DNP SpartaIRB Submissions:
From Proposal to Approval

Section 1: Distinguishing Research from Evidence-Based QI, Program Evaluation, and other Non-Research Projects *

Key differences

1. The Literature

- Research: Investigators methodically review the literature to find a gap in existing knowledge.
- Evidence-Based QI and other non-research: The literature and other resources are methodically searched to find the best available internal and external evidence to solve an active clinical problem.

2. Intent & Design

- Research: The intent is to conduct a rigorous process that generates new findings that can be generalized to other people and settings outside of the current study. Research is guided by hypotheses or research questions.
- Evidence-Based QI and other non-research: The intent is to reduce the frequency of a clinical problem by synthesizing current research and other evidence, aiming to create a clinically relevant improvement in a specific setting rather than trying to generalize the results. This type of project is guided by project aims.

3. The Participants

- Research: Participants are a specific group of people chosen using strict inclusion and exclusion criteria so they can represent a broader target population.
- Evidence-Based QI and other non-research: Subjects are the actual patients, clinicians, clients, or other population currently experiencing the specific clinical problem within that practice or population setting.

4. How Data is Handled & Evaluated

- Research: Investigators are cognizant of confounding variables and therefore use strict methods and statistics so they can make valid inferences about the relationships they are investigating.
- Evidence-Based QI and non-research: Data is collected before and after the project is implemented to compare the two time periods and determine if an improvement occurred in that specific setting. OR Data is collected in a specific setting to determine if there is a need for improvement of clinical care in a specific practice setting or if an intervention or education session may be valuable in that setting.

5. The Importance of Statistics

- Research: Statistical inferences are vital to the project, meaning power analyses cannot be ignored.
- Evidence-Based QI and non-research: There is little emphasis placed on the statistical significance of the results.

Tip for Students: If planning an evidence-based QI project, double-check that the work lines up with evidence-based QI standards by reviewing the SQUIRE Guidelines (**S**tandards for **Q**uality **I**mprovement **R**eporting **E**xcellence).

Addressing common myths used to attempt differentiating research from non-research

1. If anonymity of participants is maintained, it is evidence-based QI or other non-research

False. The level of participant anonymity or confidentiality is a protocol mechanism used to manage data security and protect privacy; **it is not a regulatory determinant** of whether a project constitutes research or non-research.

Both research and QI can be designed with fully anonymous participation or involve identifiable data. Implementing an anonymous survey does not inherently transform a research study into a QI project, nor does collecting identifiers disqualify a valid QI initiative.

2. If pre- and post-tests are used to test the knowledge and learning achievement of people who participate in an education session, especially if no identifiers are collected, it is an evidence-based QI or other non-research project.

False. When a project targets institutional employees—such as nurses, clinicians, or other staff members—and queries them on knowledge, skills, behaviors, attitudes, or competencies directly tied to their active professional roles, **the test introduces a higher magnitude of risk that can elevate the project to human subjects' research requiring informed consent.**

a. **Professional Vulnerability:** Employees represent a unique population within healthcare organizations who must navigate specific professional risks. Surveys or educational tests that may expose clinical knowledge or skill deficits can present distinct risks to an employee's professional standing, job security, or reputation.

b. **Exceeding Ordinary Risk:** While healthcare professionals have an ethical responsibility to cooperate with basic operational feedback as part of ordinary, low-risk healthcare operations, projects that scrutinize specific clinical competencies cross a threshold if they introduce more than minimal incremental risk to the individual. If the evaluation introduces elevated professional risks, or if it intends to draw generalizable conclusions about clinician knowledge, it must be handled under an approved research framework rather than routine operations. This ensures that participation remains entirely voluntary and is backed by explicit **informed consent** to protect staff from negative workplace repercussions.

3. If an education project uses a post-survey of employee participants to evaluate aspects of the education content or method, it is an evidence-based QI or other non-research project.

True. Evaluation of the education project for acceptance, usability, clear presentation, target audience, meeting a need, etc., is part of evidence-based QI or program improvement and is non-human research.

