NURSE ANESTHESIA INVESTIGATORS MANUAL

IRB Requirements for AANA Foundation-Supported Projects

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DRAFT VERSION 2

Contents

1 Introduction

The AANA Foundation supports scholarly activities across research, evidence-based practice, quality improvement, and education. As part of the Foundation's grant application and award process, investigators must provide documentation confirming whether proposed activities have been determined to constitute Human Subjects Research (HSR) and reviewed by an Institutional Review Board (IRB) in accordance with federal regulations for the protection of human participants, or have been determined to be Non-Human Subjects Research (NHSR).

Not all projects involving patients, students, clinical data, or educational activities meet the regulatory definition of human subjects research. Determinations depend on project intent, design, and whether the activity is conducted to generate generalizable knowledge. Misclassification can create compliance risk, delay funding, and impede publication.

The purpose of this manual is to provide structured, practical guidance to assist AANA Foundation applicants and awardees in evaluating whether their proposed activities require IRB review, institutional determination, or alternative documentation. The guidance may also be useful for investigators preparing submissions for AANA Foundation–related scholarly dissemination opportunities, including State of the Science poster sessions at annual conferences. This document outlines relevant regulatory principles, clarifies key definitions, presents decision-support tools, and describes documentation requirements consistent with AANA Foundation Grantmaking Policy.

This manual is instructional and advisory in nature. It is intended specifically to support activities associated with AANA Foundation funding and related scholarly dissemination projects. It supports consistent and compliant project classification but does not replace or supersede institutional IRB authority, federal regulations, nurse anesthesia program policies, or local organizational policies. Final determinations regarding whether proposed activities require IRB review or institutional determination remain the responsibility of the investigator and the appropriate institutional review authority.

2 Determining Whether IRB Review Is Required

2.1 Federal Regulations

Federal regulations require that research activities involving people or their identifiable data be reviewed by an Institutional Review Board (IRB) to ensure ethical conduct and to protect the rights and welfare of human subjects. However, not all projects involving human participants meet the regulatory definition of *human subjects research* and require IRB review. Two key principles must be considered: (1) Is the activity *research*? and (2) Are *human subjects* involved?

Under 45 CFR 46 (the Common Rule), an activity is considered *research* when it is:

> "A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

Whether a project requires IRB review also depends on the involvement of human subjects. The Common Rule defines a *human subject* as:

> "A living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Many nurse anesthesia projects—including Quality Improvement (QI), Evidence-Based Practice (EBP), and Education initiatives—are conducted to improve local clinical care or educational outcomes rather than to produce generalizable knowledge. When these activities are limited to internal improvement in quality of patient care, collect data for clinical, practical, educational, or administrative uses, and do not involve experimental interventions, they do not qualify as research. Therefore, the HHS regulations for the protection of human subjects do not apply to such activities, and there is no requirement under these regulations for such activities to undergo review by an IRB. However, there is still a need for a determination made by an IRB or other institutional representative that such activities do not qualify as research.

2.2 Institutional Processes

Some institutions require a formal IRB submission and determination for *Not Human Subjects Research* and QI/program evaluation projects. Other IRBs delegate this determination to others in the institution (e.g., Program Directors) to assess whether IRB review is needed.

2.3 Dissemination Requirements

Scientific journals often require a formal determination by an IRB of whether the findings being submitted for publication resulted from a research activity involving human subjects or

not. Formal determinations are often required for Quality Improvement or Evidence-Based Practice projects. While intention to publish does not by itself make an activity research and trigger full IRB review and approval, official determinations from the IRB regarding non-human subjects research status for evidence-based practice and quality improvement projects are often required for dissemination in scientific journals. Non-research efforts are often shared so others can learn from them (U.S. Department of Health and Human Services, Office for Human Research Protections, 2023). Investigators should seek determinations from the IRB prior to initiating any activities, understanding that lack of official determination could result in inability to disseminate. For example, the *AANA Journal* has the following policy:

> "The AANA Journal will not publish studies that have not been reviewed by your institution's IRB, even if they are deemed QI projects. Please share this information with your IRB, so they can assist you with the appropriate review decision tree: exempt, expedited, or full review. Appropriate IRB documents will need to be submitted as part of your submission to the AANA Journal."

