**Instructions**: You are encouraged to use any text in black ink verbatim in your consent form. All **Bold black text** is required. You should tailor the answers to meet the specifics of your study. Text in blue ink offers instruction and should be removed prior to submission to the IRB.

Your consent form should be written at an **8th grade reading level**. You must provide participants with a copy of the consent form for their records.

**Western Carolina University**

**Consent Form to Participate in a Research Study**

If your consent form is longer than 3 pages you must begin the form with a concise and focused presentation of key information that is likely to assist potential subjects in understanding whether or not they want to participate. Skip this section for now and only complete the section in green if your form is longer than 3 pages. If your form is shorter than 3 pages delete all green text.

**[Key Information**

**Study Purpose:**

**Major Requirements of Study:**

**Significant Risks:**

**Potential Benefits:**

**Duration of Participation:**

You are being invited to participate in a research study of [general statement about study]. You were selected as a possible participant because [describe inclusion criteria]. We ask that you read this form and ask any questions you may have before agreeing to be in the study. Participation is completely voluntary.**]**

**Project Title:** [Insert project title]

**This study is being conducted by**: [Insert researcher names and credentials. If this is a student project include the name of the faculty advisor]

**Description and Purpose of the Research:** You are invited to participate in a research study about [general description of study]. By doing this study we hope to learn [general description of study goals]

**What you will be asked to do:** [Explain in simple language the study procedures as they relate to participants, and the data that will be collected from them. All procedures listed in the IRB application and funding proposal (as applicable) should be described here. Experimental procedures (e.g., interventions, manipulations, treatments) should be specifically noted.

Include description of any data that will be gathered that is not received directly from the participant.

Describe the participant's time commitment for each component of the study.

Describe video/audio taping, if this method of data collection will be used.]

**If the study involves biospecimens the following statements must be included:**

The study team [will/will not] return clinically relevant information to you.

This research [will/will not] include whole genome sequencing.

**Risks and Discomforts:** [Describe the risks and what you will do to minimize these risks. Include all possible physical, psychological, legal, professional or personal risks and/or hazards for the participants in this section. Any risks listed in the application must be addressed in the consent form.

Example statements: “There are no anticipated risks from participating in this research.”

“We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.”

“Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time”.]

**Benefits**: There are no direct benefits to you for participating in this research study. The study may help us better understand [Briefly describe the benefits to participants (if any) and society – this section should match the benefits described in the application. Do not include payment or compensation as a benefit. If you are willing to share a copy of the results with your participants when the study is finished, you can note that here as a potential benefit.]

**Privacy/Confidentiality/Data Security:** [The information included in this section will vary based on the amount of identifying information you are collecting with your data/biospecimens. **Listed below are various privacy/confidentiality measures for different types of data. Include only the information relevant to your study and delete the rest**.]

**If collected data will be anonymous:**The data collected in this study are anonymous. This means that not even the research team can match you to your data.

**If collected data will be confidential:**The data collected in this research study will be kept confidential. Participation in research may involve some loss of privacy. We will do our best to make sure that the information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in the research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law, such as pursuant to a court order. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

We will collect your information through [recordings, interviews, qualtrics survey, etc]. This information will be stored [in a restricted access folder, an encrypted cloud based system, locked office cabinet, etc. If identifiers will be separated from data, describe storage plan for the identifiers and how long they will be retained.]

[Indicate what steps you will take to keep data confidential / secure (e.g. use of a coding system, secure storage, using summary data from a whole group, use of pseudonyms for direct quotes).]

**If data collected has the potential to trigger mandatory reporting responsibilities:**There are two circumstances where we would be required to break confidentiality and share your information with local authorities. The first is if we become aware or have a reason to believe that a child, an elder, or a disabled individual is being abused or neglected. The second is if you make a serious threat to harm yourself or others.

**If data is collected using an online survey or data collection tool (even if anonymous):**The research team will work to protect your data to the extent permitted by technology. It is possible, although unlikely, that an unauthorized individual could gain access to your responses because you are responding online. This risk is similar to your everyday use of the internet.

**If data is collected in a focus group:**

We will request that all participants respect the confidentiality of the group and do not share any other participant’s responses outside of the group. However, we cannot guarantee your privacy or confidentiality because there is always the possibility that another member of the group could share what was said. Pseudonyms will be assigned to each participant, and during the course of the interview and in all notes, you will only be referred to by your pseudonym.

