

Doctor of Nursing Practice (DNP) Project IRB Guidance Document

This document has been created to provide guidance for the conduct of DNP Projects at Clemson University School of Nursing. Students are expected to follow this guidance as they design and carry out their projects. DNP Team Leaders must ensure that their students follow guidelines outlined below, and when questions arise, they should check with DNP Program Coordinators or the Graduate Director.

Clemson University Institutional Review Board (IRB)

The IRB at Clemson University is a federally mandated body that works to protect the welfare of humans participating in research conducted by faculty and students at Clemson University. Individuals connected to Clemson who desire to conduct research with the intention of disseminating their research findings in a way that contributes to generalizable knowledge must submit the appropriate materials and forms to the IRB prior to the conduct of the research.

DNP Projects vs. Research

The definition of “research” under 45 CFR 46.102(d), is “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge...” . Research based programs traditionally focus on research that generates knowledge through rigorous research and statistical methodologies that may be broadly applicable or generalizable.

According to the American Association of Colleges of Nursing (AACN) DNP Essentials on the DNP Project, “Rather than a knowledge generating research effort, the student in a practice-focused program [DNP] generally carries out a practice application oriented final DNP Project” (AACN, 2006, p.3). The DNP project is measured according to contribution to improved outcomes rather than its contribution to generalizable knowledge. DNP projects should focus on the application of new science, its application and evaluation. (AACN, 2015)

Acceptable DNP Project Types (Adapted from NONPF, 2024)

- Quality improvement/quality assessment projects.
- Development and/or implementation of healthcare policy.
- Program development and/or evaluation/implementation of evidence-based practice.

DNP Project Type: Quality Improvement/Quality Assessment

Quality Improvement/Assessment projects are conducted in specific practice settings, systems or with specific populations to improve health or health outcomes. These projects are intended to improve a practice or process within a particular institution or ensure it conforms with expected norms. These activities are mandated by institutions as part of regulated operations.

- **Examples of QI activities that are likely NOT research include:**
 - Implementing a practice to improve the quality of patient care
 - Collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes
 - Measuring and reporting provider performance data for clinical, practical, or administrative uses
 - A group of affiliated hospitals implements an application to reduce prescription amount errors, and collects patient prescription information from medical charts to assess whether the application helped reduce error rates as expected.
- **Examples of Activities that are likely QI and Research**
 - A project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for

the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results.

- Collaborative (multi-site) – All the sites are trying to improve some aspect of clinical care (ex. implementing an application to help improve making clinical decisions). The whole department decides this app will improve care, and implement the app. They collect data as the app is implemented, and in addition, analyze this data for generalizable knowledge.
- A teacher implements a practice to have all students reflect on their learning by keeping a journal, with the intention of improving teaching practice. However, the teacher also wants to prove that this method works, so they analyze student journals with grades to generalize the success of this method.

Adapted from DHHS QI FAQ: <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>

Research vs. Quality Improvement Comparison

	RESEARCH	QUALITY IMPROVEMENT
INTENT	Develop or contribute to generalizable knowledge (e.g., testing hypothesis)	Improve a practice or process within a particular institution or ensure it conforms with expected norms; not designed to contribute to generalizable knowledge
DESIGN	Systematic; follows a rigid protocol that remains unchanged throughout the research; may involve randomization	Adaptive, iterative design; may or may not be systematic; generally does not involve randomization
MANDATE	Activities not mandated by institution or program	Activity mandated by institution or clinic as part of its operations
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings are not expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional practice and identify corrective action(s) needed
POPULATION	Usually involves a subset of individuals; no obligation to participate; may involve statistical justification of sample size to achieve endpoints	Responsibility to participate as a component of the program or process; information on all or most involved in the practice or process is expected to be included; exclusion of some individuals significantly affects conclusions
BENEFITS	Participants may or may not benefit directly; often a delayed benefit to future knowledge or individuals	Directly benefits a process, program, or system; may or may not benefit participants
RISKS	May place participants at risk	Does not place participants at risk with the possible exception to risks to privacy or confidentiality of data
ANALYSIS	Statistically prove or disprove hypothesis	Compare program, process or system to established standards
DISSEMINATION OF RESULTS	Intent to disseminate results generally presumed at outset of project as part of professional expectations, obligations; results expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies	Intent to disseminate results generally not presumed at outset of project; dissemination often does not occur beyond the institution evaluated; when published or presented to a wider audience the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks rather than to develop or contribute to generalizable knowledge

