IRB Reviewer Checklist
Type 1, 2 or 3 Research (Exempt, Expedited or Full Review Applications)

Protocol #: _____ **PI Name:** _____ **Reviewer:** _____

I certify that I do not have any conflict of interest related to this research or my review. ☐

SECTION 1 - GENERAL PROJECT INFORMATION	
A. Project Title.	☐ Yes ☐ No
B. PI(s) Information complete.	☐ Yes ☐ No
C. The PI is a student and this study is part of a Thesis, Dissertation, or DNP*/DSC project.	☐ Yes ☐ No
D. Faculty Advisor Information is complete.	☐ Yes ☐ No
E. Source of funding, if applicable, is complete and support documents are included.	☐ Yes ☐ No ☐ N/A
SECTION 2 - REVIEW CATEGORY AND JUSTIFICATION	
A. Type of application selected.	☐ Yes ☐ No
B. Appropriate IRB Review Category selected.	☐ Yes ☐ No
C. Justification for Review Category is acceptable.	☐ Yes ☐ No
D. Special populations involved with the project are identified.	☐ Yes ☐ No ☐ N/A
E. Estimated start / end dates are complete.	☐ Yes ☐ No
Comments:	
SECTION 3 - RESEARCH QUESTION AND DESIGN	
A. Adequate statement of research question/statement/topic and/or hypothesis.	☐ Yes ☐ No
B. Explanation of the rationale for the study is complete.	☐ Yes ☐ No
C. Research design is clear and acceptable.	☐ Yes ☐ No
PI is using secondary data for the research (data already available as part of medical records, surveys already conducted, etc.).	☐ Yes ☐ No
If yes: *The description of how the secondary data was collected, the data source, and how the PI plans to use the data is appropriate.*	☐ Yes ☐ No ☐ N/A
Comments:	

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. Adequate description of all activities involving human subjects.	☐ Yes ☐ No
B. Detailed summary of data collection (questionnaires, interviews, observations, tests, other) and methods of data recording (audiotape, videotape, computer entry, etc.).	☐ Yes ☐ No
C. Will the PI be audio or video recording participants?	☐ Yes ☐ No
If yes: *If using audio or video tapes, does PI indicate whether or not information is identifiable on audio/video tapes and how confidentiality will be protected?*	☐ Yes ☐ No ☐ N/A
D. Anticipated number of participants is specified and seems appropriate for study.	☐ Yes ☐ No
E. Time commitment for participation is clearly explained.	☐ Yes ☐ No
F. Location of data collection / research activities is specified and appropriate.	☐ Yes ☐ No
G. Description of how participants will be allowed to withdraw from the study is sufficient.	☐ Yes ☐ No
Comments:	

SECTION 5 - PARTICIPANTS	
A. Target population for the study purpose is reasonable for the purpose of the research.	☐ Yes ☐ No
B. Age of participants is selected.	☐ Yes ☐ No
C. Inclusion and exclusion criteria for participants is justifiable.	☐ Yes ☐ No
D. Number of anticipated participants is acceptable and justifiable.	☐ Yes ☐ No
E. Participant recruitment site(s) is appropriate.	☐ Yes ☐ No
F. How participants are recruited is appropriate.	☐ Yes ☐ No
Emails, flyers, brochures, posters, letters, etc., will be used to recruit participants.	☐ Yes ☐ No
If yes: *The email language, brochures, posters, letters, etc., that will be used to recruit participants are appropriate.*	☐ Yes ☐ No ☐ N/A
G. Recruitment procedures ensure voluntary participation.	☐ Yes ☐ No
H. Participants are being compensated for their time (being given $, t-shirt, course credit, etc.).	☐ Yes ☐ No
If yes: *Is the compensation appropriate and monetary value included?*	☐ Yes ☐ No ☐ N/A
If no: *Is "none" stated?*	☐ Yes ☐ No ☐ N/A
I. Research sites are indicated.	☐ Yes ☐ No
J. Signed permission letters on appropriate letterhead are attached for sites outside of JSU (public places).	☐ Yes ☐ No ☐ N/A
Comments:	

SECTION 6 - INFORMED CONSENT / ASSENT PROCESS	
A. Informed Consent will be sought from each subject.	☐ Yes ☐ No ☐ N/A
B. Informed Consent procedures appear to be appropriate and documents are included..	☐ Yes ☐ No ☐ N/A