Other outlets such as the *American Journal of Nursing*, the *International Journal of Nursing Studies*, *Medical Care*, and *JAMA* use a similar approach and have requirements for documentation of IRB review or determination for projects submitted for publication.

2.4 Guidance and Decision Tools

When determining whether IRB review is required for nursing projects such as evidence-based practice and quality improvement initiatives, AANA Foundation applicants may rely on publicly available guidance on human subjects research, such as the NIH Human Subjects Research Decision Tool (National Institutes of Health, 2024). While this tool is useful for applying the Common Rule definition and identifying levels of human subjects research review, it does not fully account for project intent or established EBP and QI frameworks.

Applicants may also seek out Artificial Intelligence (AI) tools for guidance (e.g., Open Evidence AI); however, note that such tools may incorrectly classify project activities and incur risk for proceeding with project activities without appropriate review and approval.

AANA Foundation has developed guidance and an interactive IRB Screening Tool to support investigators in applying human subjects regulations. These resources are intended to support consistent, compliant determinations for AANA Foundation grant and poster applicants while facilitating successful dissemination of scholarly work in scientific journals and presentations at the AANA State of the Science poster session at annual conferences.

Table 1 illustrates how selected activities conducted by nurse anesthesiology investigators may be determined to constitute human subjects research or not based on project intent.

Table 1: Selected Activities and Typical DNP Classifications

Activity	**Typical DNP Classification**
Evidence synthesis + practice change	Not Human Subjects Research – Evidence-Based Practice
Local Quality Improvement with standard care	Not Human Subjects Research – Quality Improvement
Retrospective chart review using de-identified data for local evaluation	Not Human Subjects Research
Retrospective chart review using identifiable data to answer a research question	Human Subjects Research
QI when participants lack direct benefit or may face added risk to generate generalizable results	Human Subjects Research
Program evaluation for internal decision-making	Not Human Subjects Research
Evidence-Based Practice with randomization beyond usual care	Likely Human Subjects Research
Evidence-Based Practice while testing a novel intervention	Human Subjects Research
Education to support practice change or implementation	Not Human Subjects Research
Education to test the effectiveness of an educational intervention	Human Subjects Research
Publishing results of Evidence-Based Practice, Quality Improvement, program evaluation, or practice-change education	Does not automatically = Human Subjects Research

Additionally, an interactive decision matrix has been developed to guide users to determine the goal of their project activities and whether such activities constitute research (human subjects or not), Quality Improvement, Evidence-Based Practice, or Education. This matrix helps users arrive at the determinations described in Table 2.

Table 2: Determinations and Next Steps

Determination	**Next Steps**
Human Subjects Research	Requires IRB review and approval
Non-Human Subjects Research	IRB review is not required; institutional review requirements may apply
Quality Improvement	Typically does not require IRB review for routine QI/QA; institutional confirmation advised for non-routine QI/QA

Determination	Next Steps
Evidence-Based Practice	Not research; determination recommended
Educational Activities	Educational initiatives for training or practice change typically do not require IRB review; research evaluating educational strategies for generalizable knowledge requires IRB review

2.5 Other Related Considerations

Multi-site studies. There may be occasions where an institution/investigator is funded as part of a multi-site study. It is AANA Foundation policy that if the prime awardee of an AANA Foundation grant involves human subjects at any site, the prime awardee is engaged in human subjects research. In such cases, it is expected that the prime awardee is responsible for the single IRB review, with other collaborating institutions relying on the prime awardee through a reliance agreement. In such circumstances, investigators are encouraged to have *a priori* discussions with participating sites and AANA Foundation to assist in navigating human subjects requirements.