Adapted in part from University of Wisconsin-Madison Health Sciences IRBs Comparison of the Characteristics of Research, Quality Improvement, and Program Evaluation Activities

Retrieved from: https://research.vcu.edu/media/office-of-research-and-innovation/humanresearch/research_qi_guidance.pdf

DNP Project Type: Healthcare Policy

Health policy projects may focus on governmental policy at the federal, state or local level or organizational policy. The purpose of this type of project is to examine, propose or collaborate on policy changes using a systematic process. The project may include proposing changes to existing policies, creating a new policy, or coordinating with existing grassroots organizations/health systems. Since this project will involve some type of evaluation (with stakeholders, etc.) it will follow the same review guidelines as a Quality Improvement/Quality Assessment project.

DNP Project Type: Program Development/Evaluation

Program development and evaluation involves a systematic process for implementing, collecting, and analyzing information guided by standards to make judgements regarding a program. The goals for program development and evaluation are intended for modifying program plans, operations, and outcomes to improve the effectiveness and guide further program development. Evidence based practice projects evaluate or create processes for clinicians to guide clinical decision making with the integration of scientific evidence for outcomes and quality care improvement.

DNP Project Type: Evidence Based Practice (EBP)

EBP projects involve a systematic approach that integrates current scientific evidence into clinical practice. This project integrates the review and appraisal of the best available evidence combined with clinical expertise in the identified patient or population to guide improvement of healthcare delivery.

DNP Project Utilizing Secondary Data Analysis

Secondary human subjects research makes use of existing information (data) or biospecimens collected previously for a different purpose. The existing information or biospecimens may have been collected for a non-research purpose or for a different (IRB-approved) research study. Although secondary research projects do not involve interactions or interventions with human subjects (i.e., research participants), they may still require IRB review if the data or biospecimens include private identifiable information, since the definition of "human subject" at 45 CFR 46.102(f) includes living individuals about whom an investigator obtains identifiable private information for research purposes.

Projects that Need CU-IRB Office Review

- Any methodology that meets the IRB definition of research.
 - Projects to be conducted by CU employees should be reviewed by CU IRB unless:
 - The project meets the definition of Quality Improvement and does not include any elements of research
 - Any DNP Project conducted at CU facilities (Redfern, Clemson Rural Health)
 - Projects being conducted at a facility without an IRB or HIPAA compliance office
 - If the facility's IRB office determines that the project falls into the Exempt or Expedited Review categories
 - Use of secondary data (information collected for a different purpose) may require HIPAA review or if identifiable information is being utilized
- Any interview/interactions that focus on data collection (depression scale), surveys about personal behaviors or attitudes, open ended questions, even if no identifiable information is being collected are required to be reviewed through IRB (facility or CU).

Projects that Do Not need CU-IRB Office Review

- Interviews or interactions where questions focus on process, products, or policies are allowed without IRB review. Questions may not ask the individual's opinions but focus on factual data.
- Publicly available identifiable data do not require IRB review. This includes: census data, labor statistics, national domestic violence rates, social media data from public platforms or public user accounts.
- Students must avoid using certain terminology in their proposal, information letter and surveys. Specifically, students must avoid using the terms "research" or "research study." Instead, they must use the term "DNP Project, Quality Improvement Project, etc." Students must also adopt the terms "understanding of participation" in place of "informed consent" and "project participants" in place of "study participants."

<https://www.clemson.edu/research/division-of-research/offices/orc/irb/whatneedsreview.html>

Procedures for Reviewing and Approving DNP Projects

- All projects being conducted at an outside facility must contact that facility's IRB office for direction on required processes for IRB review.
- Any letters obtained from the facility's IRB office will stand in place of letters from the CU IRB office.

The DNP Project Lead (chair) and Team Members will be responsible for reviewing and approving their student's project. If students submit project proposals that do not meet the guidelines for an appropriate DNP

project, then the Project Lead and Project Team Members will provide detailed feedback and will work with the students to ensure that any necessary changes will be implemented.

Informed Consent vs. Understanding of Participation

Participants involved in projects deemed “human subjects research” by IRB must include an Informed Consent (<https://www.clemson.edu/research/division-of-research/offices/orc/irb/forms.html>). Projects that do not involve “human subjects research” may have an **Understanding of Participation** for individuals who choose to participate in the DNP Project.

