

IRB Policies and Procedures  
Point Loma Nazarene University

*Statement of Purpose*

**Point Loma Nazarene University is committed to the protection of the well being of human participants.**

An institution that encourages the conduct of research with human subjects has an ethical obligation to ensure that adequate safeguards are implemented in the conduct of that research to protect the rights and well being of the subjects of that research. The Institutional Review Board (IRB) has been charged with the development of review procedures to enhance the capacity of the institution to protect the subjects of research performed by faculty/staff and students of the institution. The IRB is mandated to protect the welfare of human subjects in research and should not be conceived as functioning as an advisory board for the enhancement of the research activities of individual investigators.

*Composition of Institutional Review Board*

Vice President for Student Development or designee, Faculty member from the Department of Psychology, Faculty member from the Department of Sociology and Social Work, Faculty member from the School of Nursing, and Student from ASB, all ex officio members. The chair must be a full-time faculty member of PLNU and is elected annually at the end of the spring semester.

*Duties of the Institutional Review Board*

The IRB will implement this policy in accordance with all relevant laws and regulations. To do so, the IRB will create procedures, forms and other instruments, as it deems necessary. If anything in this policy or in IRB procedures, forms, or other instruments (collectively “policy”) can be construed to conflict with governing law, then the IRB will bring such possible conflicts promptly to the attention of the Provost, pending amendment of the policy, will implement the policy in a manner that conforms with the IRB’s understanding of the law.

There are three categories of proposal evaluation: exempt from further review, expedited review and full review. Proposals meeting the criteria for exemption still must be submitted to the IRB Chair to be filed. Proposals meeting the criteria for expedited review will be evaluated by the IRB Chair and one other member of the IRB. Full review proposals will be evaluated by the entire IRB at designated times.

*Responsibilities of Researchers, Faculty Advisors, Instructors and Research Sponsors*

- A. It is the researcher’s responsibility to comply with all relevant laws and regulations affecting research involving human subjects.

- B. The researcher must submit to the IRB Chair a research proposal following the guidelines presented on the Cover Sheet, which is to accompany all research proposals.
- C. At the end of the study, the researcher must submit a Summary/Continuation Form to the IRB Chair. If the research will continue beyond the yearly anniversary from the previous approval, a Summary/Continuation Form must be submitted *in a timely fashion* prior to that date. It is the researcher's responsibility to determine whether full or expedited review is possible at the one-year anniversary of approval date. (See 45 CFR 46.110 by clicking *Regulations* at <http://www.hhs.gov/ohrp>.) 45 CFR 46.110 specifies the guidelines for determining when expedited review is possible. Should the researcher fail to submit the Summary/Continuation Form in a timely fashion the research **MUST** stop until the form is completed and acted upon.
- D. If during the research an adverse event occurs (See <http://www.osp.cornell.edu/Compliance/UCHS/Adverse.htm>), the researcher **MUST** stop the research and immediately report the event to the IRB.
- E. Instructors conducting classroom projects and faculty advisors of student projects are responsible for insuring that student research conducted under their direction must conform to the requirements of federal law and regulations on research regarding human subjects. Instructors and advisors must review the current Federal Policy for the Protection of Human Subjects, 45 CFR 46 (1991, as amended) to determine whether the process for IRB review must be initiated and, if so, which level of review (see Sections A, B, and C) is appropriate. In doing so, instructors and advisors should pay particular attention to the definition of 'research' [45 CFR 46.102(d)] and the categories of exemption from detailed review [45 CFR 46.101(b)] contained in the Federal Regulations. Click *Regulations* at <http://www.hhs.gov/ohrp>. Evidence of IRB approval of thesis/dissertation research involving human subjects must appear in the bound copy of the project. If unsure how to proceed, instructors and advisors should contact the appropriate College/School representative on the IRB prior to continuing with the project.
- F. PLNU sponsors have primary responsibility to ensure that all research conducted by outside agents under their sponsorship is conducted in accordance with all relevant regulations, laws and PLNU policies.

### *Administrative Responsibilities*

The IRB Chair will call the first meeting of the committee, schedule meetings for proposal review, and send a letter to the P.I. regarding the evaluation of the committee. If approved, the informed consent is stamped, signed and returned to the P.I. by the IRB chair. Additionally, the IRB chair will file minutes of meetings with the Provost's office. The IRB chair will prepare an annual report that includes a listing of all proposals

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submitted to the IRB and an indication of the action taken. This, along with copies of the proposals, will be filed in the College Archives.

*Violations of Human Subject Policies and Procedures*

The IRB will investigate alleged violations of these policies and procedures, and report its findings to government agencies as required by law (See 45CFR 46.113 by clicking *Regulations* at <http://www.hhs.gov/ohrp>) to the Provost, and to the President.

*Institutional Research*

Research (See definition at 45 CFR 46.102d by clicking *Regulations* at <http://www.hhs.gov/ohrp>) conducted by the University for the evaluation of its programs or to provide information for planning, policy formation, and decision making, is subject to the same criteria as any other research as defined in 45 CFR 46.102d.

*Thanks are extended to the University of San Diego on whose Institutional Review Board Policy this policy is substantially based.*