FDA regulation. Investigators are encouraged to also consider whether their project may be subject to FDA regulations. This consideration is important, regardless of whether the project is determined to be human subjects research or not. If the project involves an FDA-regulated drug, device, biologic, or diagnostic test, FDA regulations may apply, and thus IRB review may be required. If the data or specimens are intended to support an Investigational New Drug, Investigational Device Exemption, or FDA marketing application, or to evaluate safety or effectiveness, FDA regulations may apply, and thus IRB review may be required. In such circumstances, investigators are encouraged to consult the IRB.

HIPAA and Privacy Regulations. Investigators should also consider whether their project involves access to or use of protected health information (PHI). HIPAA and other applicable privacy regulations (e.g., FERPA for student education records) may apply depending on the type and source of data used, regardless of whether a project is classified as human subjects research. Projects involving PHI may require authorization, waiver, or other institutional approvals. Investigators are encouraged to consult their IRB or institutional privacy office when PHI is involved.

3 Case Studies and Common Determinations

Example 1: Capstone Project Using Patient Data

Scenario: A DNAP student evaluates compliance with post-operative nausea and vomiting (PONV) protocols by reviewing anesthesia records from the past six months. De-identified data (no access to identifiers or code link) is shared with the student and results will be published in a peer-reviewed journal.

Decision Point	Analysis
Systematic Investigation	Yes
Generalizable Knowledge	Yes
Human Subjects	No (de-identified data)
FDA regulated	No
IRB Review required	No

Common Misconception: "Any project using patient data requires IRB approval."
Teaching Point: Retrospective chart review does not automatically require IRB review when data are fully de-identified. Project intent (e.g., local care evaluation versus research) and whether investigators or any member of the research team had access to, or could access, identifiable data (e.g., through employment) determine whether the activity requires IRB review.
Likely Determination: Non-Human Subjects Research; IRB review is not required.

Example 2: EBP Project With Pre- and Post-Implementation Surveys

Scenario: A group of CRNAs implements an evidence-based airway checklist and surveys anesthesia staff about perceived usability before and after implementation. The goal is to improve consistency and quality of documentation.

Decision Point	Analysis
Systematic Investigation	Yes
Generalizable Knowledge	Unclear; not research if local improvement only; research if changing standard clinical practice
Human Subjects	Yes (surveys)
FDA regulated	No
IRB Review required	Yes if non-routine QI; no if local EBP

Common Misconception: "Surveys always equal human subjects research."
Teaching Point: EBP-driven Quality Improvement projects do not automatically equal research; project intent matters.

Likely Determination: Evidence-Based Practice; IRB (often Exempt under Category 2) or administrative determination recommended.

Example 3: Non-routine Quality Improvement Project

Scenario: CRNAs pilot two preoperative patient reminder approaches—nurse phone calls versus EHR-generated reminders—to reduce day-of-surgery cancellations, with results shared externally.

Decision Point	Analysis
Systematic Investigation	Yes
Generalizable Knowledge	Potentially
Human Subjects	Yes
FDA regulated	No
IRB Review required	Yes

Common Misconception: "Calling a project QI means it isn't research."
Teaching Point: Random assignment reflects a research design, and plans to publish can indicate intent to generate generalizable knowledge.
Likely Determination: Human Subjects Research (often reviewed by IRB under Expedited Categories 5 and 7).

Example 4: Evidence-Based Improvement of Care

Scenario: Based on evidence that patient misunderstanding leads to unnecessary prolonged fasting, CRNAs standardize how fasting instructions are explained during pre-op assessment for training consistency purposes.

Decision Point	Analysis
Systematic Investigation	No
Generalizable Knowledge	No
Human Subjects	Yes (nurses)
FDA regulated	No
IRB Review required	No

Common Misconception: "Standardizing education automatically makes this a quality improvement project or research."
Teaching Point: EBP focuses on improving care by applying known evidence to everyday clinical practice without systematically evaluating outcomes.
Likely Determination: Evidence-Based Practice, not research.

