Institutional Review Board
For the Protection of Human Subjects
POLICIES AND PROCEDURES MANUAL
2013

General Policy

1. Statement of Applicability and General Policies:
    1.1. Wayland Baptist University has established the Institutional Review Board (IRB)

of the Faculty Senate). Unless a member of the IRB serves ex-officio, IRB

and is therefore subject to IRB review. A draft of the grant proposal, providing the goals, methods and expected outcomes of research should be provided before

4.8.3. If there is any doubt as to whether the project should be reviewed by the IRB, the IRB should be contacted for assistance.

4.8.4. In the event the IRB review is not needed for a particular classroom research project, the student researcher and the instructor are not relieved of the obligation for ethical use of human subjects. Consequently, the researchers should adhere to ethical standards and use informed consent when appropriate.

4.8.5. If there is reasonable expectation on the part of the instructor and the student that the study will be funded (regardless of source) and/or published, IRB approval must be obtained.

4.8.6. In instances where a class of students will be conducting group or individual research projects as a part of the classroom instruction, and the instructor believes that, under our guidelines, IRB approval is required, the instructor shall present for Committee approval one form setting forth the parameters of the research being conducted by the students. The instructor should describe the types of research to be undertaken by the students, the nature of the subjects used, and the kinds of procedures to be used in the research projects. This means that individual forms are not to be filled out by each student researcher as long as the research falls within the parameters described in the "umbrella" form. Any research not within the described parameters would require separate approval.

5. Categories of Research

5.1. The IRB recognizes three categories for review:

5.1.1. Full Review. Research that presents more than minimal risk and/or involves vulnerable populations. Consent is required unless waived by the IRB.

5.1.2. Expedited Review. Research that is minimal risk and falls into one of two categories listed in 5.3.2. Consent is required unless waived by the IRB.

5.1.3. Exempt Review. Research that is minimal risk and falls into one of five categories listed in 5.2.1. Consent is not required, although some information is advisable.

5.1.4. All three categories of research must be presented to the IRB for review, and not begin prior to written approval being received from the IRB chair.

5.2. Exempt Review

5.2.1. Exempt Review shall be conducted by the WBU IRB chairperson or by his/her designee. Research is exempt when the only involvement of human subjects falls within one or more of the categories below and involves only minimal risk to the human subject: 1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 2) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available 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. 3) Research involving the use of educational tests (such as cognitive, diagnostic, aptitude, achievement tests), survey procedures,

or experts will be required to advise the WBU IRB in its review of a protocol,

7.2.4. Where a study involves children who are wards of the state, the regulations require that the researcher appoint an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis [45 CFR 46.409(b)].

subject. In reviewing the study, in addition to the usual criteria for approval, the IRB must find the following:

7.3.7. Any possible advantages accruing to the prisoner(s) through his/her participation in the study, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his/her ability to weigh the research risks against the value of such advantages in the limited choice environment of the prison is impaired, The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers,

7.3.8. Procedures for subject selection within the prison are fair to all prisoners and immune fromd baccand

welfare, and the procedures for protecting subjects implemented by the researcher and the adequacy of those procedures (e.g., informed consent). The Vice President of Academic Affairs is the final authority as to the course of action taken by WBU on the matter.

11.1.11. If the IRB determines that a researcher is deliberately or continuously out of compliance with the procedures stated in this manual, with 45 CFR 46, WBU's Assurance, has failed to adhere to stipulations of the IRB, or is found to have placed the welfare of subjects at unnecessary risk, the IRB will report the matter promptly to the Vice President of Academic Affairs, with or without a recommendation for specific action.

11.1.12. Repeated or willful violations of federal and state laws as well as WBU policy regarding use of human subjects in research are extremely serious matters. In such circumstances, the IRB has the authority to suspend or terminate approval of a study, or refuse to approve further research with human subjects by a researcher.

11.1.13. Policy violations could lead to violation of federal and state laws. In these cases the IRB will refer the matter to the WBU legal counsel.

11.1.14. The IRB may temporarily or permanently suspend approval of a study at any time. This suspension may not be overridden at any level at WBU (45 CFR 46.112).

11.1.15. The IRB may take such action in a wide variety of circumstances, including serious

13.2. Approve the proposal on the condition that it be revised according to recommended changes, in which case the application is returned to the principal investigator and/or faculty advisor for revision. A clean copy of the revised proposal must then be resubmitted to the WBU IRB. Data collection from human subjects may not begin until the investigator is notified by the chairperson that the revised proposal has been approved.

13.3. If the WBU IRB concludes upon reading the application that the type of review requested is not appropriate for the proposed research the application may be returned to the investigator, with the suggestion that it be resubmitted in the correct category.

13.4. The WBU IRB may disapprove of the proposal, based on inadequate protection of human subjects. The application for research review and reviewer evaluation will be forwarded to the School Dean, who will notify the investigator of the Board's decision. The application will be kept on file, along with a copy of the reviewer evaluation. A revised proposal may be resubmitted to the Board and the author(s) of the proposal may meet with the IRB for consultation.

13.5. The proposal should include the following: the purpose and rationale of the research, a description of the participants to be used in the study,

15.1.1.1. An electronic copy of the complete research proposal sent to the Vice President of Academic Affairs

assent and parental consent for all studies, unless a waiver is requested by the researcher and granted by the IRB.

