

**Pacific Lutheran University
Human Participants Review Board
Instructions for Unit Designates**

The HPRB appreciates your willingness to serve as a Unit Designate for your department, school, and/or division. We rely on your disciplinary expertise in helping to ensure PLU investigators use ethical and sound methodologies and give careful consideration to the protection of all participants. You play a critical role in supporting students, your colleagues, and the university as a whole in the research process.

The HPRB thanks you for:

- contributing to student learning, through your thoughtful and constructive feedback... and your patience with new researchers;
- making it possible for PLU researchers to publically disseminate their scholarship, as many journals and professional organizations now require studies to have ethics board approval prior to data collection and presentation at conferences or publication; and
- helping protect PLU by minimizing risks to participants and mitigating potential liability for the institution.
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We also thank you for your patience and feedback regarding Mentor, the online submission system we implemented in Fall 2018. Now that we have had time to see how students, faculty supervisors, and UDs use Mentor, we have created some new instruction sheets to guide you through the process. Please contact us at hprb@plu.edu with questions, comments, concerns, and/or compliments 😊.

OVERVIEW OF THE HPRB PROPOSAL PROCESS IN MENTOR

PROCESS BEFORE PROPOSAL COMES TO YOU:

- Step 1: PI completes diagnostic pre-survey in Mentor to determine level of review (exempt, expedited, full board, QI, not research). This is optional but recommended.
- Step 2: PI creates a new proposal in Mentor.

FOR non-STUDENT PIs:

- Step 3: PI answers all questions in all proposal sections in Mentor (this can be done over time; all edits are saved automatically). When complete, PI clicks button on main protocol page to Submit Proposal.

FOR STUDENT PIs:

- Step 3: When proposal survey is complete, student clicks button on main protocol page to request faculty supervisor's signature.
- Step 4: Faculty supervisor receives an automatically generated email from Mentor, saying proposal is ready for review by the faculty supervisor.
- Step 5: Faculty supervisor reads through entire proposal and all uploaded study documents (e.g., consent, debriefing) that appear on the main protocol page.
- Step 6: Faculty supervisor provides feedback within Mentor *before* proposal is officially submitted to the HPRB for review. Once comments are complete, faculty supervisor emails student to say feedback is available in Mentor. Student makes necessary changes and lets faculty supervisor know 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, faculty supervisor provides an electronic signature, which automatically submits the proposal to the HPRB for review by a Unit Designate.

- Step 7: Student and faculty supervisor receive an automatically generated email saying that the proposal has been received by the HPRB.
- Step 8: Proposal is assigned to a UD for review. Currently, our HPRB Administrator, is doing the assignment, though we will eventually move to an automatic assignment system. If there are multiple UDs, the system will assign it to the UD with fewer reviews, unless that UD is listed as the faculty supervisor.

AFTER PROPOSAL COMES TO YOU:

