**Outline Informed Consent Document**

**FOR PHYSICAL AND BIOMEDICAL RESEARCH**

**Instructions: Fill in the information relevant to your study using the prompts in blue. Remove all text in red.**

It is very important to write your consent form in layperson’s language that can be easily understood by your participants. (An 8th grade reading level is recommended for the general population.) This template includes language recommended by the IRB. Please adapt it as necessary to be sure your consent form explains your research project clearly.

**DELETE all instructions** (including this section) and suggested language that is not applicable, then **UPLOAD a copy of the consent form to the IRB application exactly the way your participants will see it, all text in black.** This will be the official copy that will be stamped and must be used for all participants.

**Consent to Participate in Research**

**The following information describes the research study in which** **you****are being asked to participate. Please read the information carefully. Afterwards, you will be asked to sign if you agree to participate.**

**INVESTIGATOR(S)**

This research, to be conducted by (name, title, department), [if the PI is a student, add under the supervision of (name, title, department)]. (If there are any co-investigators associated with another institution, provide the same descriptive information.)

**PURPOSE**

The purpose of this research is (briefly describe the purpose of the study in plain language/terms - but not in a way which might bias your participants)**.**

[For all deception studies include this paragraph: Research designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study. At that time, we will provide you with a full debriefing which will include an explanation of the hypothesis that was tested and other relevant background information pertaining to the study. You will also be given an opportunity to ask any question you might have about the hypothesis and the procedures used in the study.]

**EXPECTED DURATION**

Participation in this study will require about (amount of time; include details if there are multiple sessions or time commitments).

**PROCEDURES**

The research will be conducted using the following procedures: (Describe the step-by-step activities in which the participant will be involved, including whether you will be audio or videotaping. If any interventions with the participant are "experimental," i.e., not yet scientifically validated with respect to safety and efficacy, identify them as such.)

**CONFIDENTIALITY**

**OPTION 1**: This research is anonymous. No information will be collected that would identify you.

OR

**OPTION 2**: I will keep your information strictly confidential. All notes and questionnaires will receive a code number and be kept separate from your signed consent form. The list which has your name and code number will be kept in [if a physical copy: a locked file in the (name of department) at the College of Charleston] [or if the coded list is electronic: secure electronic storage] and destroyed when the research is complete. At no time will you be able to be identified in any reports or publications which result from this research. [If data security breach is an identified risk: Describe the extent to which confidentiality of research records identifying the participant will be maintained. As appropriate, discuss privacy concerns during collection of the data, identifiers that will be recorded which may link the participant to the data, persons who will have access to the data, measures that will be followed to ensure security of the data, how data will be reported, and ultimate disposition of records.]

OR

**OPTION 3**: If you will be identifying people by name and/or title include the following. I will keep your information strictly confidential. However, if you are willing to permit me to quote you in the report of my research, please check the item just above the signature line. You will be given an opportunity to review the section of my report in which your quote appears before completion of my research.

[Additional statements which may be included if appropriate.

The (audio or video)tape will be destroyed after it is transcribed.

OR

The (audio or video)tape will be kept for (time and location) for use in this research only OR for future research use OR for educational purposes.]

**POSSIBLE BENEFITS**

**OPTION 1**: Although it is not anticipated that you will benefit directly through your involvement in this study, this research is expected to benefit (define the larger population) by (describe potential benefits to the larger population)**.**

OR

**OPTION 2**: Benefits that you may experience through participation in this study include (describe potential benefits to the individual research participant including any compensation to participant such as cash payment, gifts, free services, or extra credit in academic courses, and how you will handle it if the participant withdraws.)

**POSSIBLE DISCOMFORTS AND/OR RISKS**

**OPTION 1**: We know of no significant risks or discomforts associated with this study.

OR

**OPTION 2**: This research study is expected to present minimal risk to you. Past experiences indicate the most common and foreseeable consequence of participation in this activity will be (describe risks and safeguards). If you should experience any discomfort or injury, see your medical provider immediately.

OR

**OPTION 3**: This research study is expected to present some risk to you. Past experiences indicate that you are likely to experience (describe risks). (Add information about safeguards). If you should experience any discomfort or injury, see your medical provider immediately.

[If the study places the participant at some risk of injury, include the following statement:

The College/University of Charleston, SC will not provide compensation or medical (and/or

psychological) treatment of any kind to you for an injury which occurs as a direct result of your

participation in this study.] [The following optional statement may be added: You will be

required to show proof of third party (health insurance) coverage prior to being enrolled in this

study.]

[Include if appropriate: **ALTERNATIVE PROCEDURES**

(Describe any options available to an individual who does not take part in the study, e.g., treatment without being in a research study, participating in another study or getting no treatment.)]

**DATA STORAGE AND USE**

Your personal data collected for this research will be stored until (period for which the data will be stored and whether personal identifiers will be removed from the data) [OR if undetermined, (explain the method for determining length of data storage and whether personal identifiers will be removed from the data). Projected future use of your personal data includes (details about any projected future use, such as future research or educational purposes and whether personal identifiers will be removed from the data).]

**COSTS**

There are no costs associated with your participation in this research study.

OR

(Describe any costs to the participant for participation in the research study. Also describe how you will handle it if the participant withdraws.)

**RESEARCHER CONFLICT OF INTEREST**

**OPTION 1:** The researcher(s) have no conflicts of interest with regard to this research.

OR

**OPTION 2:** This research is being funded by (provide the name of the funding source if the source has a financial or proprietary interest in the research, such as product or procedure development).

OR

**OPTION 3:** The researcher(s) have a financial interest in the development of (this product or procedure).

**VOLUNTARINESS**

Your participation is completely voluntary, and you may discontinue participation at any time. Your consent is voluntary and may be withdrawn at any time. [If appropriate add: Your decision to participate or not, or to discontinue participating, will not result in any loss of benefits to which you are entitled OR will not have any effect on your grades in this class.]

**CONTACT INFORMATION**

If you have any questions concerning this research study please contact (name of PI) at (telephone number) or (email) [if PI is a student, add or my faculty advisor at (telephone number) or (email).] You may also contact Research Protections & Compliance on the Office of Research and Grants Administration, at 843-953-5885 or email compliance@cofc.edu if you have questions or concerns about research review at the College of Charleston or your rights as a research participant. You will be given a copy of this form to keep.

**This research study has been approved by College of Charleston Institutional Review Board for the Protection of Human Research Participants and covers all relevant requirements of the EU General Data Protection Regulations.**

**OPTION 1: ORAL CONSENT** (do not include signature lines)

I understand that my completion of the interview OR survey OR questionnaire OR (specify) signifies my consent to participate in this research project.

OR

**OPTION 2: SIGNED CONSENT**

I have read this consent form, and I agree to participate in this research study. [If appropriate, add and certify that I am at least 18 years old.]

**OR**

The information in this consent form has been explained to me, and I have been given the opportunity to ask questions. [If appropriate, add and certify that I am at least 18 years old.]

[If appropriate, add:

In any reports or publications which result from this research,

I permit you to quote me \_\_\_\_ Yes \_\_\_\_ No

AND/OR

You may use \_\_\_my name, \_\_\_ job title, \_\_\_pseudonym or \_\_\_other identifier (specify appropriate identifier).]

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

Printed Name of Participant

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

Signature of Participant Date

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

Signature of Person Obtaining Consent Date

[OPTIONAL: If you would you like to receive a copy of the results of this study, please print your contact information (mailing address or email):]