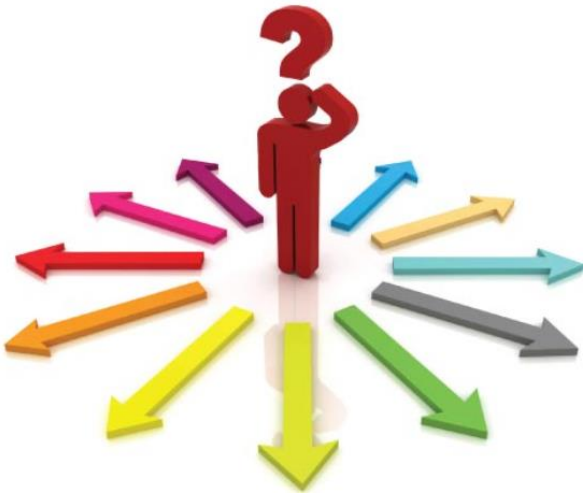
WELCOME

Culture of Excellence

KAISER PERMANENTE SOUTHERN CALIFORNIA/HAWAI'I

Webinar
Navigating the IRB Process for the Research vs. Non-Research Determination Form



Southern California & Hawai'i Nursing Research

Webinar: Navigating the IRB Process for the Research vs. Non-Research Determination Form

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Agenda

KAISER PERMANENTE SOUTHERN CALIFORNIA/HAWAI'I

Navigating the IRB Process for the Research vs. Non-Research Determination Form

Step-by-Step Process on How to Complete a Research vs. Non-Research Determination Form

Tuesday, September 9th, 2025
11:00pm-12:30pm (PST)

TIME	AGENDA
11:00- 11:05	**WELCOME** **Lina Kawar, PhD, R.N.R.M., RN, CNS**
11:05-11:15	Overview and Definitions of Research, EBP, and QI (IRB definition) **Veronica Timple, PhD, RN, CCRN-K**
11:15-11:25	IRB Role and Human subject Protection/ IRB Permission vs. Approval **Lina Kawar, PhD, R.N.R.M., RN, CNS**
11:25-11:35	Preliminary Steps/Resources Required Prior to Completing the Human Subject Form **Quincyann Tsai, MSN, RN**
11:35-11:45	Process for IRB permission, Project Lead Responsibilities and Next Steps **Emma Aquino-Maneja, PhD, DNP, RN, Med, CCRN**
11:45-11:55	How to Complete a Human Subject Determination Form, Parts and Examples **Mayu Yamamoto, DNP, RN**
11:55-12:05	Key Points, Tips, Pitfalls to Consider when Submitting the Form as Projects **Joria Rainbolt-Clemente, DNP, CNS, Gero-BC**
12:05-12:10	Common IRB Pitfalls **Lina Kawar, PhD, R.N.R.M., RN, CNS**
12:10-12:30	FAQ's & Answers/Closing Remarks **All/Lina Kawar, PhD, R.N.R.M., RN, CNS**

Objectives

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- Describe the differences between research studies, EBP and QI projects
- Discuss KPSC/HI IRB process for research, EBP, PI, and QI
- Explain the steps for completing a human subject determination form with examples
- Identify key points, tips, and pitfalls to consider when submitting the form as projects

Regional Nursing Research and EBP Team
Kaiser Permanente, Southern California and Hawaii

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Regional Director, SCAL/HI
Nursing Research/EBP Program
Cochair, National Nursing Research Council & Nurse Scientist

Veronica Timple
PhD, RN, CCRN-K
Regional Nurse Scientist

Quincyann Tsai
MSN, RN, PhD(c)
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Senior Analyst

Gina Alvarez
Research Project Manager II

Regional Nursing Research and EBP Partners/Presenter

Emma Aquino-Maneja
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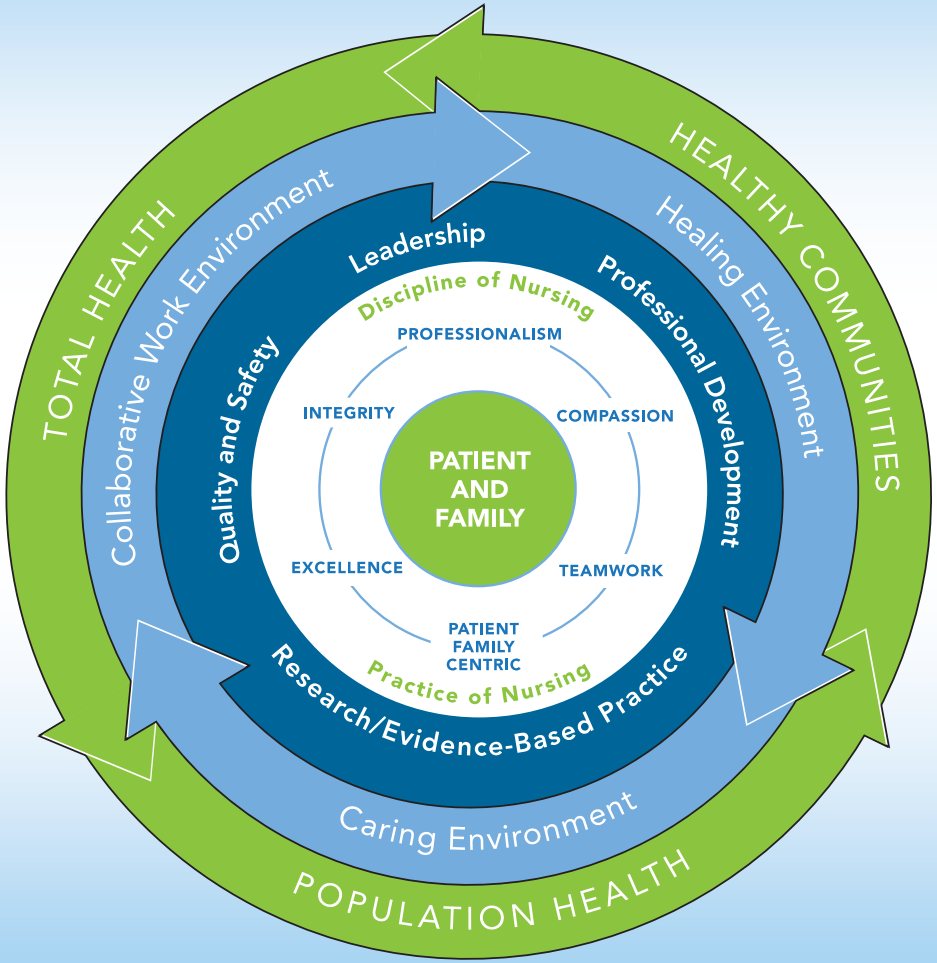
Regional Practice Specialist
Professional Nursing Practice Team

Joria Rainbolt-Clemente
DNP, CNS, GERO-BC
Clinical Nurse Specialist
Regional Nursing Research Liaison
OC-Irvine Medical Center

Mayu Yamamoto
DNP, RN
Senior Clinical Practice Nurse
Professional Development & Research
Ambulatory Clinical Services

Overview of Quality Improvement, Evidence Based Practice, and Nursing Research

Veronica S. Timple, PhD, RN, CCRN-K
Regional Nurse Scientist



Is my project a QI, EBP, or Research?

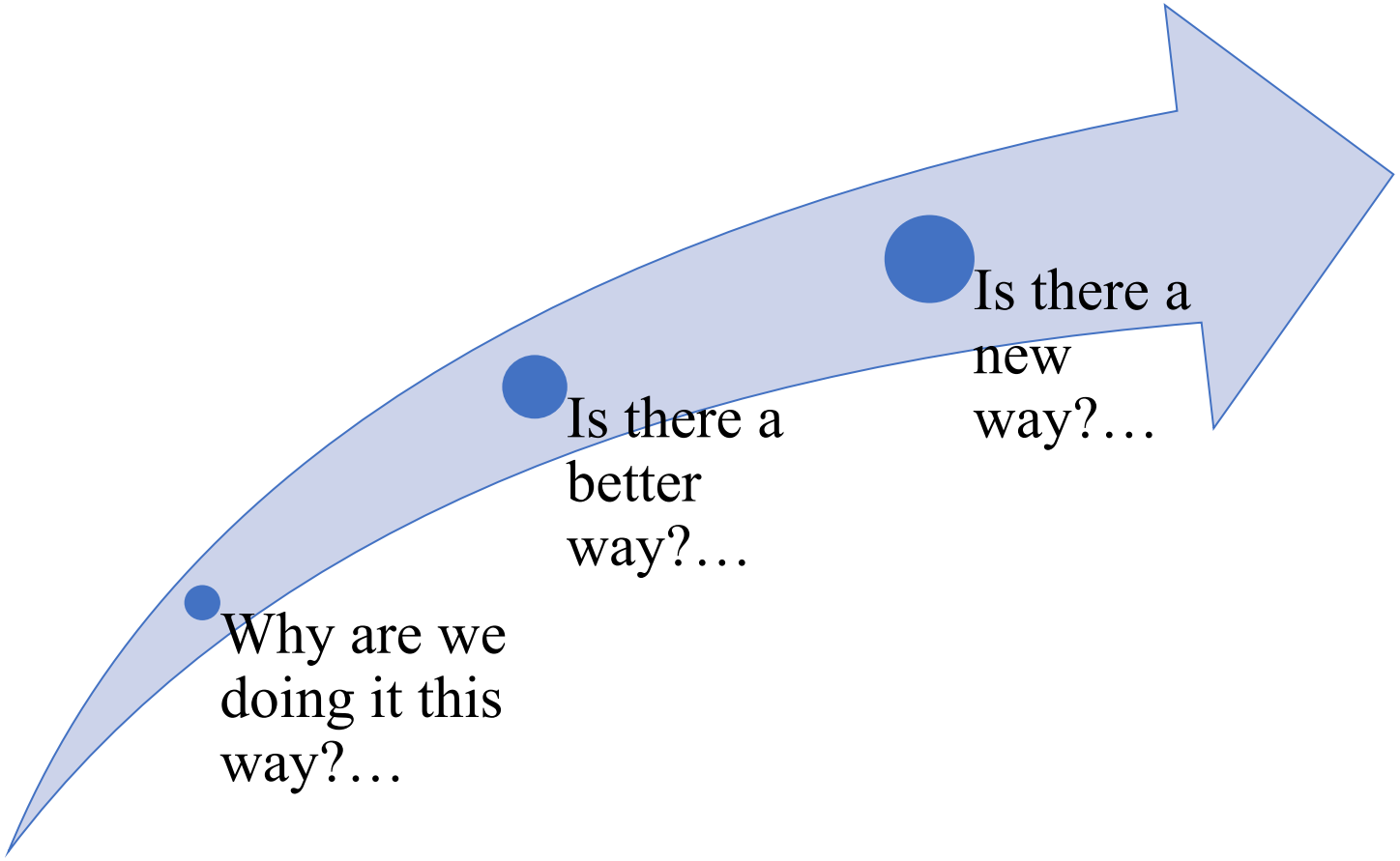
Which project is a QI, EBP, and Research?