Example 5: Educational Research in a Nurse Anesthesia Program

Scenario: Faculty evaluate a new simulation curriculum by comparing it to the standard educational practice. Students are randomized to standard curriculum vs. experimental.

Decision Point	Analysis
Systematic Investigation	Yes
Generalizable Knowledge	Possibly
Human Subjects	Yes (students)
FDA regulated	No
IRB Review required	Yes

Common Misconception: "Educational projects in educational settings fall under normal educational practice, not research."
Teaching Point: Students are human subjects, and educational experimental interventions require IRB review.
Likely Determination: Human Subjects Research (often reviewed by IRB under Expedited Category 7).

Example 6: DNP Faculty Education for Practice Change

Scenario: DNP faculty provide an educational session to nurse anesthesia students and clinical preceptors on updated ASA fasting guidelines to promote consistent patient education in clinical practice. No data are collected beyond routine educational feedback, and there is no plan to systematically evaluate outcomes.

Decision Point	Analysis
Systematic Investigation	No
Generalizable Knowledge	No
Human Subjects	Yes (students and preceptors)
FDA regulated	No
IRB Review required	No

Common Misconception: "Any formal teaching activity conducted by faculty is research."
Teaching Point: Routine educational activities to implement established guidelines or improve clinical consistency are not research when they are not designed to systematically evaluate outcomes and generate generalizable knowledge.
Likely Determination: Education for practice change, not research.

Example 7: Device Study in an Educational Context

Scenario: Nursing anesthesia faculty participate as co-investigators in a study evaluating a new non-invasive blood pressure and oxygenation monitoring device intended for use during general anesthesia. This is pilot testing on DNP students with intent to market the device.

Decision Point	Analysis
Systematic Investigation	Yes
Generalizable Knowledge	Possibly
Human Subjects	Yes
FDA regulated	Yes
IRB Review required	Yes

Common Misconception: "Because the device is non-invasive and is not used on patients yet, IRB review is not required."
Teaching Point: The educational or training context does not exempt studies with medical devices from IRB oversight. Faculty investigators must obtain appropriate IRB review and approval prior to initiating the research.
Likely Determination: Human Subjects Research; likely full board review due to the new medical device requiring risk determination per FDA regulations.

Example 8: Multi-Site Collaboration

Scenario: The PI's institution is the prime awardee. The PI will only analyze coded data provided by participating clinical sites who will survey patients.

Decision Point	Analysis
Systematic Investigation	Yes
Generalizable Knowledge	Yes
Human Subjects	Yes, participating sites
FDA regulated	No
IRB Review required	Yes — single IRB review for non-exempt research required per AANA Foundation Grantmaking Policy

Common Misconception: "Because the prime awardee has no participant interaction or identifiable data, IRB review is not required."
Teaching Point: A lead PI responsible for overall study conduct may have access to the code key for coded data; when identities can be readily ascertained, the activity constitutes human subjects research. Multi-site research commonly raises issues related to institutional engagement and IRB oversight. For non-exempt studies, the prime awardee may rely on the IRB of an actively engaged site.

Likely Determination: Engaged in Human Subjects Research (often reviewed by IRB under Expedited Categories 5 and 7).

Example 9: Multi-Site Randomized Clinical Drug Study

Scenario: A researcher serves as the lead investigator on a multi-site clinical study evaluating whether a new FDA-approved medication reduces postoperative nausea and vomiting in adult surgical patients. Participating hospitals randomize patients to receive either the new medication or standard care and collect outcome data.

Decision Point	Analysis
Systematic Investigation	Yes
Generalizable Knowledge	Yes
Human Subjects	Yes, adult surgical patients
FDA regulated	Yes
IRB Review required	Yes — single IRB review for non-exempt research required per AANA Foundation Grantmaking Policy

Common Misconception: "Because the medication is already FDA-approved, the study is minimal risk and may not require full IRB review."
Teaching Point: Use of an FDA-approved drug does not automatically make a study minimal risk. When a drug is studied to evaluate safety or effectiveness, especially with randomization or altered use, the study may require convened IRB committee review.
Likely Determination: Human Subjects Research; full board review.