4. Retrospective review and analysis of institutional data regarding a specific issue in patient care, clinician documentation, or other clinical outcomes, is always research so the idea of this type of project being evidence-based QI or other non-research project should be dismissed.

False. If data is being collected in a single institution setting with the intent to compare treatments, documentation, outcomes, or other matters to address specific care issues in that unit or institution, the project may be considered part of evidence-based QI or program improvement and is then non-human research. The difference will depend on intent, design, and how the data is handled, evaluated, and used.

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* This document provides general guidelines to assist DNP students in differentiating research from evidence-based QI and other non-research. Institutional Review Boards (IRBs) may interpret human subject protection regulations differently, and official institutional policies supersede the information provided here.

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Reviewed by Esther Bernhofer, PhD, MA, RN, PMGMT-BC 09.04.2026

Section 2: Successfully submitting your DNP project to the CWRU IRB: Instructions for getting started

To Begin - Important General Information

- This is a general overview of the process. Individual situations vary and IRB policies, processes, and forms are subject to change.

- This document provides general guidelines to assist DNP students in differentiating research from evidence-based QI and other non-research. The CWRU and other Institutional Review Boards (IRBs) may interpret human subject protection regulations differently, and official institutional policies supersede the information provided here.

- All CWRU IRB submissions begin with submissions through **SpartaIRB**. All further instructions will reference SpartaIRB, which is the starting point and the platform where all IRB submissions and reviews take place.

- To access the SpartaIRB system you will need to request an account here. All local (CWRU) study/project team members must have a SpartaIRB account to be added to the study/project.

- All study/project team members **must have current Human Research Protection (HRP) certification – formerly CREC - completed and up to date.** It does not need to be complete before you submit, but the protocol will not be approved without it. HRP Training Information, including how to check your status is found here: https://case.edu/research/training/hrp-certification .

- The principal investigator (PI) for the SpartaIRB application must be CWRU faculty – usually your advisor/chair of your committee. **Students should list themselves as a co-investigator.**

- All requested changes and responses to the CWRU IRB occur via the SpartaIRB system (https://spartairb.case.edu/).

- See SpartaIRB Help menu for information on setting a "PI Proxy" to give another study/project team member more permissions if needed.

- If your project is going to be conducted at another institution which has its own IRB, you will need to obtain permission from their IRB FIRST before applying to SpartaIRB. **Be sure to find out early what the IRB application requirements are at the institution where you will be doing your project so that you can plan accordingly and work through it in a timely manner.** Special allowances for templates, permissions, and documentation may be required by the institution where the study/project is taking place and will be approved by CWRU IRB on a case by case basis.

- All faculty members must have a current conflict of interests (COI) disclosure form on file before final approval. Other team members only need to have a COI form on file if a study or project is externally funded/supported, greater than minimal risk, or when there are indications that there may be a conflict of interests. More information about CWRU's conflict of interest policy can be found on the COI page. Direct COI questions to the COI team at cwrucoi@case.edu.

- Please keep in mind that the time to approval is highly dependent upon the time and quality of the submission.

- **Students should work closely with their advisors on their submissions**.

- You may contact the CWRU IRB with any questions before starting a protocol in the CWRU SpartaIRB system or email IRB staff at cwru-irb@case.edu .

Depending on the type of project you will be doing, there are two distinct pathways to a proper SpartaIRB application.

Pathway Option 1.

Option 1 is the pathway for 'exempt' research. To facilitate the review process you may use the **terms 'study' or 'research' throughout the protocol and application. It is better if you and the IRB reviewer are using the same language. Avoid labeling your project QI in the IRB protocol, as QI projects use a different protocol (see below).** Exempt research means that the research protocol meets the requirements for minimal risk to human subject participants. Following review by the SpartaIRB Scientific Reviewer, the research protocol will be reviewed by a designated IRB reviewer to make the proper determination. If approved, the research will be exempt from further IRB review.

Examples of exempt research include (not limited to):

- online surveys
- education implementation with knowledge questions/surveys (sometimes pre-post survey design)
- certain types of observation studies

This option will also have **separate tracks** to address the specific needs of the type of research and the requirements of certain institutions.

Pathway Option 2.