A. Investigating the effects of a new wound care treatment on healing rates in diabetic patients.

B. Reducing patient wait times in the emergency department by streamlining triage processes.

C. Implementing hand hygiene protocols based on latest research to decrease hospital-acquired infections.

Questioning Attitude



Core Concepts: Definitions

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QI Quality Improvement

- Refers to systematic pattern of actions to enhance processes and outcomes

EBP Evidence-Based Practice

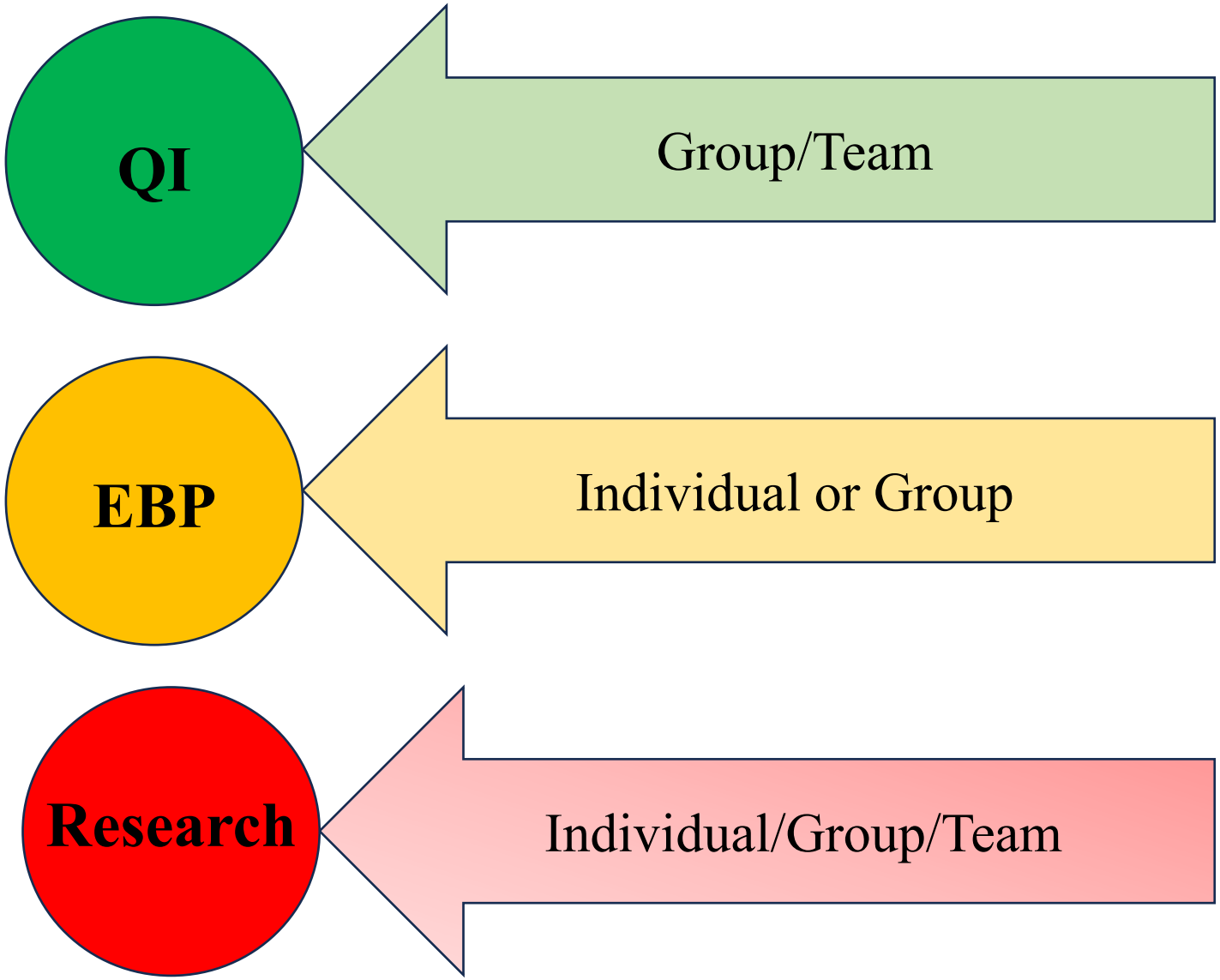
- Integrates the best research evidence with clinical expertise and patient preferences to guide care decisions

Research Nursing Research

- Is a systematic investigation to generate generalizable knowledge

Core Concepts: Purpose

Core Concepts: Structure



Core Concepts: Process

QI

- Process Improvement Methods: Driver diagram, PDSA, DMAIC

EBP

- EBP Methods: John Hopkins, IOWA, ARCC Model

Research

- Research Methods: Quantitative, Qualitative, Mixed Methods, or Triangulation

Core Concepts: Outcomes

QI	EBP	Research
• Improved procedures or processes	• Practice changes, new protocols, standards	• New knowledge that can be tested and applied to practice

Which project is a QI, EBP, and Research?

A. Investigating the effects of a new wound care treatment on healing rates in diabetic patients.

RESEARCH

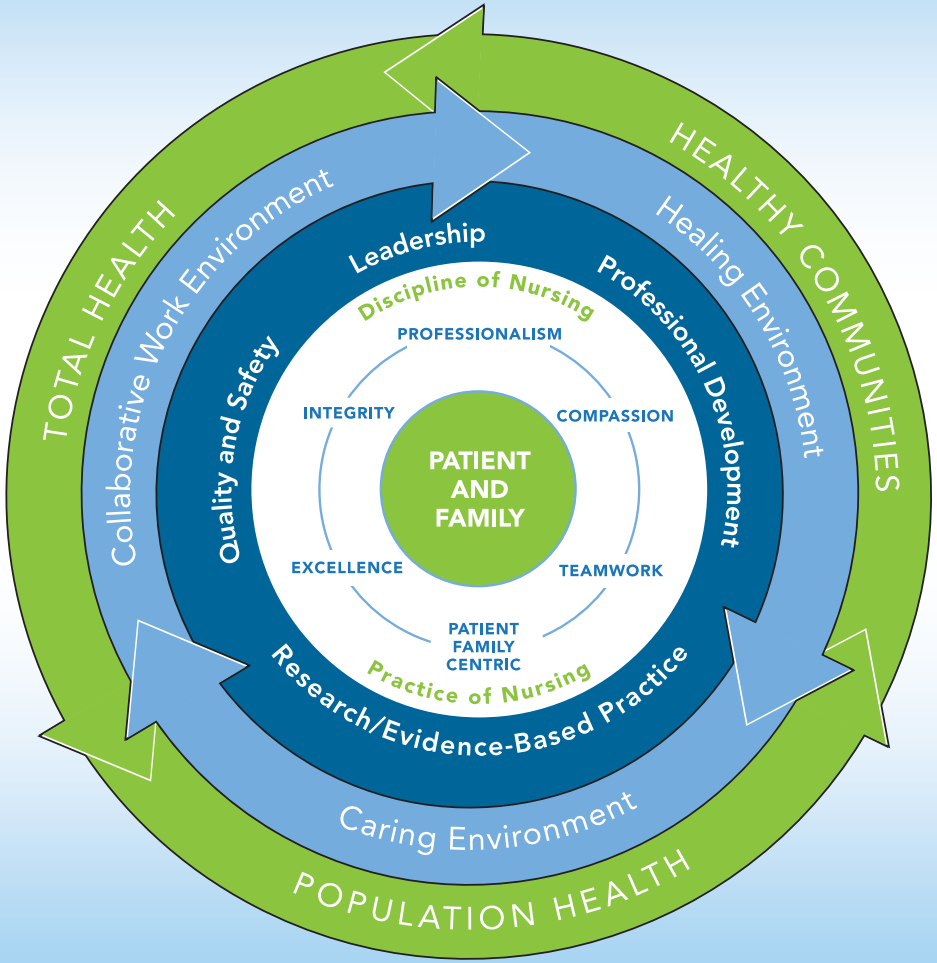
B. Reducing patient wait times in the emergency department by streamlining triage processes.

