

Pacific Lutheran University
School of Nursing
HPRB Guidelines for Quality Improvement Projects

The following guidelines are developed to provide instruction to students and faculty conducting Quality Improvement projects or questioning whether a project is Quality Improvement or “human subjects research.” Please follow the steps below:

- Go to the PLU HPRB website: <https://www.plu.edu/hprb/>. Go to the appropriate tab for Students or Faculty and read through the information for STEP 1 (Do you need review?).
- You can also go directly to our online proposal submission site, Mentor, through Quick Links on the left side. There is a pre-survey that will help you determine if your project is QI. To get to the pre-survey in Mentor, click on the HPRB tab. Click on My Proposals (along the left). Then click on the Create New Proposal button. This launches a pre-proposal survey. Complete the Pre-Proposal Diagnostic Survey (please see typical answers for a QI project on the following pages).

If your project is likely QUALITY IMPROVEMENT (QI):

And your PROJECT SITE HAS ITS OWN IRB:

- **Submit your proposal to the institution/site where you are conducting the project.** When you receive official verification from that IRB, please keep that document for your records. It is for your protection. It may also be needed if you eventually want to submit your results for publication, as journals may require some proof of IRB review and verification as QI. The PLU HPRB does not need a record of this.

And your PROJECT SITE DOES NOT HAVE AN IRB:

- **Submit your proposal to the PLU HPRB using Mentor.** Through Mentor, your project will be assigned to one of the nursing HPRB Unit Designates for review. Your Unit Designate will send comments to the HPRB chair and you will receive an email letter from the chair when your review is complete. You may be asked to respond to stipulations before a final determination is made. If your project is verified as QI, you will receive an official letter, stating that the project is QI and not subject to IRB review (per federal regulations). When you receive official verification, please keep that document for your records. It is for your protection. It may also be needed if you eventually want to submit your results for publication, as journals may require some proof of IRB review.

If your project is likely HUMAN SUBJECTS RESEARCH:

- Submit a full proposal to the PLU HPRB using Mentor. Unless your project involves minors (or other vulnerable participants), it will be reviewed under Expedited Review (e.g., for interviews, focus groups, non-anonymous or sensitive surveys) or Exempt (e.g., for no risk, anonymous surveys). You may receive a letter requesting revisions (stipulations). Once your proposal or revisions are approved, you will receive official HPRB approval. This approval will be good for one year.

If you are a student and your Nursing instructor wants you to understand how to submit a full HPRB proposal:

- You will complete an HPRB proposal in Qualtrics (rather than Mentor) using the following link. https://plu.az1.qualtrics.com/jfe/form/SV_cMxTKKGYIGXVCGp. You will be able to download a copy of your completed proposal and submit it to your instructor. **NOTE:** If you are completing the proposal for practice as required by your instructor, you should NOT also complete a full proposal through Mentor.

Diagnostic Pre-Survey Answers for a Quality Improvement Project

If you believe your project is a Quality Improvement (QI) project, here's how your answers would typically look in the Mentor pre-diagnostic survey (**highlighted**), but not in all cases. Please answer honestly, based on your knowledge of your own project. Your project may include some, but not all, components of a Quality Improvement project. Ultimately, it will be up to the HPRB or external IRB to make the determination.

Please do not use the browser's "Back" button. It will boot you out of the survey!

1. Opt Out Type: Multiple Choice

If you are confident that your proposal is exempt or merits full board or expedited review, you may opt out of this diagnostic survey and go directly to proposal submission form.

If you are submitting a Quality Improvement/Quality Assessment (QI/QA) project, you **must** take the QI survey (option 3).

Answer: 1. Proceed directly to HPRB proposal submission form.

2. Continue with diagnostic survey.

3. **I believe this project is Quality Improvement.**

2. Q11: Purpose 1 Type: Multiple Choice **Required**

Is the activity intended to improve the process/delivery of care while decreasing inefficiencies **within a specific health care setting**?

Answer: 1. **Yes** 2. No

3. Q12: Purpose 2 Type: Multiple Choice **Required**

Is this a systematic investigation designed with the intent to contribute to **generalizable knowledge**?

Answer: 1. Yes 2. **No**

4. Q13: Scope Type: Multiple Choice **Required**

Is the activity intended to **evaluate current practice** and/or attempt to improve it based upon existing knowledge?

Answer: 1. **Yes** 2. No

5. Q14: Evidence Type: Multiple Choice **Required**

Is there sufficient evidence to support implementing this activity to **create practice change**?

Answer: 1. **Yes** 2. No

6. Q15: Clinician/Staff Type: Multiple Choice **Required**

Is the activity conducted by **clinicians and staff** who provide care or are responsible for the practice change **in the institutions where the activity will take place**?

Answer: 1. **Yes** 2. No

7. Q17: Pop. Sample Type: Multiple Choice **Required**

Will the activity involve a sample of the population (patients/participants) **ordinarily seen** in the institution where the activity will take place?

Answer: 1. **Yes** 2. No

8. QI8: Funding Type: Multiple Choice **Required**

Is the project funded by an outside organization with a **commercial interest** in the use of the results?

Answer: 1. Yes 2. **No**

9. QI9: Consent Type: Multiple Choice **Required**

Will the planned activity only require **consent that is already obtained** in clinical practice, and could the activity be considered part of the **usual care**?

Answer: 1. **Yes** 2. No

10. QI10: Benefits 1 Type: Multiple Choice **Required**

Will future patients/participants at the institution where the planned activity will be implemented **potentially benefit** from the project?

Answer: 1. **Yes** 2. No

11. QI11: Benefits 2 Type: Multiple Choice **Required**

Will the project occur **regardless** of whether individuals conducting it may benefit professionally from it?

Answer: 1. **Yes** 2. No

12. QI12: Risk Type: Multiple Choice **Required**

Is the risk to patients/participants **no greater** than what is involved in the care they are already receiving **OR** can participating in the activity be considered acceptable or ordinarily expected when practice changes are implemented within a health care environment?

Answer: 1. **Yes** 2. No

13. QI13: Publication Type: Multiple Choice **Required**

Will the results of the project be **published, presented or disseminated** outside of the institution conducting it? [Note: Activities determined to be program evaluation and QI projects may be published or presented, but they should not be described as research studies.]

Answer: 1. **Yes** 2. No

Based on your responses, we believe your project **meets the criteria for Quality Improvement**.

IF YOUR QI SITE:

HAS ITS OWN IRB: You **must** have your project reviewed by that site. They will qualify your project as QI. Exit this survey.

DOES NOT HAVE AN IRB: Submit to the PLU HPRB for QI verification.

Begin by contacting officials at project site to get their approval to work with their patients/staff. See HPRB website for template:

<https://www.plu.edu/hprb/documents/template-for-permission-from-off-campus-research-site/>

Complete the full HPRB proposal questionnaire on Mentor. Upload an approval letter from your project site on the main protocol page (**failing to do so will delay your QI verification**). Upload any relevant questionnaires, recruitment materials, consent documents, and debriefing materials to the main protocol page. We need to review these materials.

Answer: (NOTE: Pick the one that is appropriate for your project site.)

1. End survey (don't proceed to PLU HPRB submission; instead submit to IRB at project site).

2. Proceed to HPRB proposal submission at PLU (if project site does **not** have its own IRB).