

Human Participants Review Board

Purpose:

Pacific Lutheran University, through the operation of its Human Participants Review Board (HPRB) protects all human participants in research conducted in connection with the university from unnecessary and morally objectionable exposure to risk. The term, “risk” in the research context refers to potential physical harm as well as possible psychological, social, legal, economic, and/or moral adverse effects. The HPRB is registered with the Department of Health and Human Services [DHHS] Office of Research Protections [OHRP], and its policies and procedures conform to federal and state regulations for the protection of human subjects in research.* In carrying out its mandate, the HPRB provides ongoing education to the PLU community on protection of human participants in research, and it oversees research to ensure safety and compliance.

Board Members & Appointments

The HPRB consists of five members appointed by the University president for three-year overlapping terms. PLU complies with the following additional federal regulations for institutional review boards:

- At least three board members shall be faculty.
- One member shall not otherwise be affiliated with the university and shall not be part of the immediate family of someone who is affiliated with the university.
- Members shall include at least one person whose primary concerns are in scientific areas and at least one person whose primary concerns are in nonscientific areas.
- The board shall be sufficiently qualified through the experience, expertise, and diversity of its members, (including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes), to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the board shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The board shall therefore include persons knowledgeable in these areas.
- In appointing members of the board, the president may consult with the Provost, deans, and other faculty information sources to identify appropriately qualified members to serve on the board.

**See DHHS Code of Federal Regulations (Title 45 CFR 46) on HPRB website: <http://www.plu.edu/~hprb>.*

HPRB Functions:

- Review and approve, require modifications in, or withhold approval of all proposals for research at PLU that are conducted with human participants for their risk potential, including potential physical harm as well as psychological, social, legal, economic, and/or moral adverse effects;

- Monitor ongoing research with human participants at PLU and carry out authorized procedures to ensure that corrective actions are taken if unacceptable human participant risks are identified. The HPRB has authority to suspend research if unacceptable risks are not (or cannot) be corrected;
- Serve as a counselor to investigators on strategies to minimize risk to research participants and protect participants' rights;
- Support the university's education of investigators regarding protection of human research participants;
- Make recommendations to the Provost on the university's compliance procedures with federal regulations regarding research involving human participants;
- Report non-compliance with federal regulations to the DHHS Office of Human Research Protections [OHRP];
- Respect the academic freedom of investigators in choices of subject matter and methodology, so long as these choices are consistent with human subjects protection guidelines;
- Maintain adequate documentation of HPRB activities.

HPRB Unit Designates:

HPRB unit designates shall be chosen within the administrative units of the university in which research is conducted with human participants. The responsibilities of the unit designates are to:

- receive all new HPRB applications (research proposals) from investigators in their respective units;
- do initial review of HPRB applications (research proposals) for completeness, clarity, and their eligibility for exempt (versus non-exempt) status;
- give conditional approval of "exempt status" for HPRB applications that ONLY include research activities specified as "exempt research" by the HPRB (see HPRB Policy & Procedure Manual, Chapter 3);.
- forward proposals to the chairperson of the HPRB with a recommendation for exempt or non-exempt review status;
- serve as a liaison between the HPRB, faculty, and administrators in their respective units to facilitate timely communications.

For detailed information on HPRB policies and procedures and related federal regulations, see the HPRB Policy and Procedure Manual on the HPRB website [<http://www.plu.edu/~hprb>]. Hard copies of the HPRB Policy and Procedure Manual (with full Appendices) and related support materials are available for review in the Provost Office.