C. Informed Consent Document	
Informed Consent document follows JSU template (http://www.jsu.edu/academicaffairs/irb.html).	☐ Yes ☐ No ☐ N/A
Informed Consent document is at an appropriate reading level.	☐ Yes ☐ No ☐ N/A
D. Informed Consent Document includes:	
• Title of the study.	☐ Yes ☐ No ☐ N/A
• The purpose of the research.	☐ Yes ☐ No ☐ N/A
• A description of the research procedure.	☐ Yes ☐ No ☐ N/A
• Location where the research will take place.	☐ Yes ☐ No ☐ N/A
• Length of time the participant is expected to participate.	☐ Yes ☐ No ☐ N/A
• A description of any potential risks to the subject, including physical, psychological, social harm, discomfort, or inconvenience.	☐ Yes ☐ No ☐ N/A
• Whether identifying information will be collected, and if so, how it will be kept confidential.	☐ Yes ☐ No ☐ N/A
• Benefits of the research to society and/or the individual.	☐ Yes ☐ No ☐ N/A
• If confidentiality cannot be maintained/guaranteed, has the subject been made aware?	☐ Yes ☐ No ☐ N/A
• 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).	☐ Yes ☐ No ☐ N/A
• A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.	☐ Yes ☐ No ☐ N/A
• A statement that the subject may withdraw from the study at any time without penalty.	☐ Yes ☐ No ☐ N/A
• Who to contact for answers to questions or in the event of a research-related injury or emergency.	☐ Yes ☐ No ☐ N/A
Comments regarding consent:	
E. Are participants between the ages of 7 and 17? (If no → skip to SECTION 7)	☐ Yes ☐ No ☐ N/A
Informed Assent will be sought from each subject.	☐ Yes ☐ No ☐ N/A
Informed Assent procedures appear to be appropriate.	☐ Yes ☐ No ☐ N/A
Parent/legal guardian permission form is complete.	☐ Yes ☐ No ☐ N/A
F. Informed Assent Document	
Informed Assent document follows JSU template (http://www.jsu.edu/academicaffairs/irb.html).	☐ Yes ☐ No ☐ N/A
Informed Assent document is at an appropriate reading level.	☐ Yes ☐ No ☐ N/A
Study title on Assent document is identical to that listed on the protocol.	☐ Yes ☐ No ☐ N/A
If no: *Has justification been provided for the use of a different title?*	☐ Yes ☐ No ☐ N/A
G. Is more than minimal risk involved?	☐ Yes ☐ No ☐ N/A
H. Does the protocol call for a waiver or alteration of any elements of informed assent?	☐ Yes ☐ No ☐ N/A
If yes: *Are all the criteria for a waiver or alteration appropriate, that is:* *1. The research involves no more than minimal risk to the subjects?* *2. The waiver or alteration will not adversely affect the rights and welfare of the subjects?* *3. Whenever appropriate, the subjects will be provided with additional pertinent information after participation?*	☐ Yes ☐ No ☐ N/A
I. Informed Assent Document includes:	
• Title of the study.	☐ Yes ☐ No ☐ N/A
• The purpose of the research.	☐ Yes ☐ No ☐ N/A

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

SECTION 7 - POTENTIAL RISKS AND BENEFITS	
A. Potential Risks to Participants	
Description of potential risks to participants is adequate (including likelihood, level of seriousness, and efforts / safeguards to minimize risk).	☐ Yes ☐ No
Research procedures subject participants to significant psychological, physical, social or legal risks.	☐ Yes ☐ No
If yes: *Is the justification for why the risks are necessary adequate?*	☐ Yes ☐ No ☐ N/A
If yes: *Does the PI identify medical or psychological resources that will be made available to the participants, if needed?*	☐ Yes ☐ No ☐ N/A
B. The research design involves the deception of participants.	☐ Yes ☐ No
1. If yes: *Explanation of why deception is necessary is adequate.*	☐ Yes ☐ No ☐ N/A
2. If yes: *PI includes a plan for debriefing participants about the deception after participation in the research is complete.*	☐ Yes ☐ No ☐ N/A
C. Adequate description of how the results of the study will benefit society and/or participant.	☐ Yes ☐ No
D. Potential benefits to society outweigh the risks being incurred by the participants.	☐ Yes ☐ No
E. Adequate description of how participants will be provided with pertinent information after participation.	☐ Yes ☐ No
Comments:	

SECTION 8 - CONFIDENTIALITY AND DATA SECURITY	
A. The specific steps that will be taken (i.e., during study participation, after study participation and with the publication of study results) to ensure the subject's participation will be confidential are provided and are adequate/appropriate.	☐ Yes ☐ No

B. PI lists where the data will be stored, the security of the location and the duration data will be kept.	☐ Yes ☐ No
If no: *What information is missing?*	
C. The individuals who will have access to the data are appropriate.	☐ Yes ☐ No
Comments:	
In this reviewer's opinion, this project is ready to be approved:	☐ Agree ☐ Disagree ☐ Revisions Requested (as noted in comments)
Additional Reviewer Comments:	

IRB OFFICE ONLY **Basic Protocol Information**	
Principal Investigator's Name(s) is listed.	☐ Yes ☐ No
Project Title is listed.	☐ Yes ☐ No
PI signature / date.	☐ Yes ☐ No
Faculty Advisor verified; signature / date.	☐ Yes ☐ No ☐ N/A
Supervisor signature / date.	☐ Yes ☐ No ☐ N/A
NIH IRB Training Completion Date and Reference Number.	Date and Reference #:
Research funding proposal is attached, if applicable.	☐ Yes ☐ No ☐ N/A
Informed Consent and/or Assent documents are attached, as applicable.	☐ Yes ☐ No ☐ N/A
Data Collection instruments (surveys, focus group guides, tests, observation guides, etc.) are attached, if applicable.	☐ Yes ☐ No ☐ N/A
Recruitment flyers, ads, letters, emails, etc., are attached, if applicable.	☐ Yes ☐ No ☐ N/A
If the actual research activities take place somewhere besides JSU (ex. a clinic, school, etc.), are the appropriate approval / verification letters attached?	☐ Yes ☐ No ☐ N/A