**INFORMED CONSENT DOCUMENT**

**Project Title: Title**

**Investigator(s):** List the full names of all individuals (include degrees where appropriate, such as Ph.D.) who will obtain Informed Consent from the research participants. Include the name of the Principal Investigator and all other key investigative personnel

**PURPOSE**

This study involves research. The purpose of this research is [complete this sentence by including a general description of the project – what is being investigated, what knowledge is to be gained.]

I am/ We are [select the appropriate phrase] inviting people to participate in this research because they [complete this sentence by describing why people reading the consent are possible subjects for your project. For example, they: (a) have been diagnosed with lung cancer; (b) are taking an introductory psychology class; (c) are teachers in the Honolulu City school district; (d) are joggers; (e) are healthy adults in the community… etc. If appropriate, indicate the total number of subjects expected to participate in the study.]

This project will last for [complete this sentence by indicating the length of time for one subject’s participation. If more than one contact is involved in the study, length of time for each contact and how long in between each contact.]

**PROCEDURES**

Those agreeing to participate can expect the following to occur. [Describe, step by step, what is going to happen to the research subject if he/she decides to participate. Describe any procedures that are experimental. Use subheadings as appropriate. For complex protocols, consider including a table that shows the procedures/tests performed at each visit.]

**RISKS**

The possible risks associated with participating in this research project are as follows: [Describe the risks – psychological, physical, pain, drug toxicity, emotional, legal, privacy issues, etc. In addition, also describe what will be done to address the possible risks. For example: “A licensed clinical social worker is readily available to meet with the individual in the event that the participant becomes emotionally upset.” If there are no known risks, state that there are no foreseeable risks to participating.]

**BENEFITS**

There may/will be [select the appropriate phrase] no personal benefit for participating in this study. However, it is hoped that in the future, society could benefit from this study by [Complete the sentence by describing the possible benefits to society. Note that compensation is not a benefit and should be described in the Costs and Compensation section.]

**ALTERNATIVE TREATMENT**

For treatment/therapy projects – omit if not applicable to your research.

Instead of participating in this study, the alternative treatments are: [List the alternative treatments. If the subject can receive the same intervention without participating in the research, that must be noted. Describe how the alternatives will be presented to the study subject.]

**COSTS AND COMPENSATION**

There will/will not (select one) be any costs to the participants for participating in this research project. [Clearly describe any monetary costs to the participants, if any. If there are costs that might be covered by a medical or hospital insurance carrier, add a sentence regarding checking with the insurance carrier prior to deciding whether to participate.]

Participants will / will not (select one) be compensated for their time and inconvenience for participating in this research project. [Clearly describe the monetary (total amount, average total amount, amount per visit, amount per hour, etc.) or non-monetary compensation. If compensation is pro-rated when a participant withdraws prior to completing the study, explain how it is pro-rated.]

**CONFIDENTIALITY**

Records of participation in this research project will be maintained and kept confidential to the extent permitted by law. However, federal government agencies[[1]](#footnote-1) and the Concord University HSRB may inspect and copy a subject’s records pertaining to the research, and these records may contain personal identifiers. [The next sentence should describe the methods that will be used to ensure confidentiality, for example: coded names or identification numbers, removal of all identifying information, secure storage area, etc.]

In the event of any report or publication from this study, the identity of participants will not be disclosed. Results will be reported in a summarized manner in such a way that participants cannot be identified.

**RESEARCH RELATED INJURY**

This section may be eliminated if it does not apply or choose the phrase (1, 2, or 3) that applies to your study.

1. In the event of research related injury, medical treatment is available at (insert the name or the Affiliated Medical Center here) and will be paid for by the sponsor, (insert the name of the sponsor here), to the extent that these costs are not covered by the research participant’s medical or hospital insurance carrier. [If the sponsor will not provide complete coverage, or if there are other restrictions, explain what will be covered.]
2. No compensation for treatment of research related injury is available from Concord University unless the injury is proven to be the direct result of negligence by a University employee.
3. The cost of treatment for any research-related illness or injury is the responsibility of the research participant and/or his/her medical or hospital insurance carrier.

**VOLUNTARY PARTICIPATION**

All participation is voluntary. There is no penalty to anyone who decides not to participate. Nor will anyone be penalized if he or she decides to stop participation at anytime during the research project. [Describe the procedures for withdrawing. If appropriate, describe the consequences of a subject’s withdrawal and the procedures for withdrawing.]

If new information related to a participant’s willingness to continue to participate develops during the course of the study, participants will be promptly informed.

**TERMINATION OF STUDY BY INVESTIGATOR/SPONSOR**

Under certain circumstances, the subject’s participation in this research study may be ended without the subject’s consent. This might happen because [Describe why the study might be ended without the participant’s consent.]

**QUESTIONS**

Questions are encouraged. Questions about this research project and questions about the rights of research participants or research related injury may be addressed to the HSRB Chair (Dr. Stephen Pridgen at spridgen@concord.edu or hsrbchair@concord.edu)

Subject’s name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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(Signature of Subject) (Date)

**Include a Legally Authorized Representative signature line if applicable to your study.**

**INVESTIGATOR STATEMENT**

I have discussed the above points with the participant or the legally authorized representative, using a translator when necessary. It is my opinion that the participant understands the risks, benefits, and obligations involved in participation in this project.

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(Signature od Investigator) (Date)

1. If the research includes drug/device studies, list **U.S. Food and Drug Administration** after “federal government regulatory agencies.” Omit this phrase if it is not applicable to your research project. [↑](#footnote-ref-1)