QI

C. Implementing hand hygiene protocols based on latest research to decrease hospital-acquired infections.

EBP

IRB Role and Human Subject Protection: IRB Permission versus Approval SCAL/HI Market



Lina Najib Kawar, PhD, RNRM, RN, CNS
Regional Director, SCAL/HI Nursing Research/EBP Program

IRB Permission versus Approval

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Permission is needed for all projects

- Evidence based practice (EBP)
- Quality Improvement (QI)
- Performance/Process Improvement (PI)
- Sharing data externally to KP

Approval is required for all research activities

- Original Research study
- Study Modification
- Study Replication
- Reopening a study
- Data only study

Who, Why, and When to Seek IRB Permission/Approval

All employees are required to submit

- Work related projects/research
- School related projects/research
- Collaboration with external colleagues
- Abstract submission or dissemination

Attain IRB permission/approval prior to implementation

Institutional Review Boards (IRBs)

Review research studies and ensure that ethical standards are met in relation to the protection of the rights of subjects before conducting the study

* **Dr. Lina Najib Kawar, Regional Nursing IRB Representative**

* Dr. Veronica Timple is the regional nursing CTOB representative
* Quincyann Tsai is the regional nursing QIC representative

- Nazi experiments
- Untreated syphilis in black men
- San Antonio contraceptive study
- Jewish chronic disease study
- Beecher (1966) *N Engl J Med*, 22 studies performed unethically

1974

Identified **three basic principles** essential to the ethical research conduct with humans

Respect for Persons

> To respect autonomy is to give weight to the autonomous person's considered opinions and choices while refraining from obstructing his or her actions...
>
> – Belmont Report

Beneficence

> Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term beneficence is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation.
>
> – Belmont Report

Maximize possible benefits and minimize possible harm

Justice

> Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.
>
> – Belmont Report

Human Subject

- A living individual about whom an investigator conducting research obtains:
  - Data through intervention or interaction with the individual
  - Identifiable private information
  - Private Health Information (PHI)
  - Including data already collected
  - Medical records

Protection of Human Rights

In research include,

- Freedom of choice
- Self Determination
- Confidentiality
- Anonymity
- Privacy
- Voluntary
- Fair Treatment
- Protection from
  - Discomfort or harm
  - Coercion

Role of IRB

- Assess for “fair” recruitment
- Evaluate inclusion and exclusion criteria
- Determine investigator-subject relationship
- Establish role of IRB in study
- Assess risk and benefit
- Assess consent forms and process

Review consent for

- Autonomy/Self determination/Freedom of choice
- Protection from Coercion
- Risk and benefit

Clarity and process

Additional protections

Voluntariness

Special Considerations

Research Approval Categories

All Plans and Materials must be reviewed and approved by the IRB

- **Exempt review**: Low risk, non-vulnerable, not sensitive, short duration (e.g., educational R) – chairperson/experienced
- **Expedited review**: Minimal risk (no substantive increase beyond risks of ordinary life), nonvulnerable, nonsensitive topic (e.g., chart review, questionnaires) - subcommittee
- **Full board review:** Required for research involving more than minimal risk to human subjects, ensuring ethical standards are met before proceeding (e.g., vulnerable populations)– All IRB members monthly meeting

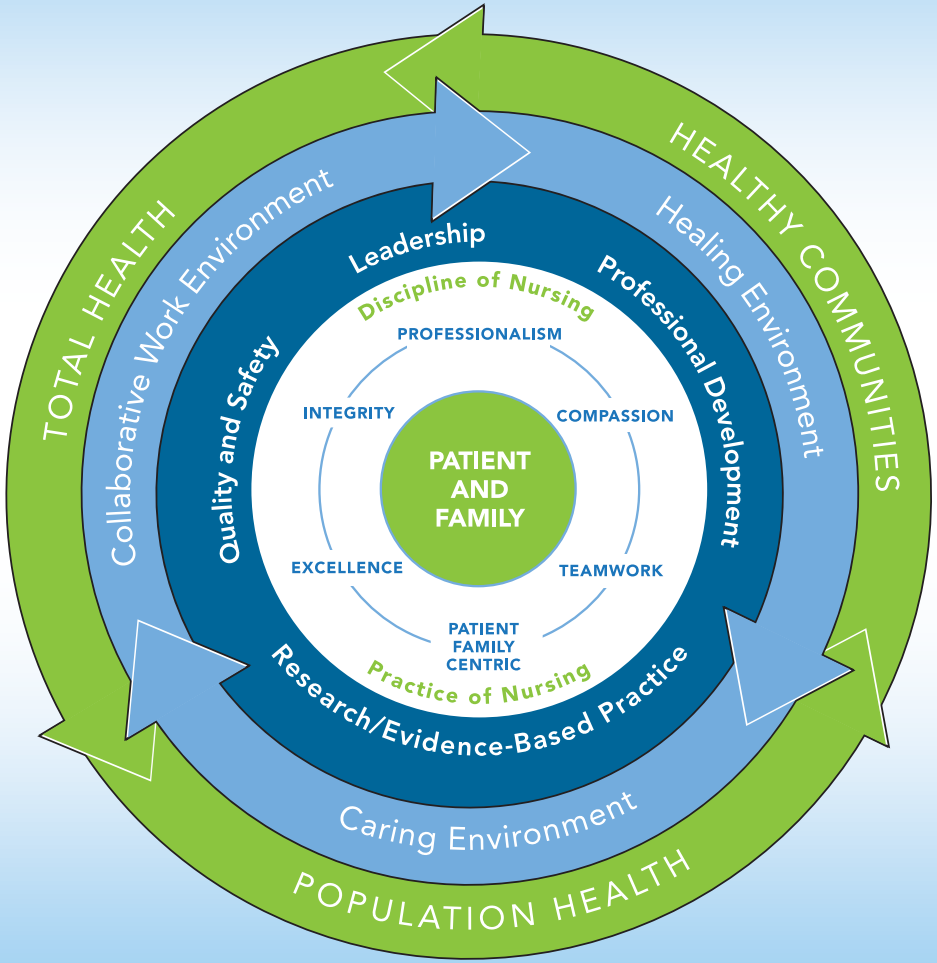
- **Seeking IRB oversight for research, EBP, QI, and/or PI projects**
- **Securing support and buy-in from key stakeholders**