**If photographs/audio/visual recordings will be collected:**

[Photographs/Audio/visual recordings] will be collected during this study and used to [describe purpose]. The recordings will be [kept indefinitely, destroyed after transcription, destroyed after X years, etc]. The recordings [will/will not] be shared with [the general public or other researchers]. You [do or do not] have to agree to be recorded in order to participate in the main part of this study.

**If direct quotes may be used in dissemination:**

If you give the research team permission to quote you directly, the researchers will give you a pseudonym and will generalize your quote to remove any information that could be personally identifying.

**If collecting identifiable information or biospecimens one of the following statements is required:**

Identifiers might be removed from your [information/biospecimen] and the de-identified [information/biospecimen] might be used or distributed to other researchers for future research without your additional consent.

Identifiable [information/biospecimens] might be used or distributed to other researchers for future research without obtaining additional consent from you.

Your [information/biospecimens] will not be used or distributed for future research studies.

**If collecting biospecimens this statement is required:**

Biospecimens collected for this study will become property of Western Carolina University. You will not share in any commercial value or receive compensation if any commercial products are developed using the biospecimens.

**If this project is funded by NIH and collects identifiable information, all of the following is required:**

This research is covered by a Certificate of Confidentiality issued by the Department of Health and Human Services. This means that we cannot disclose or provide any identifiable information about you to any federal, state, local, civil, criminal, administrative, or legal proceeding. For example, your identifiable information may not be subpoenaed pursuant to a court order.

This certificate does not limit the ability of personnel from the federal or state government agency sponsoring this research to request information needed for auditing or program evaluation purposes or for information that must be disclosed to meet the requirements of the Food and Drug Administration (FDA).

The information protected by this certificate may not be disclosed to anyone outside the research team except in the following situations: if there is a federal, state, or local law that requires disclosure (such as mandatory reporting of child abuse or communicable disease); if you have consented to disclosure, including for medical treatment; or if your information is used for other scientific research as allowed by federal regulations governing research involving human participants.

This certificate does not prevent you from voluntarily releasing information about yourself or your involvement in the research. If you would like the research team to release your information to an insurer, medical care provider, or other individual not connected to the research, you must provide additional consent to the allow the researchers to release it.

**Voluntary Participation:** Participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty. If you choose not to participate or decide to withdraw, there will be no impact on your [grades/academic standing, employment, access to medical care][If applicable, describe how individuals may withdraw from the study]

[If the research involves experimental treatments/interventions, describe any non-experimental alternatives that may be available. For students receiving course credit, alternatives to research participation should be mentioned here.]

**Compensation for Participation:** [Indicate whether the participant will receive payment, extra credit, or other form of compensation for being in the study, and the amount of compensation to be received]

**Contact Information:** For questions about this study, please contact [name of researcher] at [phone and/or email contact information]. You may also contact Dr. [insert faculty PI name], the principal investigator and faculty advisor for this project, at [contact information].

**If you have questions or concerns about your treatment as a participant in this study, you may contact the Western Carolina University Institutional Review Board through the Office of Research Administration by calling 828-227-7212 or emailing irb@wcu.edu. All reports or correspondence will be kept confidential to the extent possible.**

**You will be given a copy of this information to keep for your records.**

**Examples of signature variations – choose language as applicable to your study**

**Signed consent is not necessary in all situations, and not recommended if your study is otherwise anonymous. If you think that signatures will not be practical/possible or could jeopardize your research, please describe in your IRB application how you plan to document consent (i.e. asking participants to click on an “I approve” box).**

I understand what is expected of me if I participate in this research study. I have been given the opportunity to ask questions, and understand that participation is voluntary. My signature shows that I agree to participate and am at least 18 years old.

Participant Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Name of Researcher Obtaining Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

If you would like to receive a summary of the results, once the study has been completed, please write your email address (as legibly as possible) here:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[Use when direct quotes or audio/video may be used]**

I do □ or do not □ give my permission to the investigators to quote me directly in their research.

The investigators may □ or may not □ digitally record this interview.

Participant Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**[Parent/legal guardian consent for a minor’s participation]**

My signature below indicates that I give consent for my child, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, to participate in this study. I understand what is expected of my child and that his/her participation is voluntary.

Parent/Guardian Name (printed):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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