INSTITUTIONAL REVIEW BOARD

GUIDELINES FOR THE PREPARATION OF A PROPOSAL

March 2017

As detailed in the IRB Manual, Section VII, “Proposal Submission,” Principal Investigators who are conducting human subjects research are required to submit a complete proposal using the IRB Proposal Form (March 2017). This document, Guidelines for the Preparation of a Proposal, provides additional information to assist in the completion of the IRB Proposal Form. Proposals must be submitted as a Microsoft Word document. The IRB cannot adequately review proposals or supporting documents submitted as PDFs, JPGs, Google Docs, HTML, etc. The only exception is that pages which require a signature (the title page, the IRB Proposal Checklist and the Principal Investigator Assurances) may be submitted in a PDF format. Proposals shall be submitted to the Institutional Review Board (IRB) chair or the chair’s designee. Proposals shall not be distributed by the investigator to individual board members. Proposals should be submitted as early as possible prior to the intended date for commencement of research activities. Some proposals may require a Board meeting. Approval can usually be granted within two to three weeks of receipt of the application; however, the IRB does not guarantee approval within a certain period of time from submittal of application. Factors that affect approval time include the level of review, quality of the proposal, complexity of the proposal, the extent and magnitude of comments from the Board and the completeness and timeliness of the response to the Board’s review by the researcher.

All investigators and research advisors must successfully complete the CITI Program’s Human Subjects Research course. A copy of the certification of completion of the training must be included with the proposal.

The proposal, as approved by the Institutional Review Board (IRB), becomes part of the agreement between Indiana Wesleyan University (IWU) and the investigator(s) about the way in which a project will be conducted. Therefore, the research protocol must be an accurate description of the research project. The protocol, informed consent documents and other supporting materials become part of the public record of the IRB’s deliberations. Any change in the approved protocol, including supporting documents, must be approved by the IRB. In order to ensure the integrity of the research study, the protocol will not be available for review by the public until the research project is completed.
Each IRB approval is of limited duration (commonly one year) with a specified expiration date. If the project will extend beyond the approval expiration date, a new proposal may be requested by the IRB for review.

A proposal is a written statement, signed by the Principal Investigator and Research Advisor (if applicable), which conforms to provisions 1 through 19 below. (Please do not include the below detailed instructions for steps 1 through 19 in your proposal):

1. A summary of the nature and purpose of the research.

2. A title page which conforms to the displayed format. Signatures must be hand-written. Signatures created by typing will not be accepted.

3. A proposal signed by the research advisor if research is to be conducted by student(s). The signature of the research advisor indicates acceptance of responsibility that the research will be conducted in accordance with ethical principles concerning the protection of human subjects and the institution. **NO STUDENT INVESTIGATOR PROPOSAL WILL BE ACCEPTED WITHOUT THE SIGNATURE OF A RESEARCH ADVISOR.** Signatures must be hand-written. Signatures created by typing will not be accepted.

4. A full description of the human subjects who will be involved, their characteristics, total number anticipated for the study and how they will be selected. Indicate explicitly whether any subjects are minors (under age 18) or are otherwise members of “vulnerable” populations (such as pregnant women, prisoners, hospital patients, or inpatients in state hospitals [such as the mentally infirm or disabled], or others whose ability or competence to give voluntary informed consent may be questioned). Populations subject to “undue influence” (e.g. college classes, employees, interest groups, clubs, Sunday School classes, and /or Bible study groups) should be considered “vulnerable” as well. The reason for using minors or members of “vulnerable” populations as subjects should be stated clearly.

5. A full description of exactly how the subjects will be used in the research.

6. If cover letters, questionnaires, interview schedules and/or follow up communications are to be used in the research, a copy of each should be attached. If such are not available at the time of submission, an informative description of their content and manner of administration should be included in the proposal. The completed versions must be approved by the IRB PRIOR TO USE.

7. A full description of how subjects will be recruited.

8. A description and assessment of the potential risks, if any, to the individual human subject, and/or the group or class of which the subject is a member, and/or to society in general as a result of the research. Such risks may be physical, psychological, spiritual or social. Assess the likelihood, severity and duration of such risks. Note that there may be unforeseeable risks that were not anticipated in advance of the project. If the research methods create potential risks, describe other less risky methods, if any, which were considered and explain why they will not
be used. An explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research-related injury to the subject and the name and telephone number of the investigator must be included. Include a statement that describes the plan for medical care or counseling in case an untoward event occurs.

9. A description of the means to be taken to minimize such risks including the means by which the subject’s personal privacy is to be protected and the confidentiality of the information obtained from the subject maintained. Assess the likely effectiveness of such precautionary measures.

10. A full description and assessment of the potential benefits, if any, to the individual human subject, and/or to the group or class of which the subject is a member, and/or to society in general as a result of the research. Compensation is not to be considered a benefit.

11. A description of how medical and/or counseling services will be provided if the subject suffers adverse health effects as a result of the research.

12. A description of any known conflicts of interest held by the Principal Investigator(s), Research Advisor and/or anyone else involved in the research.

13. An explanation of any special or unusual circumstances regarding the research which the principal investigator believes could be relevant to the IRB’s decision in reviewing the project.

14. A description of the procedures to be used in obtaining and documenting the prior informed consent of the subject. A copy of the informed consent document must be attached to the proposal. Additionally, if applicable, a verbatim copy of any accompanying oral instructions must be attached to the proposal. If online consent is being used (for example, with an online survey), the text of the informed consent that will be presented and an explanation of how the potential participant will provide consent must be included in the proposal. If subjects are minors, subject “assent” may be required as well as parental/guardian informed consent. A copy of the form “Consent for Child to Participate” is included with the proposal forms.

15. A waiver of written consent must be requested from the IRB if the investigator does not wish to use a written informed consent. If a waiver of the requirement for written informed consent is sought, the justifications for the waiver must be specified.

16. A copy of State and/or Federal documents, which permit the investigators to proceed if a new drug or device is to be tested or used in the project.

17. A copy of the certification of completion of the CITI Program’s Human Subjects Research course

18. Completed IRB Proposal Checklist

19. A copy of the Principal Investigator Assurances (see IRB Proposal Form document)
20. It is the responsibility of the investigator to supply a signed, electronic copy of the proposal (along with copies of the questionnaires, interview schedules, informed consent documents, assurances and other supporting materials) to the IRB Chair or the Chair’s designee.

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Portions of the Azusa Pacific University Institutional Review Board Handbook were helpful in the creation of this document.