4 Procedures

4.1 Purpose

This manual establishes consistent procedures for determining whether scholarly projects submitted for funding to AANA Foundation by Resident Registered Nurse Anesthesiologists (RRNAs), Certified Registered Nurse Anesthetists (CRNAs), faculty, and other research investigators require Institutional Review Board (IRB) review, and to ensure compliance with applicable federal regulations and institutional requirements.

These procedures offer guidance for regulatory classification and documentation and does not confer IRB approval or exemption authority. They do not supersede institutional IRB authority or policies.

Policies related to human subjects compliance for projects supported by the Foundation may be found in the AANA Grantmaking Policy and in grant Notices of Award.

4.2 Scope

These procedures apply to any investigator applying for AANA Foundation funding and proposing to conduct research (human subjects or not), QI, EBP, or Education projects. This includes retrospective and prospective projects involving data, specimens, educational interventions, or clinical practices.

4.3 Regulatory Framework

This section is informed by:

- 45 CFR 46 (Common Rule) and 21 CFR §§50.3 and 56.102 (FDA regulations apply when research evaluates FDA-regulated drugs, devices, biologics, or diagnostics, including studies intended to support regulatory submissions)
- Applicable guidance from the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the National Institutes of Health (NIH)
- Institutional Review Board (IRB) policies and procedures of academic and clinical IRBs
- Journal requirements

4.4 Project Classification

Scholarly projects are categorized by activity type, and some may require an IRB determination.

Human Subjects Research. IRBs review activities that meet the regulatory definition of human subjects research. Depending on the type of these human research activities, projects may undergo one of the following types of IRB review:

- *Exempt* 45 CFR 46 describes categories of minimal risk research that may be determined to be exempt (e.g., educational tests, benign behavioral interventions, some types of secondary research). An exemption means that specific regulatory requirements for non-exempt research do not apply; it does not mean the study is excused from IRB determination or oversight
- *Expedited* Expedited studies must fall within one of the federal expedited review categories and remain subject to the full range of regulatory protections. Expedited studies may or may not require continuing (annual) review. Classified research and research involving prisoners are not eligible for expedited review
- *Full Board* Human subjects research involving greater than minimal risk, sensitive topics, or vulnerable populations that requires review by the convened IRB.

Non-Human Subjects Research. Research activities that do not involve human subjects as defined by federal regulations and therefore do not require IRB review. Non-human subjects research is NOT the same as "exempt."

Activities That Typically Are Not Research. The following activities typically do not require IRB review but may require IRB determination or institutional documentation depending on project design and intent, not the label applied:

- Quality Improvement (QI)
- Evidence-Based Practice (EBP)
- Educational or training initiatives

4.5 IRB Determination Process

- All projects must be reviewed at the program level to determine whether IRB submission or institutional determination is required.
- When required by institutional policy or journal expectations, projects must be submitted to the IRB or designated institutional authority for a formal determination.
- Investigators may use approved decision-support tools (e.g., decision matrix, web-based decision guide) to assist with initial classification.
- Investigators may offer a self-attestation of human subjects determination in exceptionally rare circumstances when alternative institutional determination processes are not available.
- IRB determination is not required at the time of grant application. However, investigators are strongly encouraged to consult with their home IRBs, use the AANAF tool to assess whether IRB review may be required, and review AANAF Human Subjects Research guidance documents for planning purposes. Documentation of the appropriate IRB determination or review must be provided before awarded grant funds can be released

