Helpful Hints in Submitting to IRB

Introduction

The Institutional Review Board (IRB) at PLNU is established to protect the safety of human subjects in research activities involving the University, faculty, staff, students, and partner organizations. To accomplish this task, the IRBV works to ensure compliance with the Code of Federal Regulations, Title 45 of the Public Welfare code for the U.S. Department of Health and Human Services, part 46 governing the protection of human subjects, including subsections A through E.

All research involves some minimal level of risk. Some risks are no greater than what would be part of typical daily activity. In ensuring the protection of people involved in human subjects research the IRB focuses on the potential risk compared with level of benefit associated with the study. If there are participant risks but there is little benefit that is likely to result from the study, the IRB will want to assure that there is sufficient benefit to warrant the level of risk.

What your proposal packet must contain:

- The correct cover sheet, fully completed and signed. The current sheet has a space for a project number in the top right corner AND a space for a course number in the middle of the page (2d).
- The appropriate narrative Section A, B, or C that matches the review category you selected on the cover sheet.
- A copy of the invitation for people to participate in the study
- A description of the purpose, benefits, and potential risks involved in the study and how the project will resolve the risks
- A copy of the consent or assent form that includes a description of how anonymity or confidentiality will be preserved, and what happens to the information collected.
- Debriefing information
- A copy of the survey or instrument you will use to collect information, including evidence of permission to use any copyrighted material
- A letter of approval from the appropriate representative of other institutions involved in the study (For example: Permission from a school administrator if the study is being conducted at that location).
- Other documents as required for expedited or full review proposals – see Sections B and C.
- A clear notice that participants may skip any item and may stop participating at anytime without negative consequence.

Helpful hints for completing the Cover Sheet:

- Be sure to indicate both the review type and the category for item 3 on the proposal cover sheet;
- List any item that does not apply to the study as NA – **do not leave blanks**;
- Have your faculty advisor or PLNU sponsor review your packet and sign the cover page;
- Scan the signed cover sheet so that you can include it in your proposal packet;
- Make sure that the cover sheet is **signed**. **Unsigned proposals will be returned.**

Timeline and Helpful Hints in Submitting Your Proposal

- Submit **early.** The IRB may have questions or comments that will require response. Allow time for this possibility.
- Create a .pdf file of all your proposal documents and email it to the Chair of the IRB with **IRB + your last name in the subject line**
- For projects requiring full review, submit the application and all supporting material by the beginning of the 3rd week of the month, allow a minimum of 2 weeks after the scheduled IRB meeting for processing.
- The IRB meets one time per month during the traditional undergraduate year. Please advise the IRB by May 1st if you anticipate submitting a project requiring full review during the summer months.
- Submit the cover sheet with the original signatures as a paper copy to the IRB mailing address (Currently Rohr Hall #103 on the PLNU main campus).

Management of Information in Your Proposal

- It is recommended that you to use the requested items in Section A, B, or C, as the outline for your narrative.
- Remember – confidential is not the same as anonymous. Confidential means that personally identifying information is collected and must be maintained in a manner that protects that information from being shared and protects the individual from potential harm as the result of the information. Anonymous means that no personally identifying information is collected.
- If you do not need to have personal identifies (name, DOB, SSN, ID number), make it easy on yourself – use anonymous data gathering methods.
- All research with human subjects can pose risks. The keys in protecting human subjects are: 1) advising the participants of the risks; 2) minimizing the risks; 3) gaining voluntary consent to participate; and 4) assuring that the benefits of the study outweigh the risks to participants.
- **Do not say "there are no risks in this study.** Alternate statements such as: " there are no known risks" "there are no anticipated risks," "there is minimal risk," "the risks are no greater than those in everyday life" which are followed by a statement about what will occur if an unanticipated negative event occurs.
- Describe the resources that are available to the participant if (s)he feels negatively impacted by the study. The following are examples of statements to remedy a negative impact: "If a participant experiences discomfort, (s)he can consult with the faculty adviser, the IRB Chair, or contact the PLNU Wellness Center as resources" or "Participants will be provided a list of resources to resolve their discomfort."
- Always include your contact information, your faculty supervisor information and the IRB Chair contact information in your debriefing.

SUMMARY- SUBMIT FULLY COMPLETED

Cover sheet
Section A.B or C
Consent Form/ Statement

Debriefing Instructions / Statement
Information Gathering instruments (surveys, tests, tools, description of measures)
Permission to use instruments or surveys protected by copyright
Permission to conduct research if being conducted in another setting or institution

REMEMBER

Review and consult the regulations at 45 CFR part 46 when determining which category governs your research.
Each project **must submit a summary form** at the end of the research project.
Faculty advisers may want to include a due date for submittal of this form by their students.

IMPORTANT LINKS

Federal Regulations: HHS- OHRP, 45 CFR part 46
http://www.hhs.gov/ohrp/ (then choose regulations)

Point Loma IRB homepage on the portal
https://portal.pointloma.edu/web/institutional-review-board