Option 2 is the pathway for quality improvement (QI) and evidence-based-practice (EBP) projects. **The term 'project', NOT 'study' or 'research' is to be used throughout the protocol and application to designate this work as non-research, QI, etc., and not a research study.** These projects are traditional DNP non-human research projects as determined by the project intent, aims and methodology. Following review by the SpartaIRB Scientific Reviewer, the project application will be reviewed by a designated IRB reviewer to make the proper determination of non-human research.

Examples of QI, EBP, program evaluation and other non-research projects include (not limited to):

- quality improvement intervention project at an institution/organization
- education implementation based on current evidence that does not measure knowledge of participants but rather acceptance and usefulness of the education provided
- program or process evaluation of an existing program/process
- de-identified data collection from data bases for purposes of identifying future research or clinical needs
- public health surveillance activity **conducted, supported, requested, ordered, required, or authorized by a public health authority**

Both options begin with preparing to work in SpartaIRB

1. Log into https://spartairb.case.edu/ with your CWRU username and password below the CWRU logo.
2. Find templates and information in SpartaIRB: Example - Navigate to **Library** (menu across the top of the page) > **Templates** tab to find the appropriate CWRU **protocol** template.
    a. Your template selection will depend on which Pathway Option you choose and will be explained further in the Pathway Options sections.

b. You may review the **"CWRU IRB – How to Choose a Protocol Template"** document in the template section to assist in the process of ensuring you have the correct template.
c. Always download a fresh template from the location above. They are updated frequently.
d. The Template tab is also useful for consent forms for research studies and other forms that may be required for your specific situation.

Prepare all other required documents, such as:

- Have your DNP proposal handy, much of the information required on the protocol template will come from that. (DO NOT submit your proposal to the IRB)
- Consent form if doing research (for pathway option 1)
- Permission or approval letter or other signed form from the IRB of the institution/organization where your study/project will be conducted.
- Recruitment materials such as emails, posters, brochures, verbal scripts, etc.
- Data Collection sheets.
- Surveys or questionnaires (with consent from author if necessary)
- Education materials – for example, PowerPoint slides in Word document form*
- Letter of permission from an authorized person to conduct your research or project at the institution, organization, and/or specific unit or population
- ***Note – for faster facilitation through the CWRU IRB approval system, all documents submitted will need to be on CWRU templates or in Word format, NOT ppt, pdf, jpeg, or any other format. Any embedded QR codes must work at time of submission.**

Additional Information

Many of your questions can be answered at https://spartairb.case.edu/
The "Help Center" tab contains many useful instructions and even videos.
"Library" tab contains multiple templates and policies – always look for CWRU named templates, not University Hospital templates (UH)
The "General Tab" under the Library Tab contains IRB compliance and these documents:

- CWRU Human Research Protection Program Plan
- CWRU Investigator Manual

Further details for Options 1 & 2 follow in the next sections 

Option 1. The DNP exempt research study

Decide which of the following tracks applies to you. All tracks assume human research, (a systematic investigation designed to test a hypothesis, generate new scientific knowledge, and produce broad, generalizable findings beyond a specific local setting). Exempt research assumes minimal-risk and bypasses full IRB review and monitoring, although it still requires institutional review and approval.

A. **Education, data collection, or other intervention research conducted at Cleveland Clinic, MetroHealth, or University Hospitals.** This option will require the approval of that institution's IRB (external IRB) AND CWRU IRB, with special allowances for alternate consent templates and other considerations**. CWRU IRB will be noted as the IRB of record.**

B. **Education or other intervention research conducted at any location (hospital or organization) that has an IRB that must approve research protocols.** This option will require the approval of that institution's IRB (external IRB) AND CWRU IRB. Special allowances for templates, permissions, and documentation may be required on a case by case basis**. CWRU IRB will be noted as the IRB of record.**

C. **Survey research done entirely online, with no education or intervention component, with the only data collected being on an electronic survey tool.** This option will only require CWRU IRB approval and no other IRB is involved.