4.6 Documentation Requirements

- Documentation of IRB determinations (e.g., IRB approval, exemption, or Not Human Subjects Research determination) must be retained in accordance with program and institutional requirements.
- Investigators should first seek (1) IRB determinations. If the IRB delegates this role to other institutional representatives, (2) documentation from another institutional official (e.g., a Program Director in an academic institution or a hospital administrator in a health system) is preferred. For institutions that do not issue formal IRB or institutional determinations for QI, EBP, or Educational activities, a completed AANA Foundation (AANAF) Attestation Form may be submitted. The AANAF Attestation Form will be accepted only when all other documentation options have been exhausted.
- Investigators are responsible for ensuring that documentation accurately reflects the project's regulatory classification at the time the work is conducted.
- The AANA Foundation Grantmaking Policy outlines requirements for documentation to receive funding. In brief, applicants are encouraged to submit determination documentation at the time of application, if activities are expected to be non-human subjects research. Awardees are required to submit either a non-human subjects determination or, for human subjects research, documentation of IRB exemption or approval prior to initiating activities and funds are released.

4.7 Roles and Responsibilities

- **Investigator Initiates** (resident/student, faculty, other investigator)
  - IRB determination early in project planning
  - Comply with institutional IRB requirements
- **Faculty Advisors**
  - Provide oversight and guidance on project classification
  - Ensure consistency with program and institutional policies
- **Program Directors or Other Institutional Administrators (e.g., in health systems)**
  - Support standardized determination processes
  - Maintain program-level documentation practices
- **Institutional Review Boards / Designated Authorities**
  - Issue formal determinations when required
  - Review projects involving human subjects or FDA-regulated research

4.8 Multi-Site and Funded Projects

For multi-site projects, institutional engagement and IRB reliance arrangements must be confirmed. Prime awardee responsibilities must be addressed in accordance with AANA Foundation Grantmaking Policy and institutional requirements.

4.9 Privacy and Data Protection Considerations

Projects may be subject to HIPAA and other applicable privacy regulations depending on the type and source of data used. These requirements apply regardless of whether a project is classified as human subjects research.

4.10 Glossary

AANA Foundation (AANAF) Attestation A signed statement by an investigator affirming that a project does not meet the definition of human subjects research and that institutional IRB or program-level documentation is unavailable. This mechanism is used by the AANA Foundation only when other forms of institutional documentation cannot be obtained for QI, QA, or EBP activities.

Aggregate Data Data combined from multiple individuals into summaries (e.g., averages, totals, or percentages) such that individual identities and unique identifiers are removed or masked and cannot reasonably be linked to a specific person.

Anonymous Data Data are collected in a way that no identifying information is ever recorded, and the investigator cannot determine the identity of the participants.

Coded Data Data where identifiers have been replaced with a code, but a link (key) exists that can reconnect the data to the individual.

De-identified Data Data that were originally collected with identifiers but from which those identifiers have been removed so that the identity of individuals cannot reasonably be determined or linked back to a specific person.

Educational Intervention for Practice Change An educational project designed to change clinical practice is an intervention that uses learning strategies to modify clinician knowledge, skills, or behaviors with the goal of improving patient care and clinical outcomes.

Educational Research A systematic investigation in which an educational method, strategy, curriculum, or intervention is the focus of evaluation to contribute to generalizable knowledge. When it involves interaction or intervention with learners or the collection of identifiable data, it meets the definition of Human Subjects Research.

Evidence-Based Practice (EBP) Applying or translating the best available evidence into practice using clinical expertise and considering patient preferences to improve care, without systematic investigation or hypothesis testing.

FDA-Regulated Research Research involving FDA-regulated drugs, devices, biologics, or diagnostics that is conducted to evaluate safety or effectiveness or to support regulatory submissions, and which may be subject to FDA regulations regardless of whether data or specimens are identifiable.

Generalizable Knowledge Knowledge that is intended to extend beyond a specific program, population, or institution and to contribute to broader scientific or professional understanding. Intent to publish or present findings alone does not determine generalizability.

Human Subjects Research (HSR) A systematic investigation designed to contribute to generalizable knowledge that involves interaction or intervention with living individuals or the use of identifiable private information or identifiable biospecimens, as defined by 45 CFR 46.

Institutional Review Board (IRB) A committee formally designated to review, approve, and oversee human subjects research in accordance with federal regulations.