- Step 1: As Unit Designate, you will be notified by email that you have been assigned as a reviewer. If there is any problem with you reviewing the proposal, contact hprb@plu.edu and let us know.
- Step 2: The email provides a direct link to the proposal. You can also access the proposal by signing into Mentor, clicking on the HPRB tab, clicking on Reviewer in the menu on the left, and then clicking on the Proposal Title. Mentor can be accessed on the HPRB website (www.plu.edu/hprb) using the Quick Links on the left side.
- Step 3: Once in the proposal, on the main protocol page, click on → **ACCESS HPRB PROPOSAL SECTIONS HERE (to edit, review, revise)**. PI responses can be seen by clicking on the arrows by each proposal section (e.g., >> Project Summary) or by clicking the box to Expand All Sections (at top right). You should read carefully through all proposal sections, looking for inconsistencies across sections, incomplete or confusing responses, incorrect responses, etc. **See separate handout for list of common issues.**
- Step 4: You should also read through all uploaded study documents (e.g., consent, debriefing). These are attachments at the bottom of the main protocol page.
- Step 5: Here are the main ways you should provide feedback on the proposal:
- Write comments directly to the PI at the bottom of each question (by clicking on Reader Comments) and typing into the box. They will NOT be visible to the PI, but upon reviewing them, the HPRB chair can make them visible to the PI (or edit them, if needed, and then make them visible to the PI). **This is the most important form of feedback and most helpful to the chair.**
 - If there is information you want to convey to the chair (and not the PI), there are two ways to do that. You can write these comments in the UD survey (described in Step 6 below), which is never seen by the PI. You can also write comments to the chair in Reader Comments and just make a note that they are not to be shared with the PI.
 - **After** writing Reader Comments for a particular question, click on the Request Revisions box below. This will let the chair know where to find your comments. Mentor marks proposal sections with questions requiring revisions in red at the top (e.g., **Revisions Required: 3**, meaning there are three questions needing to be revised). Mentor also marks individual questions requiring revisions by underlining Reader Comment at the bottom of the question.
 - **PLEASE DO NOT USE** the single Request Revisions box on the main proposal page (located at the top right, above → **ACCESS HPRB PROPOSAL SECTIONS HERE (to edit, review, revise)**). This is for the HPRB chair to formally request revisions. It generates an email that goes out to the PI.
 - You can also edit attached study documents directly. Access attachments (e.g., recruitment scripts, consent documents, study instruments, debriefing, etc.) on the main proposal page (at the bottom). If these are Word documents, you can edit them directly and/or provide comments using the Review function. You can then upload back into Mentor and the chair can give the PI access to them.

Step 6: There is also a Unit Designate survey. You can access it on the main protocol page. There is a **Review** button at the top of the page. Click on this and the UD survey will come up.

The UD survey is designed to give you an idea of what you should be looking for. It may be helpful to open a second Mentor window and have the UD survey in one window and the HPRB proposal in the other, so you can go back and forth between the two. The UD survey questions include check boxes, as well as places to include comments. You can write comments directed to the chair and NOT the PI here.

It is not necessary to duplicate comments you wrote in the proposal sections here. Instead, just say, "see proposal section for comments."

Step 7: **CRITICAL:** When you have completed the UD survey, **change the status to Completed** (in the drop down menu). **DO NOT** select Pending Revisions. The only way that I will be notified that your review is ready for me to look at is if you select **Completed**. When the status is changed to Completed, Mentor automatically notifies the HPRB chair that the proposal is ready for the next level of review.

AFTER YOUR REVIEW IS COMPLETE:

Step 1: HPRB chair reviews all materials, conveys UD comments to student/faculty supervisor, provides additional comments if needed, and generates an email to the student/faculty supervisor that either:

- Requests revisions: 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., **Revisions Required: 3**, meaning there are three questions that need to be revised). Questions requiring revisions are indicated by underlined Reader Comments at the bottom of the question.
- Makes a final determination on the proposal (e.g., approves it, verifies is as Quality Improvement, verifies that is not considered "human subjects research" as defined by federal regulations).

Step 2: If revisions are requested within proposal sections, PI makes changes by:

- Editing responses to the questions directly using the Edit Answer button.
- Responding in Reader Comments (e.g., to provide further information or provide a rationale for not making the requested changes)
- Once complete, PI clicks Submit Revisions for Review box at the bottom of each question. This makes the **Revisions Required** text go away and be replaced by **Revisions Submitted**.

Step 3: If revisions are requested to study documents, PI makes necessary changes by:

- Editing study documents and uploading revised versions on main protocol page
- Adding missing documents on the main protocol page

Step 4: When all materials are complete, PI clicks Submit Revisions for Review button at top left of main protocol page. This notifies the HPRB chair that materials are ready for review.

Step 5: This cycle can continue... or it can end with a final determination letter from the HPRB chair.

If there are any questions or feedback on these instructions or Mentor, please contact the HPRB at: hprb@plu.edu.