

Human Participants Review Board Checklist for Student Researchers

(v09/05)

- For clarification in any area, please visit the web site: <http://www.plu.edu/~hprb/>
 - For information on your responsibilities as a researcher for the protection of human participants, please enter the following web site and complete the self-study module: <http://cme.nci.nih.gov/>
1. Are you **conducting research**? _____ *Research is defined as a systematic investigation (including development, testing and evaluation) designed to discover or contribute to knowledge. Not all research involves human participants, but when they are involved researchers and their teams are legally and ethically obligated to protect human participants. If your answer is “no,” you do not need to continue.*
 2. Does your research **involve human participants**? _____ *The human participant is a living individual about whom a researcher obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information. Since data is collected directly or indirectly by the researcher, protection of participants extends to a wide range of research, including that which involves tissue specimens, medical records, genetic material, behavioral and/or biomedical assessments, and treatments. If your answer is “no,” you do not need to continue.*
 3. Is your study **properly designed, scientifically sound** and believed to yield valid results? _____ *You and your faculty member should answer this question prior to submitting the proposal to HPRB. If the study is not well designed, you may be subjecting human participants to inconvenience and risk for no real reason? If your answer is “no,” please review and revise your study design.*
 4. In **recruiting and selecting participants** for research:
 - Have you ensured that selection is equitable and that participation is voluntary? _____
Have you ensured that there is no real or imaginary pressure to participate? _____
If your answer is “no” to these questions or you are not sure of your answer, please consult with your faculty supervisor prior to submission.
 - Are your participants vulnerable? _____ *(Vulnerable research participants are persons who are relatively or absolutely incapable of protecting their own interests such as children, prisoners, fetuses, individuals with questionable capacity to consent, the terminally-ill, and students/employees.)* If you are using a vulnerable population, then you must include additional safeguards for their safety and welfare. Please consult with a HPRB member prior to continuing.
 - Have you used recruitment posters or advertisements? _____. If your answer is “yes,” you must include a copy with your proposal and documents. *Recruiting materials are considered part of informed consent. Where are you recruiting?* _____
 - If you are planning to recruit study participants in a school, agency or other organization that is not PLU, you need a letter on the agencies’ letterhead signed by the official(s) who have authority to grant permission to recruit, interview, or survey participants at the agency. A copy of this letter must be included with your proposal.
 5. Prior to obtaining informed consent, you must determine the **risk** involved with study participation. Please read the definition of risk on at the following web address, http://www.plu.edu/~hprb/info/definitions_risk.html, prior to determining risk. Check the possible risk involved in study participation:
_____ Physical? _____ Psychological? _____ Social/Economic?
_____ Legal (self-incrimination)? _____ Confidentiality? _____ Minimal?

If you have checked any of the above risks other than minimal, does your proposal describe how you will minimize the risk? _____. (If the answer is “no,” you need to consult with your faculty supervisor prior to submission.)

Research studies dealing with drug and alcohol use, illegal behaviors, sexual behaviors, violence, self-destructive behaviors, and like topics often involve risk that fits in one or more of the above risk categories and will go to full HPRB review.

6. Are you maintaining **anonymity**?_____ Is it impossible for you to identify the participants in your study? If your answer is “no,” then have you planned to do the following to insure **confidentiality**? _____ (*Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged without permission to others in ways that are inconsistent with the understanding of the original disclosure.*)

Substitute codes for identifiers or encrypt identifiable data. _____
 Remove face sheets (containing identifiers such as names and addresses) from survey instruments containing data. _____
 Properly dispose of computer print-outs and other papers. _____
 Limit access to identifiable data to researcher. _____
 Store paper research records in locked cabinets or provide security codes for computerized records. _____
 If using audio or video tapes, maintain in a locked cabinet until transcribed and then destroy. _____

If your answer to any of the above was “no” instead of “not applicable” or “yes,” then you need to consult with your faculty supervisor on how to maintain confidentiality of your subjects.

Does your study involve **sensitive, stigmatizing, or illegal personal information**? _____ (*In studies of participants with sensitive, stigmatizing or illegal personal information, keeping the identity of participants confidential becomes paramount. Confidentiality is not enough, anonymity is the standard. Any identifiers must be removed from the instruments.*) If you answered “yes,” your proposal should clearly outline how anonymity is maintained.

7. Have you insured **informed consent** of your participants? The following components must be addressed in order to achieve informed consent:
- a. An explanation of the purpose of the research to include what will be done with the results, who the researcher is (state if student researcher) and his/her PLU affiliation _____
 - b. The expected duration of the subject's participation; _____
 - c. A description of the procedures to be followed _____
 - d. A description of any foreseeable risks or discomforts to the subject, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them; _____
 - e. A description of any benefits to the subject or to others that may reasonably be expected from the research. _____
 - f. A statement describing to what extent records will be kept confidential, including a description of who may have access to research records;* _____
 - g. For research involving more than minimal risk, an explanation and description of any resources that are available if required; where further information may be obtained, and whom to contact in the event of a research-related adverse experience. _____
 - h. An explanation of whom to contact for answers to pertinent questions about the research (both researcher and faculty supervisor’s name and contact number) and the research subject's rights (include the telephone number of the Office of the Provost, 535-7125);
 - i. A statement that participation is voluntary and that refusal to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which the subject is otherwise entitled. _____

- j. A statement that participants will be given a copy of the consent form _____

If you answered “no” to any of the above, there are sample consent form templates available at :
<http://www.plu.edu/~hprb/> .

After you have completed your **informed consent** document, ask the following questions. (*In order for consent to be informed, it must be **understandable to the participants; be written, include all the basic components, and be completely voluntary.***)

- a. Is it written at a reading level understandable to research subjects? _____ (This depends upon your participants. Most recommend that consent forms be readable to those who haven't graduated from high school. To find out how to check the reading level of your material, go to <http://www.sph.emory.edu/WELLNESS/reading.html> .)
- b. Is the document formatted well? Does it have headings that break the text into short sections?

- c. Does your document include information on how to contact the researcher(s)? _____

If you answered “no” to either of the above, rewrite your consent document.

8. Would your study be compromised, by including all the elements of informed consent? _____ If you answered yes, you may consider using **deception**. Any use of deception requires a full board review. And the following must be addressed:
 - a. Has it been carefully determined that deception is the only way to accomplish the end and that the deception is justified by the study's potential benefit? _____ If you answered “no,” please consult with your faculty supervisor.
 - b. Are you planning to deceive participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences? _____ If you answered “yes,” your study will not be approved.
 - c. Do you have a plan to explain the necessity of the deception to the study's design to the participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research? (*This debriefing should completely inform the participant of the purpose and the procedures as well as the reason for the initial deception.*) _____ . If you answered “no,” please consult with your supervising faculty. You must include such a plan to have your proposal approved.
9. Have you included a sufficient **number of copies**? _____ (*You will need five copies if participation involves greater than minimal risk, a sensitive subject (alcohol, drug, sexual, illegal, or violent activity, etc), deception, and/or a vulnerable population. All others must submit two copies. Your review may be held up if inadequate copies are submitted.*)