Jacksonville State University
Application for Institutional Review Board Review

General Instructions for Completion of Protocol: Unless otherwise instructed, type all information in the area below each question, using as much space as necessary. *Note: All fields must be completed for the application to be considered "Complete." Incomplete applications will not be processed. Do not delete or omit any sections.*

SECTION I - GENERAL PROJECT INFORMATION

A. Project Title:

B. Principal Investigator(s): *Note: Supervising faculty members who will be co-authoring with their student(s) should list themselves as co-principal investigators, otherwise as faculty advisor.* Please note the signature page is located at the end of the application.

1. Name:	Department:	
College:	Email:	Phone:
2. Name:	Department:	
College:	Email:	Phone:
If PI(s) is a Student: Is this study part of a Thesis, Dissertation, or DNP*/DSC project?		☐ Yes ☐ No

C. Faculty Advisor Information:

Name:		Title:	
College:	Department:	Email:	Phone:

D. Source(s) of Funding for the Protocol:

(*Any grant(s) or other financial or material support must be documented and included in your application.)*

SECTION 2 - REVIEW CATEGORY AND JUSTIFICATION

A. This is application a ☐ New ☐ Renewal | If Renewal, date of last IRB approval:

B. IRB Review Category Requested: ☐ Exempt ☐ Expedited ☐ Full Board Review

C. Identify which of the Following Special Population will be Involved with this Project:

☐ None ☐ Children under 14 ☐ Fetuses ☐ Abortuses ☐ Prisoners ☐ Intellectual Disability
☐ Mentally Disabled ☐ Pregnant Women

D. Justification for Review Category Requested:

E. Estimated Start Date: Estimated End Date:

Note: Start date cannot predate IRB approval

SECTION 3 - RESEARCH QUESTION AND DESIGN

A. Research Question/Statement/Topic and/or Hypothesis:

B. Brief Explanation of the rationale for this study (200 words or less):

C. Research Design: *(Note: With secondary data, please describe how data were collected, from what source(s), and how they will be used.)*

IMPORTANT: If <u>only</u> secondary data will be used for the research, Skip to
SECTION 8 – CONFIDENTIALITY AND DATA SECURITY

SECTION 4 - RESEARCH PROCEDURES

A. Describe all activities involving human subjects.

B. Describe how the data will be collected, i.e., questionnaires, interviews, observations, tests, etc.

C. If applicable, describe the methods of data recording, i.e., audiotape, videotape, data entry, etc. *(Note: If audio or video taping will be used, clearly indicate if the information is identifiable and what steps will be taken to protect the confidentiality of the participants.)*

D. Anticipated number of participants:

E. What is the approximate time commitment for the participants?

F. Location(s) and address of data collection/research activities:

G. Describe how participants will be allowed to withdraw from the study without penalty.

SECTION 5 - PARTICIPANTS

A. Describe the Target Population and justify how this population is reasonable for this research.

B. Age of participants: ☐ 18 and over ☐ under 18 (specify age(s) if under 18)

C. Describe inclusion and exclusion criteria for participants.

D. Justify how the number of anticipated participants is reasonable for this research.

E. From where will the participants be recruited? *(Note:* To *minimize the perception of coercion, the IRB strongly discourages PIs from recruiting students from their (or their supervisor's) courses.)*

F. How will you recruit the participants? *(Note: If using printed material, attach a copy. If verbally describing the study to a pool of potential participants, attach your script.)*

G. Describe how you ensure recruitment materials will clearly note participation is voluntary.

H. Compensation: If compensation (of any kind, i.e., monetary, extra credit, gifts, etc.) is to be awarded for participation in the study, describe below. Be specific and include the monetary value of any gifts. If no compensation will be given, state "None."

I. Research Site(s):

J. For location site(s) outside of JSU, please attach a copy of the signed permission letter(s) on appropriate letterhead.

SECTION 6 - INFORMED CONSENT / ASSENT PROCESS

A. Explain the process through which you will provide each potential participant all the information they need to decide whether or not to participate.

B. Append a copy of any written forms, cover letters, verbal scripts, and/or assent scripts that you will use. *(Note: Informed consent/assent documents must be submitted as a separate MS Word/PDF document.)*

C. Informed Consent documents must be written at an appropriate level for participants and follow the JSU template (http://www.jsu.edu/academicaffairs/irb.html):

- for the general population, no higher than an 8th grade level;
- for college students, no higher than a 12th grade level; and
- for prisoners, no higher than a 3rd grade level.

The IRB will verify readability using a Flesch-Kincaid Grade Level as measured in MS Word.

D. Informed Consent Documents include:

- Title of the study
- The purpose of the research
- A description of the research procedure
- Location where the research will take place
- Length of time the participant is expected to participate
- A description of any potential risks to the subject, including physical, psychological, social harm, discomfort, or inconvenience
- Whether identifying information will be collected, and if so, how it will be kept confidential
- Benefits of the research to society and/or the individual
- If confidentiality cannot be maintained/guaranteed, has the subject been made aware?
- How confidentiality of records identifying the participant will be maintained (including where the data is stored, who has access to the data and how long the data will be kept)
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
- A statement that the subject may withdraw from the study at any time without penalty
- Who to contact for answers to questions or in the event of a research-related injury or emergency

6e. Are participants between the ages of 7 and 17? (If no, skip to SECTION 7)	☐ **Yes** ☐ **No**
6f. If participants are between the ages of 7 - 17, an Informed Assent should be obtained from each subject. *(Note: Informed Assent document should follow the JSU template* http://www.jsu.edu/academicaffairs/irb.htm *)*	
6g. Does the research involve more than minimal risk?	☐ Yes ☐ No

6h. If the protocol calls for a waiver or alteration of any element(s) of the informed consent, justify the appropriateness of the criteria. Note the effect, if any, the waiver will have on the rights and welfare of the participants.

