

POINT LOMA NAZARENE UNIVERSITY
Institutional Review Board (IRB)

SECTION C:
FULL REVIEW
(proposed research not eligible for Expedited Review)

1. Attach a **succinct** description of the proposed research, using numbered pages. Be sure to address each of the following issues, with particular attention to potential risks to participants and what will be done to minimize those risks.
 - a. Briefly describe the study, giving its justification and rationale.
 - b. Who are the subjects? How will you recruit them? How many will be used? Specifically, note whether subjects belong to a protected group as defined in 45 CFR 46.111(b) and see Subparts B and C there for further details. Click *Regulations* at <http://www.hhs.gov/ohrp>.
 - c. What steps will you take to assure the participation is voluntary?
 - d. What will the subjects do? How will you interact with the subjects (e.g., describe any bodily invasive procedures)?
 - e. Describe all the equipment you will use or with which the subject will interact.
 - f. Attach copies of questionnaires or other materials that will be used (such as interview questions or topics, experimental stimuli or other instruments).
 - g. Note the estimated time duration of subject participation.
 - h. Will the subjects incur any expenses? If so, please explain.
 - i. Name the facilities other than PLNU where research will be conducted and provide copies of any letters of permission or support that you have obtained. If you have not obtained any letters, please explain.
 - j. List the foreseeable risk(s) to subjects, describe how you will minimize each risk, and why each risk is justifiable in light of benefits (either directly to the subject or indirectly to generalizable knowledge) to be gained by the research.
 - k. Document how informed consent will be gained. Include the exact words and method of delivery that will, prior to their agreement to participate, inform subjects of the nature of the study and of the extent of their involvement. Attach a copy of the consent form(s). This form will be examined closely.
 - l. Explain how debriefing will be handled.
 - m. If copyrighted tests, scales, or inventories are to be used attach a copy of the approval letter.
2. Send SEVEN PAPER copies of the proposal to the chair of the IRB.
3. Once your research proposal has been filed with the IRB, your project will be subject to approval for one year. After one year, you must fill out a summary of your project or fill out a continuation form and submit this to the IRB.