All Employees Student or Non-student Due Diligence and Expectations

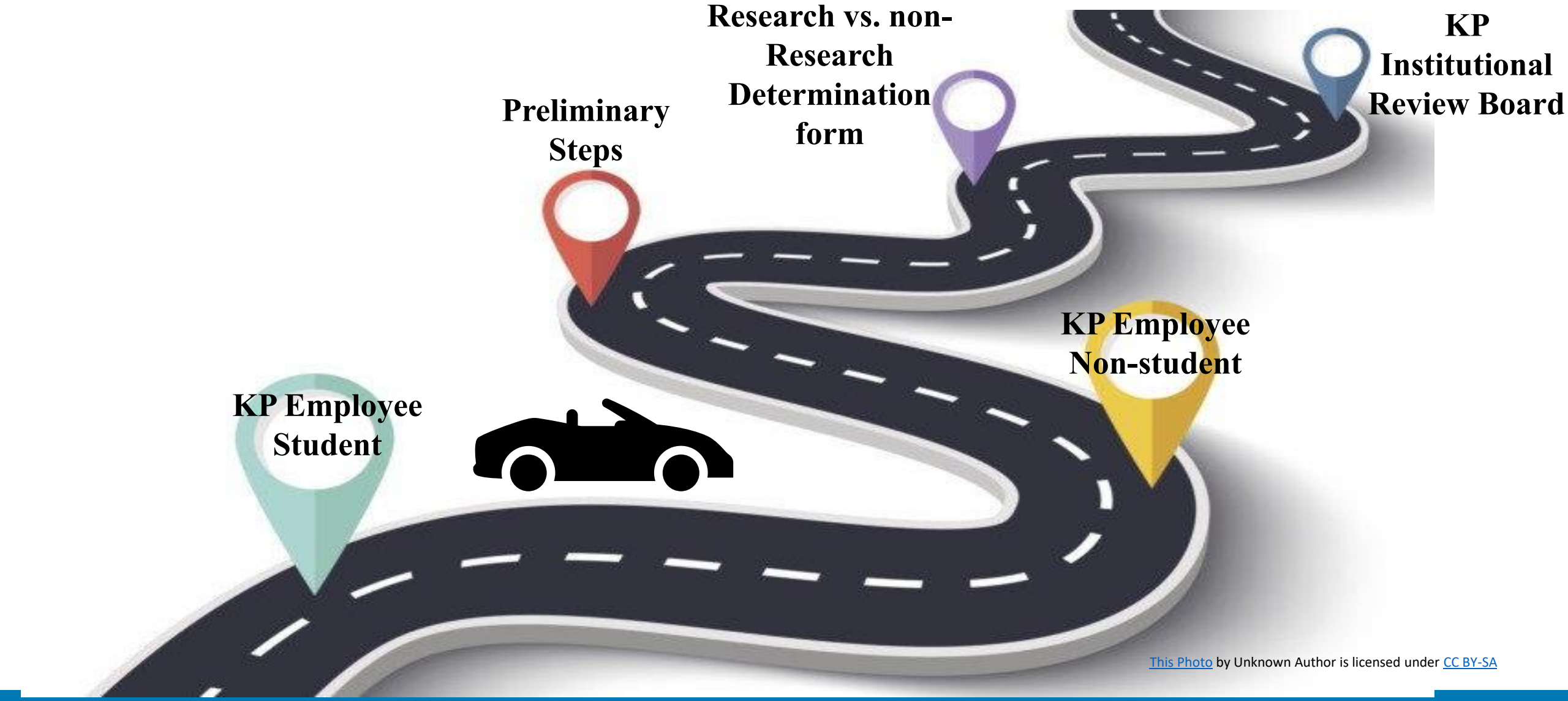
Preliminary Steps

Quincyann Tsai, MSN, RN

Regional Nurse Consultant Nursing Research and EBP



Preliminary Steps for KP Employees conducting Research and/or EBP/QI projects



The Regional KPSC/HI Nursing Research Perspective

KP employee to be successful and complete right processes

Nursing research and EBP/QI projects: high quality, with rigor to uphold standards, and useful to patient care, nursing profession and other disciplines

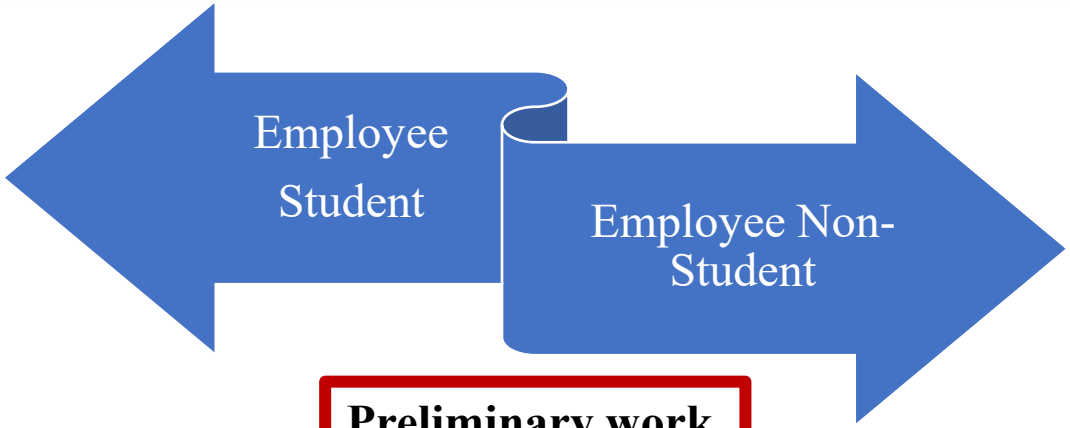
Nurses bring clinical expertise and evidence to their projects and can be successful project leads and/or research investigators

First time submitting a determination form and/or research proposal, and may need guidance and consultation

KPSC/HI provides guidance and consultation to build capacity

KPSC/HI IRB administrators are also very helpful and do consultations OR if KP employee student ask your school faculty

Preliminary Work: Similarities/Differences between KP Employee Student vs. Non-Student



Preliminary work

EBP/QI project/Permission to Disseminate External from KP

Complete Research vs. non-Research determination Form

Research Study

IRB proposal through iRIS

***Note: Both KP Employee Student and Non-Student complete these forms**

Step 1: Preliminary Work Section completed by the Project lead

1

- Identify EBP/QI project focus, setting, population, outcome
- Background, Literature support, Identified problem/gap as applicable

(*Both KP employee student and non-student)

Step 2: Initial Discussion of EBP/QI project

2

- Completed EBP/QI project proposal discussion from your school program **(*KP employee student only)**
- EBP/QI project discussion for preliminary approval from stakeholders: Chief Nurse Executive, Director, Department Administrator **(*Both KP employee student and non-student)**

Step 3: Obtain Final Approval

3

- Notify academic liaison at site of EBP/QI project to obtain approval or verification of school affiliation **(*KP employee student only)**
- Obtain written approval from school, stakeholders, CNE, Director, DA of study site **(*Both KP employee student and non-student)**

Step 4: Send off approval to

4

- Send school and DA approval to Director of Education (DOE) and/or **(*KP employee student only)**
- Local academic liaison (AL) and local research liaison

Step 5: Complete all necessary documents

5

- Complete all necessary documents required by Director of Education and/or academic liaison **(*KP employee student only)**

Preliminary Steps in a Nutshell

Preliminary Work Section

Identify study/project focus, setting, population

Background, Literature support, Identified problem/gap

Obtain school approval for EBP/QI project

Completed a draft proposal of your EBP/QI project in your school program

Discussed with stakeholders i.e., Chief Nurse Executive, Director, DA

Obtain preliminary approval

DA/manager, Director at the study site

Send off approval to

Send school and DA approval to DOE

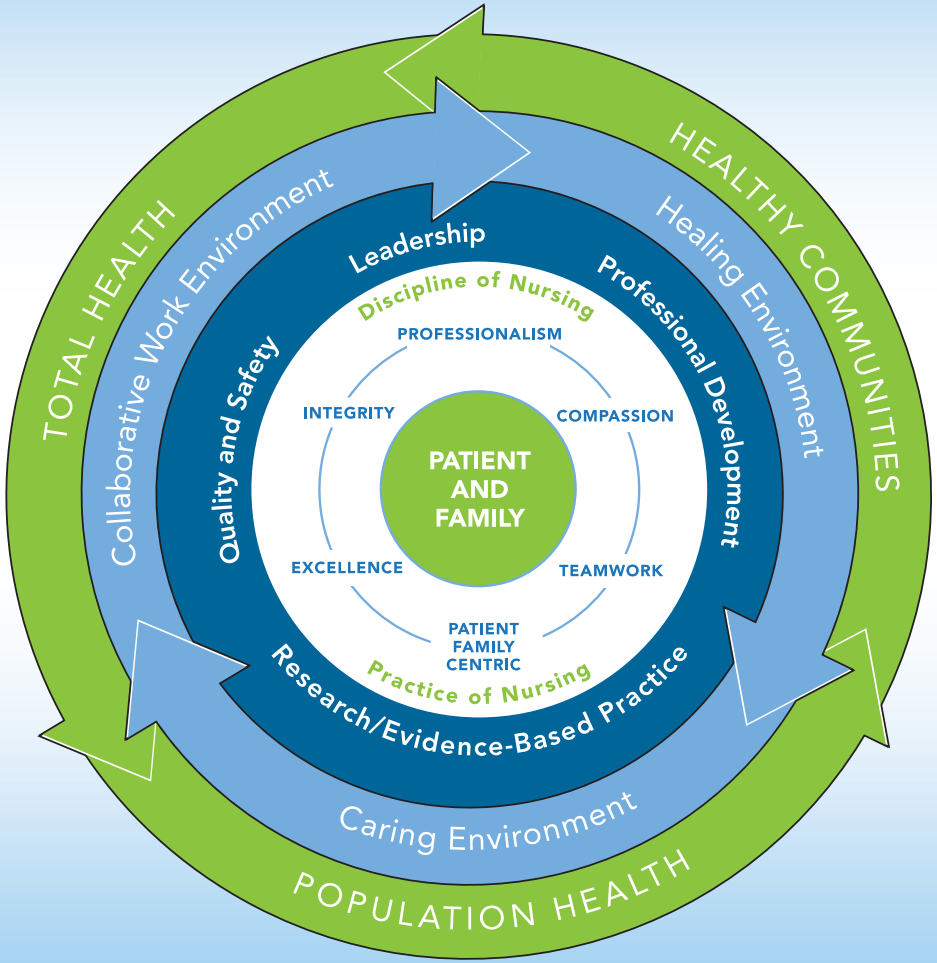
and/or Academic Liaison; notify local research liaison

Complete all onboarding requirements done by DOE and/or AL

Next Steps: Process of Completing Research versus Non-research Determination Form

Emma Aquino-Maneja, PhD, DNP, RN, CCRN

Regional Practice Specialist



IRB Process – What's Next?

1. Notify Regional Nursing Research Director via email at lina.n.kawar@kp.org and Regional Nurse Scientist at veronica.s.timple@kp.org about the proposed project.

2. Complete draft of Research versus Non-research Determination Form: irb.kp-scalresearch.org/appformrept.html

3. **Note**: For **ALL** projects (i.e., QI, EBP) obtain written verification from Quality Department indicating that the project procedures are a KP standard of practice.