6i. Informed Assent Documents include:

- Title of the study
- The purpose of the research
- A description of the research procedure
- Location where the research will take place
- Length of time the participant is expected to participate
- A description of any potential risks to the subject, including physical, psychological, social harm, discomfort, or inconvenience
- Whether identifying information will be collected, and if so, how it will be kept confidential
- Benefits of the research to society and/or the individual
- If confidentiality cannot be maintained/guaranteed, has the subject been made aware?
- How confidentiality of records identifying the participant will be maintained (including where the data is stored, who has access to the data and how long the data will be kept)
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
- A statement that the subject may withdraw from the study at any time without penalty
- Who to contact for answers to questions or in the event of a research-related injury or emergency

SECTION 7 - POTENTIAL RISKS AND BENEFITS

7a. Potential Risks to Participants: List all physical, economic, social, legal and/or psychological risks. Include risks to confidentiality, reputation and employability. Specify what you will do to minimize the risks and protect the participants.

7b. Is deception of participants part of the research design?	☐ **Yes** ☐ **No**

7b-1. If yes: Justify why deception is necessary.

7b-2. If yes: Describe the PI(s) plan for debriefing participants about the deception after the research study has been completed.

7c. Benefits of the Research: Describe potential benefits to the participants and/or society as a direct result of this research project.

7d. Describe how the potential benefits outweigh the risks being incurred by the participants.

7e. Describe, whenever appropriate, how participants will be provided with any pertinent information after their participation.

SECTION 8 – CONFIDENTIALITY AND DATA SECURITY

8a. Describe what will be done to ensure the subject's participation will be confidential and is both adequate and appropriate. This should include all parts of the study - during the study participation, after the study participation, and if/when the results of the study are published.

8b. Describe where the data will be stored and the security of the location. Also note how long the data will be kept.

8c. List the individual(s) who will have access to the data.

SECTION 9 – COMPLETION OF IRB TRAINING AND ATTACHMENT OF CERTIFICATE

To increase awareness of the investigator's role in assuring protection of human subjects, investigators are required to complete IRB Training annually. The level of training is dependent upon the level of research being conducted.

Each person involved with conducting the research project (PI, Co-PI's, Advisors, etc.) will need to have the appropriate IRB Training certificate on file in the Office of the Vice Provost. Each certificate is valid for 12 months.

Exempt Application IRB Training and Certification: CITI Training Course: Social and Behavioral Responsible Conduct of Research

Expedited and Full Review Applications: CITI Training Course: Social and Behavioral Responsible Conduct of Research

DNP students will need to attach a copy of their HIPAA Training Certificate. For faculty DNP candidates conducting survey research on their students, a copy of the faculty member's FERPA Certificate should also be attached.

If you do not have a certificate on file:

- **Access the U.S. Department of Education** PTAC website
- **Select the TRAINING drop-down menu at the top of the page; then select Online Training Modules; then select FERPA 101: For Colleges and Universities - You should expect to spend 35-45 minutes on the training and certification.**
- **Register as a new user and view the training video**
- Email a copy **of your completion certificate and retain a copy for your files (irb@jsu.edu).**

Additional resources you may find helpful:

- THE LAB: Avoiding Research Misconduct **- Interactive Movie on Research Misconduct**
- Assurance Training **- HHS's tutorial on Assurance Training**

PRINCIPAL INVESTIGATOR'S NAME(S)

PROJECT TITLE:

SIGNATURES: This page must be printed out, signed by the appropriate individuals and then scanned and inserted back into your application package. If that is not possible, please send the signed form to the Office of the Vice Provost.

Principal Investigator(s) Statement of Responsibility:

I understand and will abide by federal policy concerning human subjects research. In addition, I agree to:

- Inform the IRB immediately of any unforeseen risks or adverse effects.
- Inform the IRB immediately of any changes to research plan, including, but not limited to, changes in research procedures, populations, surveys, consent forms, and timelines.
- Keep signed consent and/or assent forms, if required, from each participant for the duration of the project, including publications.
- Submit a Continuation/Conclusion report at 12-month or shorter time intervals (as indicated on the approval letter).

I accept the responsibilities indicated above. I have attached a copy of the applicable training certificate(s).

Signature: _____ Date: _____
Principal Investigator 1

Signature: _____ Date: _____
Principal Investigator 2

Signature: _____ Date: _____
Principal Investigator 3

Faculty Advisor (For Student-Only Project)

I have collaborated in the development of the research proposal described in the attached and have reviewed all of the information enclosed and will oversee the work described. I will endeavor to ensure that all of the PI responsibilities are fulfilled. ***I have read the IRB application submitted for this project for content, clarity, and methodology to ensure it is in compliance with Jacksonville State University IRB Policies and Procedures.***

_____ _____ _____
Faculty Advisor (Please Print Name) **Faculty Advisor Signature** **Date**

Supervisor (For Faculty or Staff Project)

By my signature as supervisor, I certify that I am aware of this research project, and I will report any violation of JSU policies and procedures and/or human subject research protection laws to the IRB.

_____ _____ _____
Supervisor (Please Print Name) **Supervisor's Signature** **Date**

Email any questions and completed application with supporting documentation to irb@jsu.edu.