D. **Education, intervention, data collection, or survey research conducted at a community location that has NO IRB.** This option will only require CWRU IRB approval and no other IRB is involved. **You will still need to provide a letter of support and permission to conduct your project at that site.**

Complete the protocol template with your study information: You will use the template: CWRU Protocol Exemption (HRP-503EXEMPTC) *Have it ready with all of your other documents, including the letter of support from the other institution's IRB, to facilitate a smooth application.*

The Process to begin submitting for CWRU approval through SpartaIRB (all tracks):

1. Use your CWRU username and password to log into SpartaIRB.case.edu – Use the CWRU option
2. Click on "Create New Study" This creates a smart form for attaching documents and answering basic questions.
3. Complete the *STUDY* form: (**pay attention to the specific differences in the examples for each track that are provided in the sample templates**)
    a. **Basic Information** Page
        i. Your faculty advisor/chair is the principal investigator (PI)
        ii. "Nursing FPB" is primary department.
        iii. #7 Choose CWRU IRB to oversee the study.
        iv. #8 For tracks A or B, choose "yes", there will be an External IRB. For tracks C or D, choose "no" external IRB.

v. #9 Choose "single site" as kind of study. There should be no multi-site student studies.
vi. #10 Attach your completed protocol on the CWRU Exempt Human Research template, HRP-503EXEMPTC. **DO NOT attach anything else at question #10 other than your protocol.** There are separate sections for other documents.

b. **External IRB** page (Tracks A or B)
   i. Select EXEMPT External IRB
   ii. Upload IRB determination letter from External IRB
c. **Funding Sources page**: make sure to choose a funding source **even if you have no funding**. There is an option for "internal/departmental/not external" that you must use if you have no formal funding. **If you DO have external funding**, contact your advisor, SpartaIRB https://spartairb.case.edu/ , or CWRU IRB cwru-irb@case.edu for assistance in completing this section properly.
d. **Study Scope** page: answer "no" to questions #1, 2, and 3
e. Tap **Finish**

4. Complete the **SITE** form – link is at the top of the main Study page next to "Local Site"
   a. Click the button on the left to "Edit Site"
   b. **Basic Information** page
      i. The faculty advisor/chair is the principal investigator (PI)
      ii. "Nursing FPB" is primary department.
   c. **Funding Sources** page – complete same as above
   d. **Study Team Members** page – list only those persons who will be involved in consent process and/or data collection. **For most students, this is only the PI and you**. List your advisor/chair of your committee as the Principle Investigator as you did on the basic information page. **List yourself as the co-investigator with your contact information.**
   e. **Research Locations** page – Add the location where you, the student, will be conducting the research. This is the institution where you will be conducting the research.
   f. **Local Site Documents** page
      CWRU IRB still needs to review materials that were approved by the external IRB, such as consent, recruitment, survey documents and others. Please add every document and material that you submitted to the external IRB here (Tracks A and B). For C and D, list everything as required:
      i. **Consent Forms** section: **Only** upload consent form using the following template located in the SpartaIRB Library section: CWRU Consent Template Exempt (HRP-506Exempt Research)
      ii. **Recruitment materials** section: **Only** upload recruitment related materials
      iii. **Other attachments** section: Upload **all other documents** (E.g., surveys, interview questions, data collection sheets, letters of cooperation/support/permission, data use agreements, etc.

When the submission is completely filled out, it needs to be sent for Department Scientific Review. This may be done by the student or the PI, according to the preference of the PI. **Be sure to click on Finish and Submit**.

Pay attention to emails from SpartaIRB to revise or add/delete documents so that the Scientific Review can be completed in a timely manner. **Do not delete previous version(s) of protocols or consent documents. Instead, when uploading new versions of a document, click 'Update' next to the current document and that will 'stack' your new version with the old version. You can change the file name, version number, etc. if necessary.**

Once Department Scientific Approval is received**, only the PI - the faculty advisor/chair – can/must submit the study to the IRB.** Students do not have the ability to initially send the application to the IRB. Once it has been sent to the IRB, the submission state will change from "Pre-submission" to "Pre-review."

If you have questions while in "Pre-review", direct those questions to the assigned IRB coordinator (found on the main page of the protocol), or by using the "Comment" button on the submission.