Non-Human Subjects Research (NHSR) A systematic investigation that does not involve human subjects as defined by federal regulations, including research conducted using de-identified data or biospecimens where investigators cannot readily ascertain individual identities.

Personally Identifiable Information (PII) Information that can be used to identify a specific individual, either directly (e.g., name, social security number, student ID) or indirectly (e.g., rare medical condition or unique professional position). This includes data that, alone or when combined with other available information, can reasonably be used to identify a particular person.

Protected Health Information (PHI) Individually identifiable health information related to a person's physical or mental health, health care services, or payment for health care that is created, received, maintained, or transmitted by a covered entity, including when disclosed to an investigator.

Quality Improvement / Quality Assurance (QI/QA) Activities designed to improve local care, education, processes, or compliance through the application of standard-of-care practices and operational monitoring, without the primary intent to produce generalizable knowledge.

Systematic Investigation An activity that involves a prospective or retrospective plan, protocol, or methodology for data collection and analysis to answer a research question or test a hypothesis.

4.11 Document Review and Updates

This section will be reviewed periodically and updated as needed to reflect changes in federal regulations, institutional practices, or AANA Foundation policies.

Appendix A: Not–Human Subjects Research (NHSR) Attestation Form

(To be used only when institutional or IRB documentation is unavailable)

Project Title

_____

Principal Investigator / Project Lead

Name: _____

Credentials / Role: _____

Email: _____

Institutional Affiliation

Institution / Organization: _____

Department / Unit: _____

Project Description (Brief)
Provide a concise description of the project purpose, activities, and methods.

1. Project Classification

(Check all that apply)

☐ Quality Improvement / Quality Assurance (e.g., process improvement, compliance monitoring, outcome tracking)

☐ Evidence-Based Practice (e.g., integrating established evidence, guidelines, or best practices into routine patient care)

☐ Program Evaluation (e.g., assessing the effectiveness, outcomes, or implementation of an existing program or service for local decision-making)

☐ Educational Activity for Practice Change (e.g., providing education or training to support implementation of clinical practice)

2. NHSR Determination Checklist

By checking the boxes below, the project lead attests that the project does not meet the regulatory definition of Human Subjects Research under 45 CFR 46.

2.1 Purpose and Intent

☐ The primary purpose is to improve local care, operations, or practice

☐ The project is not designed to produce generalizable knowledge

☐ Any external sharing of findings is secondary to local improvement and does not change the project's primary purpose

2.2 Participants and Risk

☐ No additional clinical risks beyond usual care are introduced

☐ Participants are not exposed to added burdens solely for project purposes

☐ No experimental or investigational interventions are used

2.3 Data Use

☐ Data are collected as part of routine operations or clinical care

☐ No data are collected solely for research purposes

☐ Data are analyzed to guide local practice or decision-making

2.4 Regulatory Status

☐ The project is not research as defined under 45 CFR 46

☐ The project is not FDA regulated under 21 CFR 56

3. Institutional IRB Review Requirements

☐ This project has been reviewed according to applicable institutional policies and documentation is attached

☐ The affiliated institution does not require IRB or ethics committee review for this type of QI or EBP activity

☐ Documentation of institutional policy is available upon request

4. Determination

☐ Not Human Subjects Research (NHSR)

☐ IRB review not required

Attestation and Signature

I attest that:

- This project is intended for local improvement and not research.
- The information provided is accurate to the best of my knowledge. If the project scope or intent changes, I will seek appropriate review.
- I understand that the AANA Foundation may request IRB or institutional review documentation if concerns arise regarding project classification.

Project Lead Signature: _____

Printed Name: _____

Date: _____

Optional Administrative Review

(To be completed by the institution)

Reviewer Name / Title: _____

Determination Confirmed: ☐ Yes ☐ No

Signature: _____

Date: _____

References

National Institutes of Health. (2024). Decision Tool: Am I Doing Human Subjects Research?

U.S. Department of Health and Human Services, Office for Human Research Protections. (2023). Quality Improvement Activities FAQs.