## Pacific Lutheran University Human Participants Review Board Mentor Instructions for Students

We wish you the best as you begin work on your research project! There is exciting student research going on across campus, and we hope that you will work closely with your faculty supervisor to design projects using sound methodologies that meet the ethical standards in your field.

Below, we outline the HPRB application process in Mentor, our online submission system, with a focus on how you and your faculty supervisor will work together to finalize your proposal. <u>PLEASE NOTE</u>: This sheet assumes you have already completed the online CITI ethics training (see HPRB website for additional information about CITI: <u>https://www.plu.edu/hprb/students/step-3/</u>).

As you work on your application, please do not hesitate to contact the HPRB if you have any questions that your faculty supervisor can't answer. Please start by reaching out to the Unit Designate in your school or division (see: <a href="https://www.plu.edu/hprb/meet-the-hprb/">https://www.plu.edu/hprb/meet-the-hprb/</a>) or the HPRB administrator (Carol Bautista) at hprb@plu.edu. You can also contact the chair of the HRPB at <a href="https://www.plu.edu/hprb/meet-the-hprb/">https://www.plu.edu/hprb/meet-the-hprb/</a>) or the HPRB administrator (Carol Bautista) at hprb@plu.edu. You can

## **Outline of General HPRB Application Process:**

- Step 1: Go to Mentor through the HPRB website Quick Links on the left side: www.plu.edu/hprb. Once in Mentor, click on the HPRB tab. Then, click on My Proposals and click the Create New Proposal button. This will take you to a pre-survey to determine what kind of HPRB review, if any, is appropriate for your project.
- Step 2: Complete the <u>diagnostic pre-survey</u> to determine the appropriate level of review (e.g., exempt, expedited, full board, QI). There are explanations of the different review categories on the HPRB website: <u>https://www.plu.edu/hprb/students/step-4/levels-of-review/</u>.

<u>For Nursing QI projects</u>, please see separate handout (<u>https://www.plu.edu/hprb/documents/guidelines-for-nursing-qi-projects/</u>).

Assuming the pre-survey indicates your project needs to be reviewed by the HRPB, select <u>Proceed to</u> <u>HPRB proposal submission</u>.

Step 3: Complete the <u>initial information page</u> for your project. Fill in your name, the names of any collaborators (co-PIs), and your faculty supervisor, along with a descriptive project title and your anticipated start and end dates. Toggle yes/no to indicate whether your project involves international or foreign language research (if yes, there will be an additional set of questions to complete).

<u>For Review Type</u>: If you have *not* completed the diagnostic pre-survey (a), the system defaults to Full Board Review. This is most likely incorrect (unless you are doing work with minors or other vulnerable participants or your project involves more than minimal risk) and could hold up your project. Be sure to select what you believe to be the correct level of review (most PLU student projects are exempt or expedited – or QI, if you are in Nursing). Please see link for a description of review levels in Step 2 above, if you are not sure.

Step 4: Once in your proposal, on the main protocol page, click on → ANSWER OR EDIT PROPOSAL QUESTIONS HERE!. This will take you to the different proposal sections that need to be completed. You can do them one by one or click on Expand All Sections to see everything at once. Answer all questions in all proposal sections (this can be done over time; all edits are saved automatically). Go back to the main protocol page and <u>upload all necessary study documents</u> at the bottom of the page (e.g., recruitment script, consent document, surveys, debriefing, letter from research site outside of PLU). The HPRB website has step-by-step instructions and detailed explanations for what needs to be included: <u>https://www.plu.edu/hprb/students/step-4/</u>.

Be sure to pay attention to <u>specific methodological considerations</u> if you are doing online surveys, research with vulnerable populations, recording or paying your participants, etc. See the HPRB website for more information: <u>https://www.plu.edu/hprb/students/step-5/</u>.

You'll know you are done when you no longer see <u>Required Questions not Answered</u> on the main protocol page.

Step 5: When everything is complete, go back to the main protocol page and click on the button near your faculty supervisor's name to <u>request faculty supervisor's signature</u>.

