IRB FULL REVIEW APPLICATION

Section 1. Personnel/Funding Information

Title of project

Principal investigator

E-mail address Phone

Mailing address

Investigator signature Date

Other investigators (attach additional paper if necessary)

If the principal investigator is a student, please provide the following information:

Deadline for project completion

Is this project part of the requirements for a course grade? ☐ Yes ☐ No

Faculty/staff supervisor

Phone E-mail address

I have reviewed this application and will provide appropriate guidance with the project as needed.

Faculty/staff supervisor signature

If medical supervision is necessary, please provide contact information for the physician who will provide this supervision:

Physician name Phone

If this proposal is part of a grant, please indicate the following:

Title of grant

Principal investigator of grant

Source of funds (State specific name of funding source)

Government agency Foundation

Corporation Other

Section 2. Project Description

Subjects

Total number of subjects

Number of subjects in control group(s) (if appropriate)

Population(s) from which derived

Describe the method of screening potential subjects and controls, and the factors that will be the basis for excluding potential subjects from the study.

This study includes:

Prisoners ☐ Fetuses ☐ Abortuses ☐ Pregnant women ☐

Minors under 18 ☐ People with mental illness ☐

People with cognitive impairment or intellectual disability ☐

If any of the populations above are involved, explain the reasons for using these groups.

Will any subjects be from hospitals or other institutions (including other universities)? ☐ Yes ☐ No

If yes, please attach evidence of approval from this hospital or other institution. This evidence could be a letter of support from an authorized agent, a copy of an IRB or ethics panel review, or some other documentation indicating awareness and approval of the study's design, methodology, and purpose.

Location and Duration of Study

Location of study

Probable duration of entire study

Total amount of time each subject will be involved

Methodology

The following information should be provided in lay language. Attach supplemental documents (e.g., surveys, consent forms) as necessary. Use additional paper if necessary.

Describe past experimental and/or clinical findings leading to the formulation of this study. Include any relevant past or current research by the principal investigator.

Describe the study methodology and procedures that will affect the subjects, particularly in regard to any inconvenience, danger, or discomfort.

List the procedures, the length of time each will take, and the frequency of repetition.

Risks

Describe possible physical, psychological and social risks.

Estimate the frequency, severity, and reversibility of these risks.

Describe any alternative treatments and withholding of normal treatment.

Will any people be at risk other than the subjects?

What is the risk-benefit ratio?

Describe precautions that will be taken to avoid hazards and the means for monitoring to detect hazards.

State the point at which the experiment will be terminated if hazards materialize. Differentiate between the point for termination of an individual subject's involvement and for the termination of the entire study.

If an agent or therapy is being assessed, indicate the point at which the differences in outcomes between subjects and controls will be considered sufficiently significant to eliminate the need for additional subjects, or to require modification of the disclosure made to continuing and prospective subjects because of greater information concerning relative risks.

State whether the potential subject will be, or will have been, in a stressful, painful, or drugged condition, whether or not this condition is caused by the study methodology. If yes, describe the proposed precautions to overcome the effect of the condition on the consent process.

If the time period between informing the subject and soliciting a decision is less than twenty-four hours, describe the time sequence desired and the reasons why the twenty-four-hour minimum would affect the effective conduct of the study or be disadvantageous to the subject.

Confidentiality

Will any information derived from this study be given to any person or group, including the subject? If yes, describe to whom the information will be given and the nature of the information.

Describe the procedures for maintaining confidentiality.

Information for Drug and Investigational New Device Studies

If this study does NOT use any drugs (including commercially available medications and herbal supplements) or Investigational New Devices, then you do not need to complete the remainder of this form. Researchers proposing to study the effects of drugs or Investigational New Devices should answer the following questions.

If this project involves the use of any commercially available drugs, please provide the drug names.

If this project involves the use of an Investigational New Drug, please provide the following information:

Name of drug

Which Phase (I, II, III, or IV) does this study represent?

IND number

Date of end of 30-day expiration or waiver

If an Investigational New Drug is involved, but an IND number has not been issued, what are the plans for securing an IND from the FDA?

If this project involves the use of an Investigational New Device, please provide the following information:

Name of device

IDE number

For projects involving Investigational New Devices which are considered non-significant risk devices, attach a letter from the sponsor discussing the reasons for the classification.