Again, pay attention to your email and promptly answer any letters from CWRU IRB to facilitate a timely final approval.

You may begin your project when you receive final approval. **Remember that you MUST ADHERE to doing everything that was approved, and ONLY what was approved in this application!** Any deviation may result in an immediate pause of your project activities until a formal review or protocol amendment can be completed.

Remember to CLOSE the SITE record at CWRU IRB when your human subjects research activities conducted by CWRU researchers are completed. This can be done by adding a comment on the SITE in SpartaIRB requesting closure.

Keep the final approval email – you will need to submit it to the DNP office when your project is finished.

Option 2. Evidence-Based QI, Program Evaluation, and other Non-Research Projects

Preliminary considerations:

Evidence-Based QI and other non-research (applying existing evidence and local data to optimize immediate practice within a specific setting, rather than generating new, generalizable scientific knowledge) conducted at any location (hospital or organization) that has an Institutional Review Board (IRB) will require an approval letter from that institution's IRB *and* CWRU IRB. **This is inclusive of Cleveland Clinic, University Hospitals, and MetroHealth.** Some institutions will issue a letter of approval from a designated official instead of their IRB for distinct QI or other non-human-research projects. You will submit your project for approval through SpartaIRB **after it has already been approved** by that external IRB**.** Whatever permission/approval letter is provided by the project institution must be obtained and attached to the SpartaIRB application. CWRU IRB will still be noted as the IRB of record.

You will use the template: CWRU Protocol Not Human Subjects Research (HRP-503NHRC) *Have it ready with all of your other documents, including the letter of permission/approval from the other institution's IRB or designated official (if required) to facilitate a smooth application.*

You must **ALSO obtain a letter of permission from the unit or department** where you will be conducting your project. That will need to be uploaded.

Remember that NO Consent form is needed for this type of project.

The Process to begin submitting for CWRU approval through SpartaIRB:

1. Use your CWRU username and password to log into SpartaIRB.case.edu – Use the CWRU option
2. Click on "Create New Study" This creates a smart form for attaching documents and answering basic questions.
3. Complete the *STUDY* form:

    a. Basic Information Page
        i. Your faculty advisor/chair is the Principal Investigator (PI)
        ii. "No" to financial interest
        iii. "Nursing FPB" is primary department.
        iv. For "Which IRB oversees the study?", choose "CWRU"
        v. For "What kind of study?" – always choose "single site study"
        vi. For "Attach protocol", attach your completed HRP-503NHRC Protocol Template. DO NOT attach your written DNP project proposal. DO NOT attach anything else to this section!

    b. Next pages
        i. **Funding Sources**: make sure to choose a funding source **even if you have no funding**. There is an option for "internal/departmental/not external" that you must use if you have no formal funding. **If you DO have external funding**,

contact your advisor, SpartaIRB https://spartairb.case.edu/ , or CWRU IRB cwru-irb@case.edu for assistance in completing this section properly.

ii. **Research team**: list only those persons who will be involved in the project process and/or data collection. **For most students, this is only the PI (your advisor) and you**. List your advisor/chair of your committee as the Principle Investigator as you did on the basic information page. **List yourself with your contact information as the co-investigator.**
iii. **Study Scope:** answer "no" to questions #1, 2, and 3
iv. **Local Site Documents (Site Related Documents):** upload recruitment related materials, scripts that you will use in recruitment or presentations, word document versions of any teaching materials, pamphlets, or other written material that you may use, and your approval and permission letters. Upload to the designated "Recruitment materials" and "Other attachments." **You must attach all of these documents EVEN IF you've already supplied them to the project institution and received permission/approval for your project.**

When the submission is completely filled out, it needs to be sent for Department Scientific Review. This may be done by the student or the PI, according to the preference of the PI. **Be sure to click on Finish and Submit**.

Pay attention to emails from SpartaIRB to revise or add/delete documents so that the Scientific Review can be completed in a timely manner. **Do not delete previous version(s) of protocols or consent documents. Instead, when uploading new versions of a document, click 'Update' next to the current document and that will 'stack' your new version with the old version. You can change the file name, version number, etc. if necessary.**

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