Questions #3 in the Research versus Non-research Determination Form

3. Is the activity being conducted only to comply with KP requirements for quality measures to benefit patients?

☐ Yes ☐ No

Comments:

If the project is also being conducted to meet educational requirements, answer "NO".
If the answer to this question is 'NO', then this project is likely to be considered a '*systematic investigation*'.

IRB Process Continued

Submit the completed Research versus Non-research Determination Form to your faculty

Submit to the Regional EBP consultant at quincyann.d.febre@kp.org and lina.n.kawar@kp.org

Complete revisions to Human Subjects Research Assessment Form

IRB Process Continued

Submit

- Final copy of the Research versus Non-research Determination Form to IRB via email
- Include the permission letters from the Quality Department

IRB Letter

- Receive letter from IRB with decision on whether the project is considered “human subjects research” or “non-human subjects research”, as defined by the IRB

What makes the EBP/QI project deemed a "Research Study"?

IRB Definition for Human Subject

Human Subject - A living individual about whom an investigator conducting research obtains 1) **data** or biospecimens through intervention, interaction with the individuals, or **survey**; 2) **identifiable private information** or biospecimens. [45CFR46.102(e)(1)]

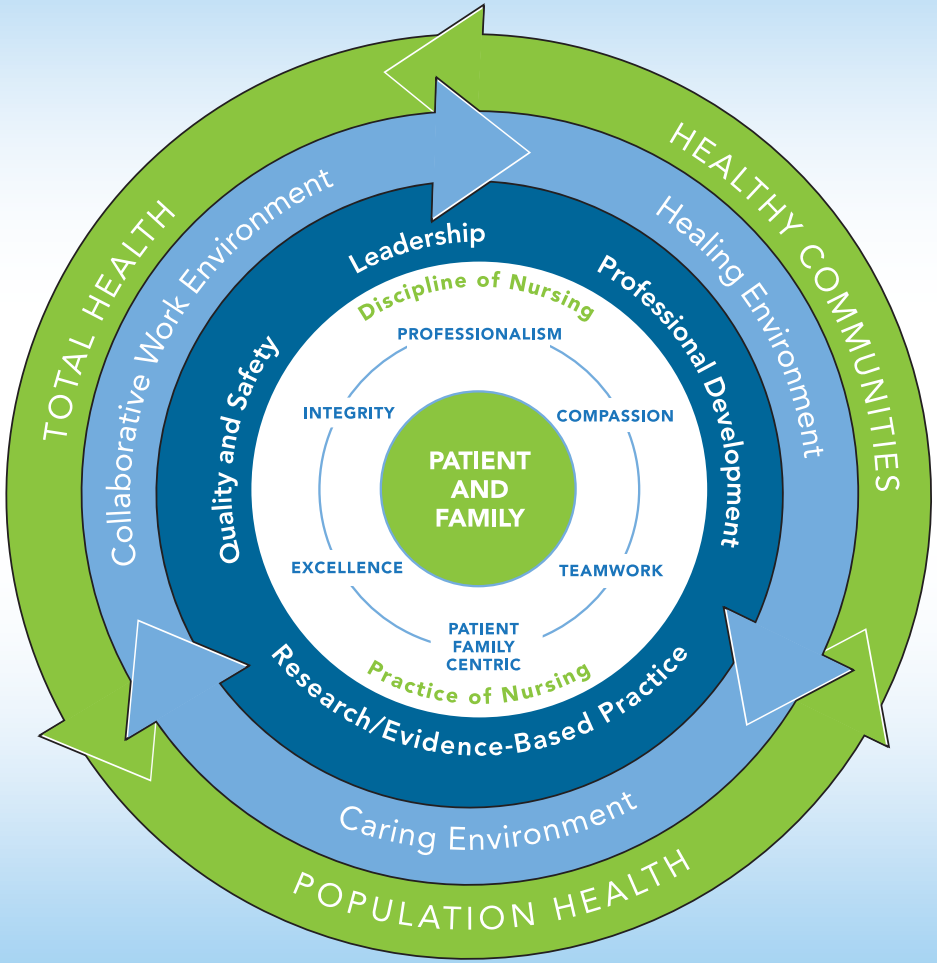
IRB Process Final Steps

**If the project is deemed research – follow step *#26*		
If IRB deemed the project as Research - go to the final steps	Obtain final approval to execute project from DA/manager prior to starting project implementation	Notify the local nursing research liaison of the project approval

Research Versus Non-Research Determination Form

Mayu Yamamoto, DNP, RN

Professional Development & Research | Ambulatory Clinical Services



Research Versus Non-Research Determination Form

- **Purpose:** To determine if a project is human subject research or a clinical investigation that will require review and oversight by the IRB in accordance with regulations
- Comprised of 10 questions
- Provide enough information about the project that the reviewer will get a complete understanding of why and how the work will be performed
- Failure to provide adequate information may result in an inappropriate determination the project

Question #1 | Project Description

1. **Provide a complete description of your project. Specify if the project will be conducted to meet an educational/degree requirement.**

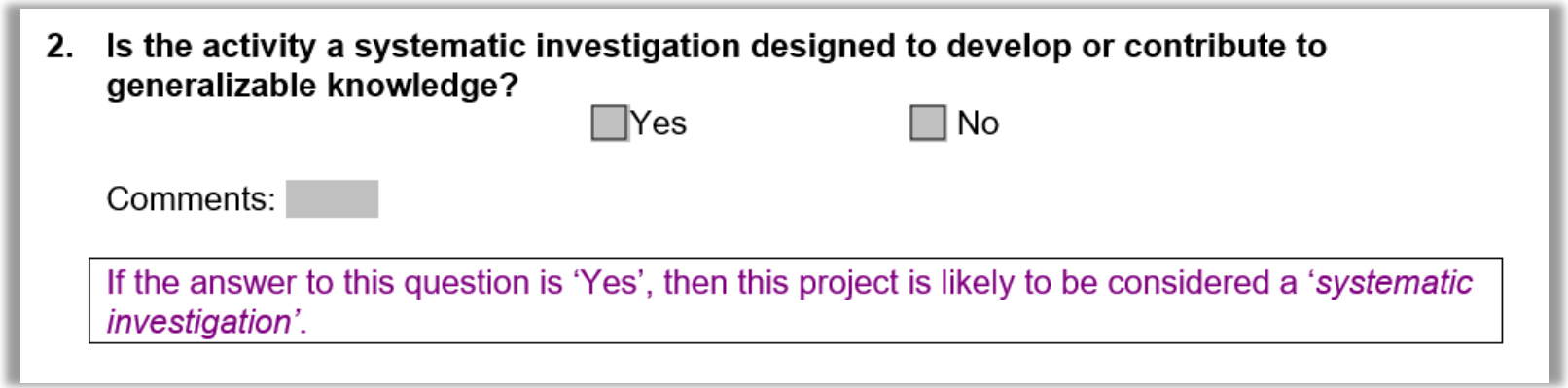
- State the reason you are conducting this project (i.e., for educational requirements, present a poster at an external nursing conference, etc.)
- Provide a concise summary of the project's purpose and methods
- Include the 5 Ws + How

Question #1 | Project Description

The 5 Ws + How

	Who?	What?	When?	Where?	Why?	How?
Topic	**Individuals Involved**	**Actions Taken**	**Timing/Period/ Duration**	**Location**	**Reasons**	**Process/ Procedures**
Question	▪ Who will be involved? ▪ Who are the stakeholders? ▪ How many participants?	▪ What will be implemented? ▪ What interactions will occur? ▪ What are your variables? ▪ What are your measures?	▪ When will the project take place? ▪ How long is the intervention? ▪ What is the timeline and duration of the project?	Where will the project take place?	▪ Why is this project important? ▪ Why is this project being done?	▪ How will the work be conducted? ▪ How will it be evaluated? (Describe the steps, intervention, methods, etc.)

Question #2 | Generalizable Knowledge



2. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?

☐ Yes ☐ No

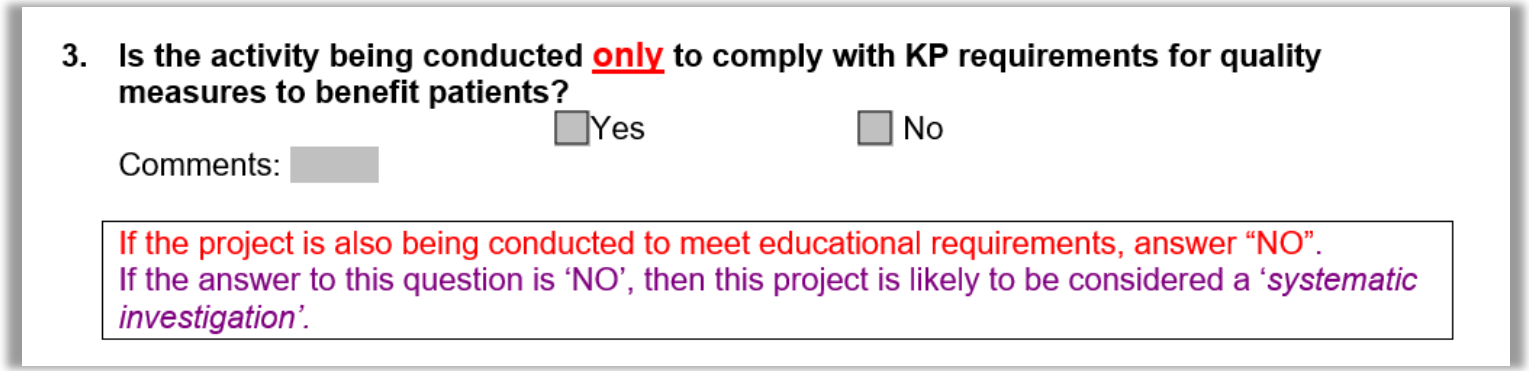
Comments:

If the answer to this question is 'Yes', then this project is likely to be considered a '*systematic investigation*'.

