Jacksonville State University

Application for DNP Quality Improvement Project

General Instructions: Please complete the DNP Quality Improvement project application. The assessment conducted by the JSU DNP QI Committee for the Protection of Human Subjects is only to determine if the submitted project meets the regulatory definition of human subjects research. *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):

Name:	Email:	Phone:

C. Faculty Advisor, Sponsor, QI Team:

1. Name:	Email:
2. Name:	Email:

D. Source(s) of Funding Project:

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

E. Project Site(s):

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

C. 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/PICOT/Statement/Topic:

B. Brief Explanation of the rationale and intent of the project. (max 250 words):

C. Will all patients participating in the project receive the minimum standard of care at this institution? ☐ Yes ☐ No
If 'no', explain why the entire population will not receive the minimum, usual care?

D. Is the purpose to measure the performance of or to determine the effect of a process change intended to improve health care delivery, please explain?

E. Describe the data collection process and the source of the data.

F. Describe how this data qualifies as secondary data.

G. Will the results be used to inform and implement improvements in patient care at this institution? ☐ Yes ☐ No
If 'no', explain why improvements in patient care will not inform and implement?

H. Is the intent of the project either to evaluate a current evidence-based practice or to replicate another researcher's intervention?

SECTION 4 - POTENTIAL RISKS AND BENEFITS

A. Will participants be exposed to additional discernible risk or burden beyond standard of care at this institution? ☐ Yes ☐ No
If 'yes', explain what risks and burdens associated with this project and how it will affect patients or personnel.

B. Does the project involve withholding standards of care supported by evidence-based practice to any segment of your identified population? ☐ Yes ☐ No
If 'yes,' explain why conventional care will be withheld.

C. Does the project involve studying the safety and effectiveness of a drug, biologic, or device (including FDA-approved/non-approved agents or off-label use)? ☐ Yes ☐ No
If 'yes', please explain.

D. Will the project be described as research in public presentation, academic dossier, or other representations (QI findings may be published but should not be represented as research)? ☐ Yes ☐ No
If 'yes', please explain.

E. Describe the potential benefit(s) of the intervention?

SECTION 5 – CONFIDENTIALITY AND DATA SECURITY

A. 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.

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

C. List the individual(s) who will have access to the data**.**

D. If house staff (RN, Unit Manager, Administrator, etc.) or medical staff will be involved in this project, please describe their role.

SECTION 6 – 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: http://www.jsu.edu/online/irb-training/story_flash.html

Expedited and Full Review Applications: https://about.citiprogram.org/en/homepage/

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.**

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:

- Obtain approval from the IRB prior to instituting any change in project protocol.
- Inform the IRB immediately of any unforeseen risks or adverse effects.
- 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**

Note: This project will be approved or denied based on the information provided. Approval of QI projects warrants that the principal investigator implements the project with no deviation from the approved application. Audits are randomly conducted to ensure compliance; non-compliance may result in termination of the project.