Your faculty supervisor will receive an automatically generated email from Mentor, saying your proposal is ready for their comments. Your faculty supervisor should read through your entire proposal, as well as all uploaded study documents (e.g., consent, debriefing).

They should provide feedback within Mentor *before* the proposal is officially submitted to the HPRB for review. There are several ways this can be done. Faculty supervisors can:

- Edit your proposal sections directly (using the Edit Answer button in each section/question).
- Write comments to you at the bottom of each question (in Reader Comments). You can find requests for edits by looking for questions where <u>Reader Comments</u> are underlined.
- Upload files with edits to your attached documents (e.g., recruitment scripts, consent documents, study instruments, debriefing, etc.) on the main proposal page (at the bottom). If your documents are in Word, your faculty supervisor can edit them directly and/or provide comments using the Review function.

When they are done, they should email you to say feedback is available in Mentor, so you can address their comments.

Step 6: You should make necessary changes in Mentor and let your faculty supervisor know the new edits are complete. This can go back and forth until the faculty supervisor is satisfied that the proposal is accurate and complete. At that point, your faculty supervisor will provide an electronic signature, which automatically submits the proposal to the HPRB for review by a Unit Designate.

## **IMPORTANT:** <u>The proposal is not submitted and will not be reviewed by the HPRB until the faculty</u> <u>supervisor signs off</u>.

- Step 7: Once the proposal is officially submitted, you and faculty supervisor will receive an automatically generated email saying that the proposal has been received by the HPRB.
- Step 8: Your proposal is <u>assigned to a Unit Designate</u> in your school or division for review. When this review is complete, the HPRB chair is notified that the proposal is ready for additional review.
- Step 9: The <u>HPRB chair reviews all materials</u>, conveys Unit Designate comments to you and your faculty supervisor, provides additional comments if needed, and generates an email letter that either:

- <u>Requests revisions</u>: These are summarized in an email letter. Comments can also be accessed directly in the proposal in Reader Comments. Proposal sections with questions requiring revisions are marked in red at the top (e.g., <u>Revisions Required</u>: 3, meaning there are three questions that need to be revised). Questions requiring revisions are indicated by underlined <u>Reader Comments</u> at the bottom of the question.
- <u>Makes a final determination on the proposal</u> (e.g., approves it, verifies is as Quality Improvement, verifies that is not considered "human subjects research" as defined by federal regulations).
- Step 10: If revisions are requested within proposal sections, you should make changes by:
  - Editing responses to the questions directly using the Edit Answer button.
  - Responding in <u>Reader Comments</u> (e.g., to provide further information or provide a rationale for not making the requested changes)

After editing each question, you should click the <u>Submit Revisions for Review</u> box **at the bottom of each question**. This will make the <u>Revisions Required</u> text go away and be replaced by <u>Revisions</u> <u>Submitted</u>.

- Step 11: If revisions are requested to study documents, you should make necessary changes by:
  - Editing study documents and uploading revised versions on main protocol page
  - o Adding missing documents on the main protocol page
- Step 12: When all materials are complete, click the <u>Submit Revisions for Review</u> box **at top left of main protocol page**. This notifies the HPRB chair that materials are ready for review.
- Step 13: This cycle can continue... or it can end with a final determination letter from the HPRB chair.
- Step 14: You will receive a letter by email with a final determination (e.g., approval or verification as QI). If anything changes with your project (e.g., new co-PI, change in participants, different method or location for recruitment, changes to questions in your surveys, a new condition, etc.), you will need to submit an Amendment. You will find an amendment tab on the bottom of the main protocol page for your project. There is a brief survey to complete about what changes you are making, along with places to upload new or revised documents.

When you amend a project, you need to go back through your answers to all proposal questions and make any necessary edits, so that what is visible represents the most recent version of your project. Please see information about amendments and continuing responsibilities on the HPRB website: <a href="https://www.plu.edu/hprb/students/step-9/">https://www.plu.edu/hprb/students/step-9/</a>.

Best wishes for the successful completion of your project! Please don't hesitate to contact the HPRB and/or your Unit Designate if you have questions or concerns.