JACKSONVILLE UNIVERSITY
INSTITUTIONAL REVIEW BOARD APPLICATION REVIEW

Type of Review Requested: ☐ Expedited ☐ Full Board

1. PROJECT TITLE:

2. STUDY PERSONNEL: Complete the information below for all persons that will be involved with the project. (Attach additional page if more space is needed for study personnel)

One JU Faculty, administrator, or staff may be listed as a Principal Investigator.

<table>
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<tr>
<th>Last Name</th>
<th>First Name</th>
<th>JU ID#</th>
<th>Faculty; Student; describe if other</th>
<th>College</th>
<th>Phone Number</th>
<th>Email</th>
<th>PI; Co-I; Sub-I; describe if other</th>
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3. TYPE OF PROPOSED RESEARCH: Check all that apply
☐ Retrospective review of records / data ☐ Prospective review of records / data
☐ Physical test / Task Treatment ☐ Mental / Psychological Testing
☐ Questionnaire / Survey / Interview ☐ Bench / Laboratory physical testing
☐ Observation ☐ Experimental or Investigative device
☐ Approved Device for a Non-approved or Novel purpose
☐ Other Describe

4. DURATION: How long will this project remain open? Enter here

5. SUBJECT INFORMATION: The IRB considers any subject that signs an informed consent as enrolled whether or not their data is evaluable. Do not exceed this number. If you want to enroll more subjects you must revise your paperwork, submit a revision to the IRB, and receive approval before exceeding the number above. Failure to do this is equivalent to enrolling subjects without IRB approval.

a. Will you enroll more than one group of subjects? ☐ No ☐ Yes How many? Enter

b. Sample size Add number for each group Age range of subjects: Enter
c. Will you enroll (check all that apply)

☐ Minor(s) < 18 years old   ☐ Prisoners

☐ Individuals with Compromised Mental/Communication Capacity

What additional protections are in place for these subjects? [Describe]

d. Will you specifically enroll (check all that apply)?

☐ Pregnant Women   ☐ JU Students   ☐ JU Staff or Employees

☐ Pregnant women, JU students, staff or employees may participate, but they will not specifically be recruited

☐ The researchers will not know if pregnant women, JU students, staff or employees participate

e. Will you specifically recruit subjects that are Hispanic? ☐ No ☐ Yes

If yes, provide rationale for specifically recruiting these subjects.
[Click to enter text]

f. Will you specifically recruit subjects from a defined racial group(s)? ☐ No ☐ Yes

If yes, select the appropriate racial group(s) and provide rationale for specifically recruiting these subjects

☐ American Indian/Alaska Native   ☐ Asian

☐ Native Hawaiian or Pacific Islander   ☐ Black or African American

☐ White or Caucasian

[Provide rationale for recruiting these subjects]

6. RECRUITMENT:

If you are enrolling/collecting data from more than one group of subjects. The following is needed for each group.

a. Who will recruit subjects? [List names]

b. Is this person the subject’s Instructor, Advisor, Mentor, Supervisor, or Provider? ☐ Yes ☐ No

c. How will subjects be recruited for this project?

☐ Advertisement (You must attach a copy of the advertisement that you will use)

☐ Other: [Describe]
d. Indicate all methods that you will use to identify and recruit subjects: (If you select any of these methods, the research protocol must clearly identify if protected health information or student record information will be collected, what will be collected, and how subjects will be protected.)
   - Clinical Records or Database
   - Inpatient population
   - Outpatient population
   - Student Records
   - Not applicable

7. INFORMED CONSENT:
   If you are enrolling/collecting data from more than one group of subjects, the following is needed for each group.

   a. Are you going to seek Informed Consent in order to enroll subjects?
      - ☐ No. Informed consent is not needed for this study.
      - ☐ Yes, written consent.
      - ☐ Yes, modified consent
      - ☐ Yes, Waiver of Documentation of Informed Consent [Justify why waiver is appropriate]

   b. Who will review the informed consent with potential subjects? [List names]

   c. What is the general setting where subjects will be asked to consent? [Describe]

   d. When will subjects be asked to consent? [Describe]

   e. Who will give consent? Check all appropriate answers:
      - ☐ The subject
      - ☐ Parent(s) of a minor subject
      - ☐ A legally authorized representative for the subject [Describe]

   f. Explain the consent process: [Describe]

8. SUBJECT PARTICIPATION AND CONFIDENTIALITY: Clarify if you are enrolling/collecting data from more than one group of subjects, the following is needed for each group.

   a. What is the expected length of time (from signing consent to completion) that each individual subject will participate? [Enter here]

   c. Where are you going to conduct this project? Select all appropriate answers:
      - ☐ Jacksonville University Campus
      - ☐ Other: [Describe]

   d. Was the study reviewed by another IRB? ☐ No ☐ Yes. Who conducted the review: [Name institution] A copy of the approval letter must be attached.

   e. Are you collecting Protected Health Information (HIPPA)? ☐ No ☐ Yes List the specific identifiers that you will collect. How will you protect this information? [Describe]
e. Are you collecting other identifiable information?  □ No  □ Yes. List the identifiers [List]

a. The study offers the prospect for direct benefit to:
   □ all potential subjects.  □ some potential subjects.  □ no subjects.

