WESTERN ILLINOIS UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Instructions for Completing the WIU IRB Protocol and Materials for the Review of Research

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1. Existing data:

If your research *only* involves the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly availability or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects you should *only* complete the following items:

- Section 1. Research Personnel
- Section 2. Funding or Anticipated Funding Source
- Section 3. Participant Population and Recruitment, items: 5, 8, and 9.
- Section 5. Study Description, items: 1, 2, 3, and 4.
- Section 6. Study Procedures, items: 1, 2, 4, 5, and 7.
- Section 7. Data Privacy and Security, items: 1, 2, and 3.
- Section 8. Risk-Benefit Analysis, items: 1, 2, 3, 5, 7, 8, and 9.
- Section 9: Miscellaneous, items: 1 and 2.
- Section 10. Assurance and Signatures

2. Completing Section 1 of the IRB form (Research Personnel):

a. Personnel:

Include all individuals who will interact or intervene with human subjects or their private, identifiable information. Additional personnel can be added under Section 9. If new members are added to your research team after IRB approval, the PI must submit the WIU Review and Monitoring Form with the information below.

i. A student investigator cannot be listed as the Principal Investigator/Faculty Advisor on the project. The Principal Investigator/Faculty Advisor on the project must be a faculty or staff member at WIU. This individual is responsible for the conduct of all research personnel.
ii. If you have an entire class conducting research under the same protocol you are not required to have all members of the class listed under this section, nor do they all have to sign under section 10. However, you must include with your IRB materials the class roster and all training certificates. Under these procedures, the Faculty Advisor is taking responsibility for the conduct of the research in the class.
iii. Faculty are not permitted to require their enrolled students to serve as research assistants/investigators (including data collection) in the faculty's personal research, unless the student has enrolled in a class designed for this purpose.

b. Training:

Before researchers engage in research that involves human subjects at Western Illinois University they must complete the mandatory online research training modules. Faculty, graduate students, or undergraduate students working on an independent project (including Honor's projects) must complete the National Institute of Health modules. Please navigate to the following link for training: http://phrp.nihtraining.com/users/login.php. Upon completion of this training, the researchers will be able to print out a "Completion Certificate". This certificate must be included as part of the protocol or on file in the Office of Sponsored Projects to be reviewed by the IRB. If you do not have a copy on file in the Office of Sponsored Projects, please submit a copy with your protocol. No protocol will be approved without this certification. Under Section I. indicate which training has been completed for all of the personnel on the research team.

As an alternative to the NIH training, researchers can complete the Social and Behavioral Research CITI training modules: http://www.citiprogram.org. For undergraduate class projects, students have the option of completing the Collaborative Institutional Training Initiative (CITI) modules. Detailed instructions can be found at: Class Projects Training. Training certificates must be submitted for all students.

3. Section 3: Participant Population and Recruitment:

a. Recruitment of Enrolled Students at WIU:

WIU has a policy that faculty are not permitted to recruit their enrolled students as participants in their own personal research projects.

b. Recruitment Materials:

Research recruitment materials must be honest and truthful representations of what the research entails. It should be considered one of the first steps of the informed consent process. You must submit all recruitment materials (e.g., email, cover letter, handout/flyer, web site/newspaper ad, and/or verbal announcement) for IRB review and approval. You must include the following information: a statement that you are conducting research, inclusion/exclusion criteria for participation (e.g., participants must be 18 or over), risks, benefits, and contact information for the research team. You should not over emphasize incentives or payments to participate.

4. Assurance Signatures:

All research protocols must be signed by each individual on the research team (i.e., all individuals who will interact or intervene with human subjects or their private, identifiable information), unless the research protocol is for the review of research from a student class project. Student research class projects should be signed by the Principal Investigator/Faculty Advisor. It should only be signed by all of the student research investigators if the faculty advisor wants all of them to sign the assurance. Regardless, the faculty advisor accepts responsibility for ensuring that all members of the research team: 1) complete the required training to fulfill their study responsibilities, 2) follow the study procedures as described in the IRB approved protocol and comply with Western Illinois University's Policy and Procedure for Human Subjects and all IRB communication and 3) uphold the rights and welfare of all study participants. All members of the research team must read and sign their own name under the assurance section, unless this is a student research class project. If new personnel are added after IRB approval you must notify the IRB by submitting the WIU Review and Monitoring Form.

5. Informed consent document:

Obtaining the informed consent of a potential human subject for participation in any research (whether an experiment, survey, interview, or demonstration) is a federally mandated safeguard for protecting the rights and welfare of all individual subjects. When consent forms require signatures of research subjects and/or their parents or legal guardians, a copy of the fully signed form must be given to the subject/parent/guardian and a copy must be retained by the researcher for a minimum of three years after completion of the project. The consent form should avoid jargon and should be presented in lay persons' language, and appropriate to the "audience." The

following list provides guidelines for meeting the basic requirements of a well-designed consent document:

- Disclose that the study involves research
- Explain the purposes of the research
- Explain the expected duration of the participant's participation
- Describe the procedures to be followed
- Identify any procedures that are experimental
- Describe any reasonably foreseeable risks or discomforts to the participant
- Describe any benefits to the participant or to others which may reasonably be expected from the research
- Disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
- Disclose the extent, if any, to which confidentiality of records identifying the participant will be maintained
- For research involving more than minimal risk, explain whether any compensation is available if injury occurs, whether any medical treatments are available if injury occurs, and if so, what they consist of and where further information may be obtained
- Explain whom to contact for answers to pertinent questions about the research, research participants' rights, and whom to contact in the event of a research-related injury to the participant
- Disclose that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled
- Inform participants if the research will be video or audio recorded.

For more information regarding informed consent procedures, please see: http://www.wiu.edu/consent.

6. Minor Assent and Parental Consent Form:

When children/minors under eighteen are involved in research, assent must be obtained from both the parent and the child/minor. "Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent". (45 CFR 46.402)

The language of the assent form should be geared to the cognitive level of the children being asked to participate in the research study. The minor should be given explanation of the proposed research procedures, the purpose of the research, and any discomforts, in language that is appropriate to the child's age, experience, maturity, and condition. A particular child subject's capacity to assent must be evaluated on an individual basis.

7. Research materials (e.g., surveys, interview items, questionnaires for data collection, etc.):

You must submit all testing instruments, surveys, interview items, and/or additional research materials which will be used in the research for review and approval (including demographic items, data collection sheets, and observational protocols). Be consistent throughout your IRB materials by using the same titles/labels to identify your materials. For all submitted documents, include a title/label at the top of the document. Avoid using acronyms unless you have provided a full citation for the measure (e.g., The Need to Belong (NTB)….). Do not submit copyrighted or print restricted materials. On the IRB protocol, in the space provided include a description of the materials and indicate that there are copyright or print restrictions.

8. Letter(s) of support:

WIU researchers who participate in off-campus research must receive approval from the WIU IRB *and from* the IRBs at any outside institutions participating in or sponsoring the research. If no IRB or IRB-like committee exists at a given institution, researchers should consult the WIU IRB on how to document the outside institution's approval. Researchers might be required to provide formal, written assurance that the research will be conducted according to ethical standards. The WIU's approval of off-campus research is made contingent on outside institutions' approvals and assurances.

Off-campus research at sites that are not formally affiliated with an institution, government, or other agency (*e.g.*, in foreign countries or remote locations) must still receive approval from the WIU IRB. The research must be approved by the local equivalent of an IRB for the off-campus site or, where there is no equivalent group, by local experts or community leaders. Appropriate permissions must be documented.