Retention of Documents

All documents related to student projects (i.e., information letters, protocols, and surveys) must be retained for 1 year post graduation. If these are electronic documents, they can be stored on a university approved cloud storage system. If the documents are paper documents, they must be scanned into the university approved cloud storage and stored by the project chair. In the event that the project chair leaves the university, the documents will be transferred to the Program Coordinator.

Publications and Presentations

Students who desire to present or publish their DNP Projects can do so as long as the distinction is made that the information was obtained through a DNP Project and not as contributing to generalizable knowledge. These projects do not have to submit the proper documentation to the Clemson University Institutional Review Board in order to present or publish. These students cannot make reference to their project being “research” or a “research study”. They also cannot make generalizations based on the findings. Publishing or presenting a DNP Project usually involves suggesting potentially effective models, strategies, assessment tools or provide benchmarks. However, if the student desires to turn the project into a research study, enroll new participants, and/or wants to generalize the findings, then an application will need to be submitted to the Clemson University Institutional Review Board prior to data collection.

Contact Information for Reporting Incidents

Should any problems arise during the conduct of DNP projects, they should be reported first to the DNP Team Leader. If they cannot be addressed, they should then be reported to the appropriate Program Coordinator. Problems would include things such as students conducting research that was not approved, unanticipated problems or adverse events that arise during the conduct of the project. See below for a definition of adverse events.

Definitions of Key Terms

- **Unanticipated problems** – situations that arise during the project that are unexpected, that appear to be related to participation in the project, and that seem to place a person at greater risk of harm than initially expected or anticipated.
- **Adverse events** – physical or psychological harm resulting from participation in the project. While unlikely to occur, some individuals could experience psychological harm, for example, based on the nature of certain questions asked.
- **Interventions** – the introduction of a variable, such as a drug, to examine its effect on a particular outcome. **Intervention**, as defined on the Clemson IRB website, includes “both physical (in person) procedures by which information or biospecimens are gathered (e.g., venipuncture) AND manipulations of the subject or the subject's environment that are performed for research purposes” (Clemson IRB website, 2023).
- **Benign behavioral interventions** - which are included in the exempt categories for the Clemson IRB protocol, are “brief in duration, harmless, painless, not physically invasive, not likely to have

a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing” (Clemson IRB website, 2023). Implementing a procedure/training and/or conducting pre/post behavior surveys is also considered a benign behavioral intervention. QI/A projects are not considered a benign intervention.

- **De-identified data**-data that has been stripped of all identifying information and there is no way that it could be linked back to the individual. Identifiable means the identity of the subject is known or may be readily ascertained by the investigator or person associated with the information. In general, information is considered to be identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that, by their nature, a reasonably knowledgeable person could ascertain the identities of the individuals. Therefore, even though a dataset may have been stripped of direct identifiers (names, addresses, student ID numbers, etc.), it may still be possible to identify an individual through a combination of other characteristics (e.g. age, gender and ethnicity). If you are not sure if your dataset contains identifiable information, please consult with the CU-IRB or submit a proposal for review.
- **Deception** – informing participants that the study is about one thing when, in fact, it is about something else. The use of deception requires a debriefing at the end of the project. Because of this, use of deception is prohibited in DNP projects.
- **Anonymous**- “the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects” (Clemson IRB website, 2023). For the data to be “anonymous,” no private identifiable information may be collected from the individual. This includes e-mail addresses, IP addresses, employee IDs, etc.

Resources

- **Student Code of Conduct:** https://www.clemson.edu/studentaffairs/community-resources/oces/documents/student_code_of_conduct.pdf
- **Clemson University Institutional Review Board:** <https://www.clemson.edu/research/division-of-research/offices/orc/irb/index.html>
- **The Office of Research Integrity:** <https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-Definitions>
- **AACN DNP Essentials:** <https://www.aacnnursing.org/essentials>
- **Department of Health and Human Services, Quality Improvement Activities FAQ:** <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>
- **Virginia Commonwealth University-Quality Improvement vs. Research:** https://research.vcu.edu/media/office-of-research-and-innovation/humanresearch/research_qi_guidance.pdf
- **NONPF:** <https://acrobat.adobe.com/link/track?uri=urn:aaid:scds:US:64fac33f-fa3e-45fd-b0cd-74495f681679>
- Moran, K., Burson, R., & Conrad, D. (2020). The Doctor of Nursing Practice Project: A Framework for Success (3rd edition). Jones and Bartlett Learning.