b. Are research subjects compensated?  □ No  □ Yes
   If yes, explain the proration of the compensation, including compensation per session, the total compensation participants are eligible to receive, and distribution (i.e., compensation given at the end of each session, compensation withheld until study is complete, etc.)

c. What measures will be taken to protect the confidentiality of any information obtained from or about subjects and any others related to the subjects?  Check all that apply.
   □ Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.
   □ Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.
   □ Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.
   □ Whenever feasible, identifiers will be removed from study-related information.
   □ A waiver of documentation of consent is being requested by submitting because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality.
   □ Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.
   □ Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.
   □ Other: [Describe]

d. Describe any additional measures that will be taken to protect subject confidentiality after the research is completed. Check all that apply.
   □ Data is de-identified during the course of the study. Identifiers are destroyed during the course of the study (paper documents shredded, electronic files deleted).
   □ Data is de-identified after the completion of the study and identifiers are destroyed at this time (paper documents shredded, electronic files deleted).
   □ No identifiers are collected in this study
   □ Other: [Describe]

9. FINANCIAL SUPPORT

Will financial or material support be obtained for this project?  (e.g. space, equipment, personnel, supplies)
   □ No.
   □ Yes, already obtained from [Enter the funding source for Investigators Name on the Contract or Grant]
   □ Yes, funding is pending. Deadline [List the deadline date] from [Enter the funding source for Investigators Name on the Contract or Grant]
10. CONFLICT OF INTEREST:

a. Does Jacksonville University hold a patent or license for any material, object, or process used in this project? ☐ No ☐ Yes. If yes, you must contact the JU Research Compliance Coordinator at juirb@ju.edu

b. Do you, your spouse, your children, or any of the Investigators or persons who are responsible for the design, conduct, or reporting of the research, their spouses or their children, hold a patent or license for any material, object, or process used in this project? ☐ No ☐ Yes. If yes, you must contact the JU Research Compliance Coordinator at juirb@ju.edu

c. Does Jacksonville University own stock in the company sponsoring the project? ☐ No ☐ Yes. If yes, you must contact the JU Research Compliance Coordinator at juirb@ju.edu

d. Do you your spouse, your children, or any of the Investigators or persons who are responsible for the design, conduct, or reporting of the research, their spouses or their children, own stock in the company sponsoring the project? ☐ No ☐ Yes. If yes, you must contact the JU Research Compliance Coordinator at juirb@ju.edu

e. Is a patent or license pending or under consideration or is there any intention to file a patent application at a later date? ☐ No ☐ Yes. If yes, you must contact the JU Research Compliance Coordinator at juirb@ju.edu

f. Do you your spouse, your children, or any of the Investigators or persons who are responsible for the design, conduct, or reporting of the research, their spouses or their children, have a patent or license pending or under consideration or is there any intention to file a patent application at a later date? ☐ No ☐ Yes. If yes, you must contact the JU Research Compliance Coordinator at juirb@ju.edu

11. Attachments: (check all that you are including with this submission)

☐ Research Protocol (required)
☐ Data collection sheet (required)
☐ Mentor Agreement Letter (needed for all student Investigators)
☐ Informed consent
☐ Minor assent
☐ Surveys and/or questionnaires
☐ Advertisements, announcements, and/or flyers
☐ Other documents that will potentially be viewed by the participants.
☐ Permission to collect data at other institution(s)

I certify that the information provided in this application is complete and correct.

________________________________________  ___________________________  ______________
Printed Name of Person                     Signature of Person            Date
completing this form  completing this form
Jacksonville University Faculty Investigator Assurance

As an Investigator, I have the ultimate responsibility for the ethical conduct of the research, for protecting the rights and welfare of human subjects, and for strictly adhering to any stipulations imposed by the Institutional Review Board or other research oversight entities.

I shall ensure that only qualified personnel conduct the study according to the approved Protocol, and in compliance with each individual’s designation.

I shall not implement changes in the approved Protocol or Informed Consent Form without prior Institutional Review Board approval (except in an emergency, if necessary to safeguard the well-being of human subjects).

I shall promptly report unanticipated problems involving risk to subjects or others, including but not limited to serious and unexpected adverse events, to the Institutional Review Board in writing within 5 working days of occurrence or notification of occurrence.

I shall complete investigator training as required by the Institutional Review Board or other research oversight entities.

If I will be unavailable to conduct or direct this research personally, as when on sabbatical, leave, or vacation, I will arrange for a co-investigator to assume direct responsibility in my absence. This will be documented on the IRB’s Temporary Transfer of PI Responsibilities form prior to my absence.

In the event that my employment with the university is discontinued, I will either transfer this study to a new principal investigator or close the project. I will notify the Institutional Review Board in writing of this change by submitting either a formal revision or a Continuing Review/Study closure report. I will do this in advance (prior to the termination of employment).

Principal Investigator (FACULTY)  Principal Investigator (FACULTY)  Date
Printed Name  Signature