- If "Yes", the project is likely to be considered research, requiring IRB review and oversight
- If "No", the project is likely to be considered a QI or EBP project

It is helpful to include supporting information in the *Comments* section.

Question #3 | Quality Measures



3. **Is the activity being conducted only to comply with KP requirements for quality measures to benefit patients?**

☐ Yes ☐ No

Comments:

If the project is also being conducted to meet educational requirements, answer "NO".
If the answer to this question is 'NO', then this project is likely to be considered a '*systematic investigation*'.

- If the project is being done for quality or process improvement purposes only, the answer is "Yes"
- If the project is being done for educational purposes (e.g., DNP project) the answer is "No"

It is helpful to include supporting information in the *Comments* section.

Question #4 | Quality Department Verification

4. **If this is a quality project, please provide: 1) verification through an email from a Quality Department staff at your medical center who can verify if your project procedures are a KP standard of care or quality practice.**

- If this is a quality project, obtain an email or letter from Quality Department to verify that the procedures are within the KP standard of care
- For students, because the project results will be disseminated outside of KP, the email or letter will need to be obtained from the Quality Department and kept for your records

Quality Department Verification | Example

Mayu L Yamamoto

From:
Sent:
To:
Cc:
Subject: RE: Verification for DNP Project

Mayu,
Medication Reconciliation is the standard of care for our medical center and any improvement of this process is a quality project. I would appreciate if you would present your project to our Quality Systems Improvement Committee when completed. Please keep in touch.

Thank you,

Kaiser Permanente
Quality Improvement Director,

Example

Question #5 | Project Plan

5. **If this is a quality improvement project, please describe the project plan (describe the design, implementation, management and activities used to determine the plans effectiveness).**

- Quality improvement projects are designed to improve performance or processes within a specific setting (e.g., department, unit, hospital).
- Provide detailed explanations of procedures, data collection and analysis methods (i.e., *Methods* section of scholarly paper)

Be clear and concise, allowing others to understand the project plan and potentially replicate the project

Question #6 | Change in Practice

6. How will this project differ from the routine (standard of) care and normal clinic operations?

If the project deviates significantly from routine standards of care, it is possible that there may be increased risks to the participants and therefore require IRB review and oversight.

- Compare and contrast current practice vs. the change that will be implemented
- If the project deviates significantly from routine standards of care, it is possible that there may be a need for IRB review and oversight

Be explicit in describing the differences between the normal standard of care and/or clinic operations and the practices involved in the project.

Question #7 | Risks and Burdens

7. **Does the project pose any additional risks (physical risks and/or risk of breach of confidentiality or undue influence) or burdens (e.g., extra appointments or visits, longer appointments, additional surveys) on the individual beyond routine care?**

☐ Yes ☐ No

If 'Yes', please comment:

If the project poses any additional burdens, it is possible that it **may be necessary to have additional oversight** of the project to look out for the best interests of the participants.

- Risks can be physical, psychological, social, legal, or economic
- Burdens include:
  - Time commitment for procedures, interviews, or data collection (e.g., surveys)
  - Inconvenience associated with scheduling and participation
  - Potential discomfort from project-related activities

Question #8 | FDA Requirements

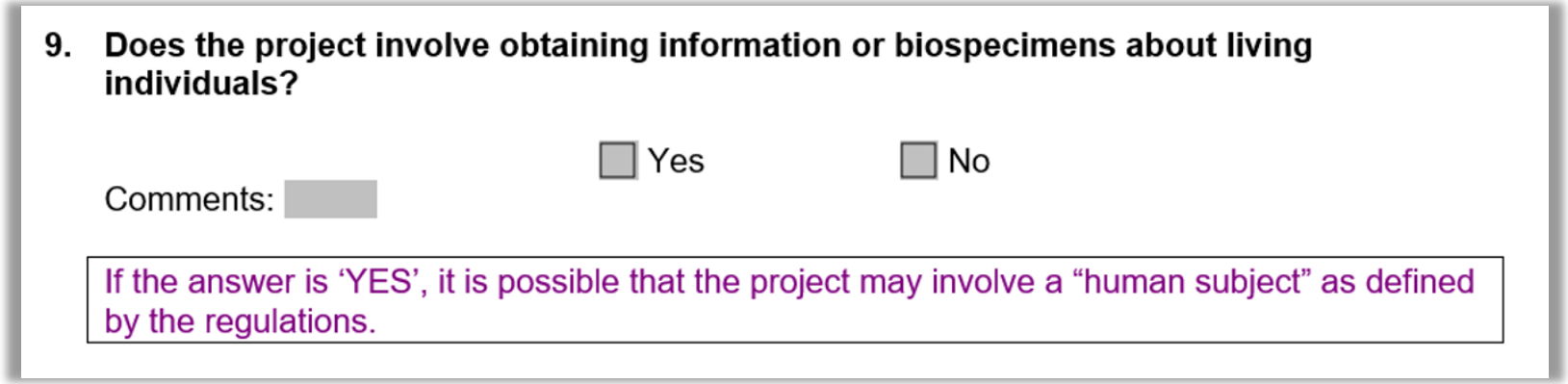
8. Will any data/samples obtained from this project be used to meet FDA requirements for a research or marketing permit?

☐ Yes ☐ No

Comments:

- Studies involving the FDA are typically for investigational drugs and devices
- FDA has strict regulations for research or marketing permits
- If answer is “Yes”, additional approvals may need to be obtained

Question #9 | Human Subject



9. Does the project involve obtaining information or biospecimens about living individuals?

☐ Yes ☐ No

Comments:

If the answer is 'YES', it is possible that the project may involve a "human subject" as defined by the regulations.

- Information about living individuals might include opinions, thoughts, behaviors, or medical information
- Biospecimens are biological samples (e.g., blood, tissues, and other bodily fluids)

If answer is "No" it is helpful to include supporting information in the *Comments* section and include an example of the information or data that will be collected (e.g., aggregate data from Tableau Dashboard).

Question #10 | Data Collection

10. If YES to Question 9, Does the project involve either:
a) Obtaining information or biospecimens by intervening or interacting with an individual? OR
b) Collecting identifiable private information or identifiable biospecimens?

☐ Yes ☐ No

Comments:

If the answer is 'YES', it is possible that the project may involve a "human subject" as defined by regulations.

- "Intervening" can include both physical procedures and manipulations of the subject or the subject's environment
- "Interacting" can involve any communication or interpersonal contact between the investigator and the subjects
- Identifiable private information includes:
  - Behaviors that occur in a context in which an individual can reasonably expect no observation or recording is taking place
  - Information that was provided by an individual who can reasonably expect it will not be made public

If the answer is "No", it is helpful to include supporting information in the *Comments* section.

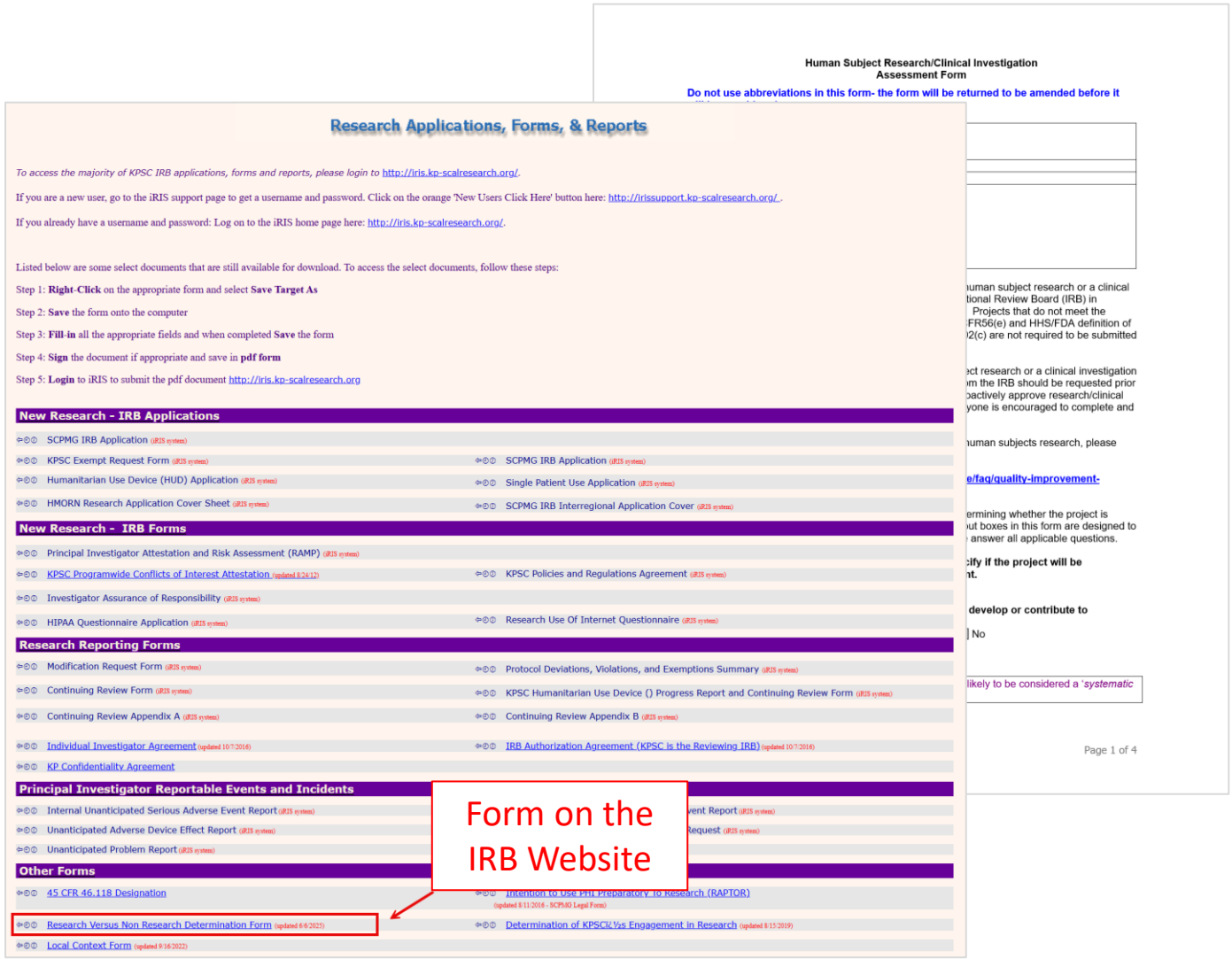
Research Versus Non-Research Determination Form

