please include a referral in this section if your study involves questions that ask about mood, depression or anxiety.

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 me 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 *me* for taking part in this research study?**

Participants should be informed about direct or indirect potential benefits to them or others or the absence of benefits. Be sure that your language does not guarantee any benefits (use the word “may”). Elements related to payment (remuneration) are NOT considered “benefits” to a participant and should be discussed within the Costs/Payments section. If there are no direct benefits, indicate, “There are no direct benefits to participants in this study.”

**Will I get paid for being in the study? Will it cost me anything?**

Costs and Payments to the Participant should be addressed explicitly, including a statement that payments will not be given if that is the case. Describe how payments will be made if the participant elects to discontinue participation during the study. If there are no costs or payments involved you may state, “There are no costs to you or payments made for participating in this study.”

**How will you keep my information 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, and what the disposition of the data will be and how long it will be kept. 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 de-identified data be used in future studies? – NOTE: this section is to be used ONLY IF YOU WILL USE DATA IN FUTURE STUDIES**

**If the PI will publish de-identified data in an open-access journal include:** All of our participants’ de-identified data will be kept indefinitely and will be posted to an on-line repository so other scientists can analyze the data and check our results.

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

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

**FOR FDA REGULATED RESEARCH ONLY (investigational devices/investigational drugs), include this wording: “**Since the study involves the use of an investigational device / drug, the FDA may review your study records if applicable.”

**What if I want to leave the study?**

“You have the right to refuse to participate or to withdraw at any time, without penalty. If you do withdraw, it will not affect you in any way. If you choose to withdraw, you may request that any of your data which has been collected be destroyed unless it is in a de-identifiable state. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have 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 to continue to participate, this information will be provided to you.”

**Voluntary Consent by Participant:**

By signing this consent form/completing this survey/activity (used for an IRB-approved waiver of signature) you are agreeing that you read, or it has been read to you, and you fully understand the contents of this document and are openly willing consent to take part in this study. All of your questions concerning this study have been answered. By signing this form, you are agreeing that you are 18 years of age or older and are agreeing to participate, in this study described to you by      .

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_