Form is available on the IRB website: https://irb.kp-scalresearch.org/appformrept.html

Please note the that file name for the form is different than the title written at the top of the document.

File Name: Research Versus Non Research Determination Form

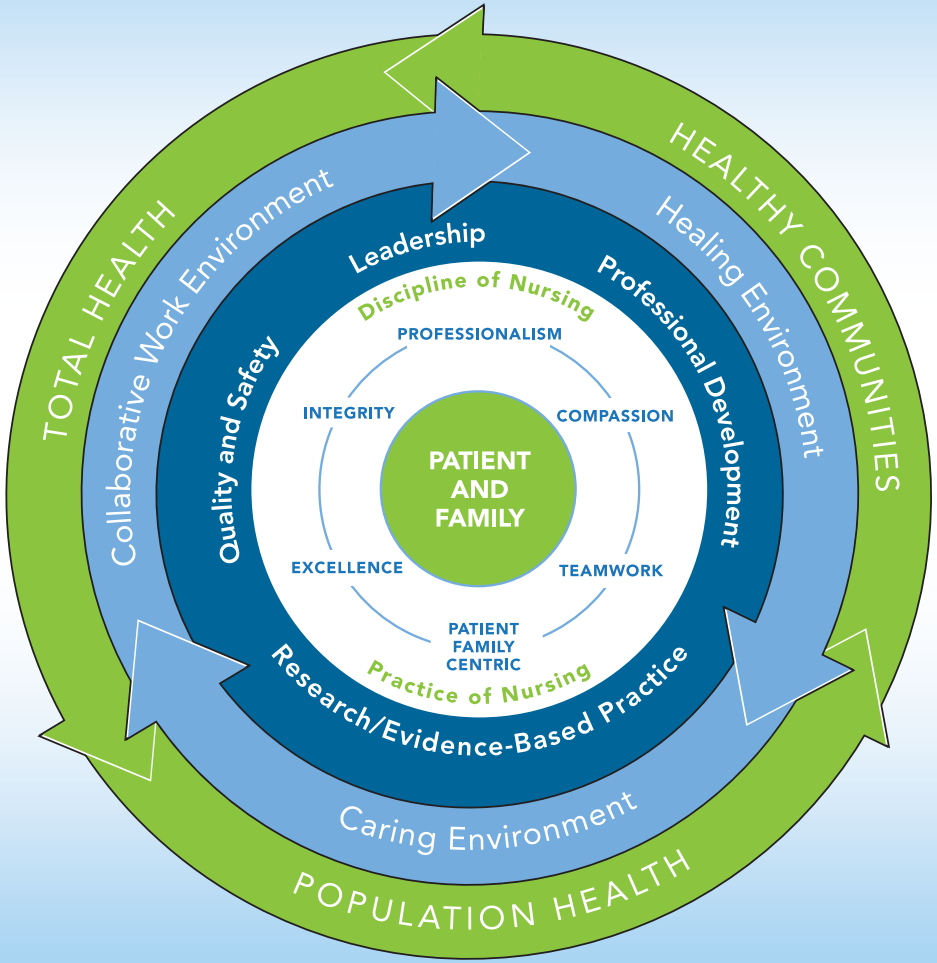
Title: Human Subject/Clinical Investigation Assessment Form



Key Points, Tips, & Pitfalls to Consider when Submitting the Research vs Non-Research Determination Form

Joria Rainbolt-Clemente, DNP, CNS, GERO-BC

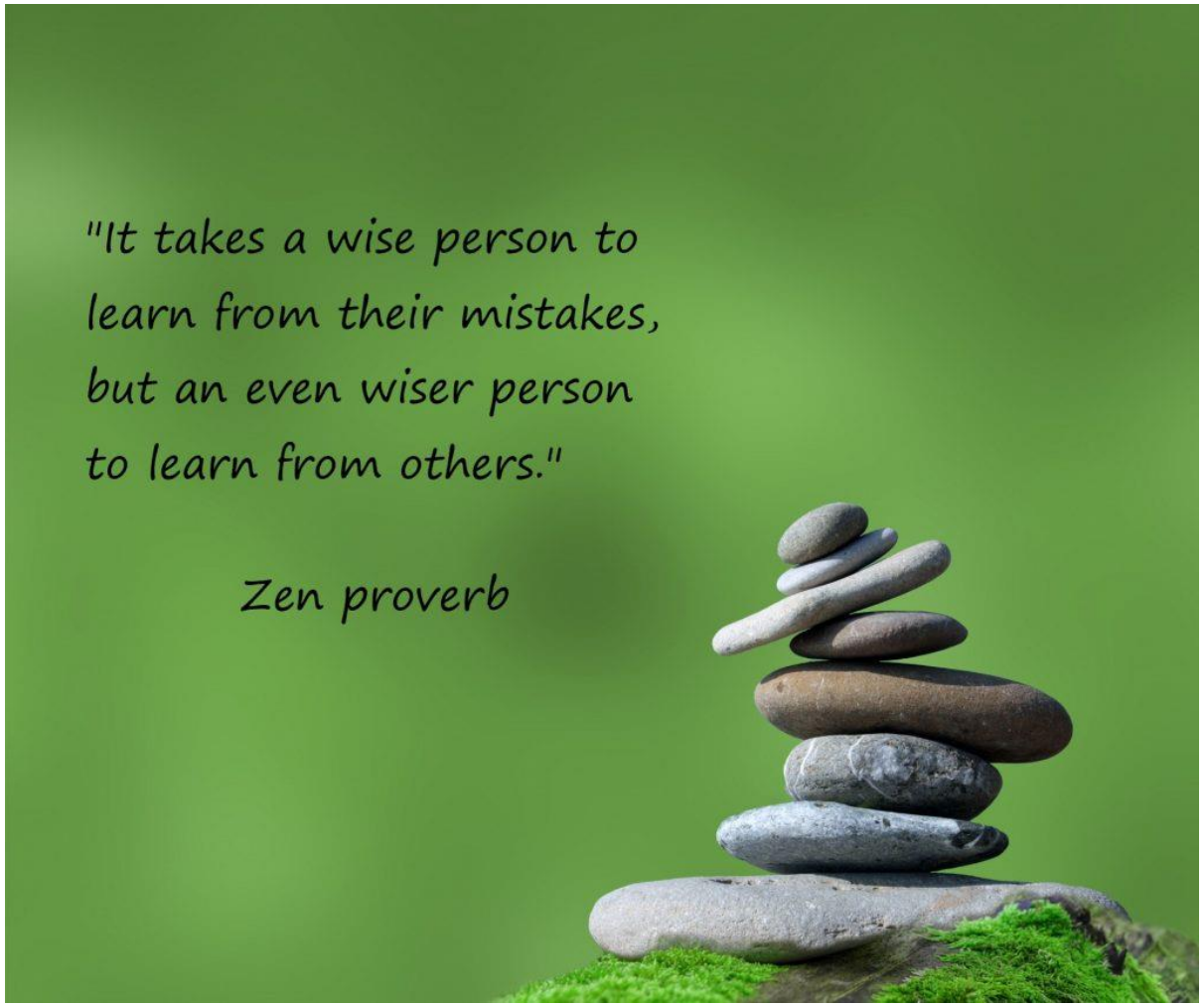
Clinical Nurse Specialist KP-Irvine, Research Liaison



Tips to Prepare an EBP Project Without Confusing It with Research

1. Start with a clinical problem you've observed in practice.
2. Formulate a PICOT question to guide your literature search.
3. Conduct a thorough literature review to find best practices.
4. Design an implementation plan based on the evidence.
5. Evaluate outcomes using existing data or quality metrics.
6. Consult your academic advisor or project committee to ensure it aligns with EBP standards.
7. Consult with Regional Nursing Research /EBP Team for any project or research study questions.

Pitfalls: Learnings from past proposals



Question #1 | Example

The following questions are designed to assist the IRB in making a determination on whether or not a project is human subjects research. The call-out boxes in this form are designed to provide insight on how the assessment will be made. Please answer all of the questions that apply.

1. **Please provide a complete description of your project and specify if project will meet any educational requirements.**
   This project is a DNP project and not a research study.This DNP project will provide education for staff working in the outpatient surgery department and has been approved by the department manger.

What do you think?

Submitting the Form for a Project

The following questions are designed to assist the IRB in making a determination on whether or not a project is human subjects research. The call-out boxes in this form are designed to provide insight on how the assessment will be made. Please answer all of the questions that apply.

1. **Please provide a complete description of your project and specify if project will meet any educational requirements.**
   This project is a DNP project and not a research study.This DNP project will provide education for staff working in the outpatient surgery department and has been approved by the department manger.

- **Pitfalls:** Failure to thoroughly address the specific form questions
  - Assuming a School, Degree, or Nurse Leaders can determine need for IRB
  - Implementing a school project without gaining student status
  - Working on a school project while on the clock

Question #2 | Example

1. **Provide a complete description of your project. Specify if the project will be conducted to meet an educational/degree requirement.**
   This project will focus on ICU nurses to understand their baseline knowledge of how to do delirium assessment for newly admitted patients after an educational in-service. This will be done at a unit meeting and collection of their baseline knowledge and adherence will be reviewed before and after which will determine the delirium assessment compliance rates from the Quality Dashboard.

What's missing?

Submitting the Form for a Project

1. **Provide a complete description of your project. Specify if the project will be conducted to meet an educational/degree requirement.**
   This project will focus on ICU nurses to understand their baseline knowledge of how to do delirium assessment for newly admitted patients after an educational in-service. This will be done at a unit meeting and collection of their baseline knowledge and adherence will be reviewed before and after which will determine the delirium assessment compliance rates from the Quality Dashboard.

- **Pitfalls:** Steer clear of research study jargon of research process
  - Generalizable knowledge
  - Direct contact with patients or medical records
  - Consent not provided

Question #3 | Example

Does an exercise intervention program administered over 10-weeks, reduce perceived stress in nurses working in the 4 East unit compared to those that will not be part of the program. The training is designed to provide nurses an isometric exercise program and breathing techniques in their everyday lives including at work and to learn skills that will help them manage perceived stress promoting overall well-being.

We hypothesis that nurses will report decreased levels of stress, increased mindfulness and overall well-being after learning and implementing mindfulness practices into their daily lives.

What's missing?

Submitting the Form for a Project

Does an exercise intervention program administered over 10-weeks, reduce perceived stress in nurses working in the 4 East unit compared to those that will not be part of the program. The training is designed to provide nurses an isometric exercise program and breathing techniques in their everyday lives including at work and to learn skills that will help them manage perceived stress promoting overall well-being.

We hypothesis that nurses will report decreased levels of stress, increased mindfulness and overall well-being after learning and implementing mindfulness practices into their daily lives.

- **Pitfalls:** Steer clear of research study jargon of research process
  - Writing a hypothesis
  - Generalizable knowledge vs unit specific
  - Direct contact with nurse, patients or medical records
  - Consent not provided

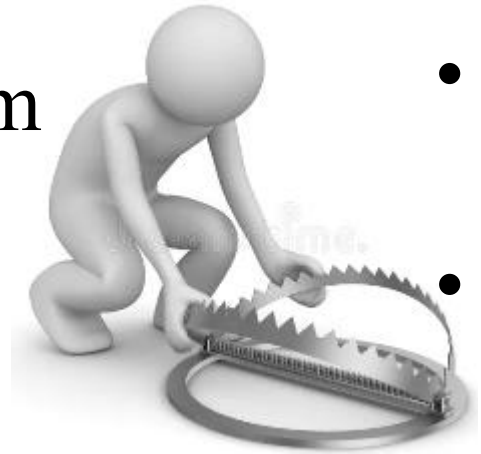
Common Pitfalls of the IRB Process

- **Disguising a research study as an EBP/QI project to avoid IRB review**

- ***Avoid gaming the system – we can tell!***

Common Pitfalls of the IRB Process

- Incorrect review request
- Incorrect study type
- No research question or hypothesis
- No sample size
- No power analysis
- No explanation of team members or external investigators



- No description of study procedures
- Population/setting not identified
- No timeline (detailed)
- No analysis plan
- No safety monitoring (intervention studies)
- No confidentiality plan

Major Devastating Errors

- Conducting EBP or QI projects without IRB permission
- Disseminating the project external to KP without submitting a Research vs. Non research form to the IRB
- Starting a research study without IRB approval
- Changing the process without submitting a modification
- Deviate from the approved process
- Violating the research protocol
- Advertising an external investigator study without securing an IRB approval

* It is the research/EBP team professional obligation to inform the IRB if any changes

Definition of Terms

- **Evidence-Based Practice** - Integrates the best published research evidence with clinical expertise and patient preferences to guide care decisions.
- **Quality Improvement** – Systematic patterns of action to enhance safe clinical processes and outcomes.
- **Process improvement -** Systematic analysis of existing work procedure/flow to implement changes that can increase efficacy and quality in clinical practice.
- **Performance improvement -** Systematic process of identifying gaps in performance and implementing approaches to improve efficacy and outcomes at an individual, team, or organizational level.
- **Institutional Review Board**- A administrative committee that reviews research and projects involving human subjects to ensure the appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. Also, to ensure research is conducted in compliance with federal regulations, state laws, and institutional policy, and grounded in the ethical principles of the Belmont Report: Respect for Persons, Beneficence and Justice.
- **Human Subject** - A living individual about whom an investigator conducting research obtains 1) **data** or biospecimens through questionnaire/survey, intervention, or interaction with the individuals; 2) identifiable **private information** or biospecimens.
- **Nursing Research** - Systematic investigation (including research proposal/protocol development, testing, and evaluation) designed to develop or contribute to generalizable knowledge.
- **Systematic Investigation**: A structured activity that is planned in advance and that uses data collection and analysis to answer a particular question.
- **Generalizable Knowledge**: Information that can be applied to populations or situations beyond study and expands the knowledge base of a scientific discipline or other scholarly field of study.

Future Consultations

A Culture of Excellence

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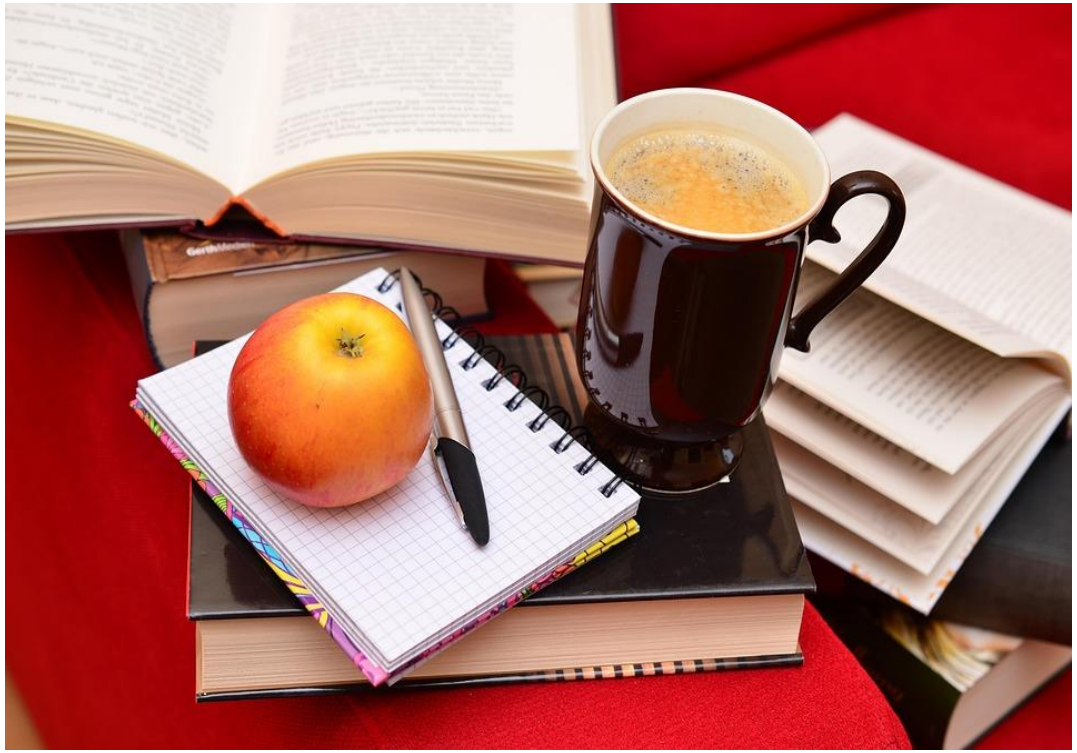


Thank you