15.2.3. The IRB recognizes that much of the research involving children poses no more than "minimal risk" for them. These suggestions are designed to assist researchers in drafting protocols for gaining children's assent to participate in research studies. Researchers whose procedures pose greater than minimal risk for their subjects can request additional assistance from the IRB in drafting protocols for assent.

15.2.4. What follows includes the definition of assent and guidelines for obtaining the assent of children of different ages. Because the ability of children to understand the elements of assent generally increases with age, researchers will likely provide less detailed explanations to younger children and more detailed explanations to older children. In addition, because there are individual differences in the development of children's ability to understand the researcher's requests, there is a necessary age overlap in the categories listed below.

15.2.5. Definition of Assent: "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent.

15.2.6. Ages 2-7 - For children between the ages of 2 to 7, the request for assent should be kept simple and direct. For example, the researcher might ask the child if he or she would join the researcher in the next room to look at pictures. If the child were to say "yes," that would imply assent for this age group. If the child were to say "no," the researcher should respect the child's wishes. It should be possible, however, to ask the child once again several minutes later. Sometimes children may not communicate verbally their refusal to participate. For example, a child may begin working on another task unrelated to the research activity. The researcher should be aware of such a cue and end the activity.

15.2.7. Ages 6-14 - For children between ages of 6 and 14, the request for assent should include: (1) a general description of the purpose of the child's participation; (2) a brief description of the experimental tasks; (3) an assurance that the child's participation is voluntary and that he or she may withdraw from the study at any point; and (4) an offer to answer questions. A researcher studying reading comprehension might say the following: "I am studying how fourth grade students read. I am going to ask you to read a few stories for me and answer questions about the stories when you are finished. You don't have to read if you do not want to do so. If at any point you want to stop, that is fine; you may stop and go back to class."

15.2.8. Ages 12-17 - For children ages 12 to 17, the request for assent should include the elements of informed consent presented to adults, but this request should be presented in language appropriate to the child's level of comprehension.

15.3.1.

15.3.1.20. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

15.3.1.21. A statement that any significant new findings developing during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject

Informed Consent Example

Title of Research: Single Parents Returning to College

Investigator: Don Ashley, Ph.D.

Before agreeing to participate in this research study, it is important that you read the following explanation of this study. This statement describes the purpose, procedures, benefits, risks, and precautions of the program. Also described is your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

Explanation of Procedures

This study is designed to examine the experience of single parents who are completing undergraduate degrees. The purpose of this study is to learn more about how single parents face the challenges presented by raising minor children and taking classes at the same time. Participation in the study involves completion of a short demographic data collection sheet and one interview, which will last approximately one hour. The interview will be audiotaped by the researcher and later transcribed for the purpose of data analysis. The interviews will be conducted at a setting that is mutually agreeable to the participant and the researcher.

Risks and Discomforts

There are no risks or discomforts that are anticipated from your participation in the study.

Benefits

The anticipated benefit of participation is the opportunity to discuss the experience of being a single-parent college student. This study may also inform Wayland Baptist University administrators and employees concerning how the university might more effectively aid single-parent students.

Confidentiality

The information gathered during this study will remain confidential. Only the researcher and an assistant will have access to the study data and information. There will not be any identifying names on the audio files, and participant's names will not be available to anyone beyond the researcher and his assistant. The audio files will be destroyed at the completion of the study. The results of the research will be published in the form of a paper presented at the North American Professors of Christian Education Conference, and may be published in a professional journal or presented at other professional meetings. The information will help college administrators, professors, and others to better understand how to provide quality services for single-parent students.

Withdrawal without Prejudice

Participation in this study is voluntary; refusal to participate will involve no penalty. Each participant is free to withdraw conseTBT1Theyee str1T-22(y)1939.leti

Cost and/or Payment to Subject for Participation in Research

There will be no cost for participation in the research. Also, participants will not be paid to participate in this research project.

Questions

Questions regarding rights as a person in this research project should be directed to Dr. Cindy McClenagan, Wayland Baptist University, Vice President of Academic Affairs at 806 291-3410.

Agreement

This agreement states that you have received a copy of this informed consent. Your signature below indicates that you agree to participate in this study.

_____

Participant Name (printed)

_____ _____

Signature of Participant Date

_____ _____

Signature of Researcher Date

Research Review Notification Example

Research Review Notification
Issued by the IRB

Researcher(s) involved with proposed study:_____

Date:_____

Title of proposal:_____

Type of Review: Exempt ____ Expedited ____ Full ____

The decision of the Committee is as follows:

- Approved____

- Approved with the following recommendations/comments:

_____
_____
_____
_____

- Disapproved ____

Comments:

_____
_____
_____
_____

Reviewer(s) Signature(s): _____

_____

_____

_____

Chair, IRB _____ Date_____

Vice President of Academic Affairs_____
Date_____

References

Code of Federal Regulations (1993). Protection of human subjects: 45CFR46. Washington, DC: Department of Health and Human Services. Indiana University. (2002). Student research policy. [Manual]. Bloomington, Indiana.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978). Belmont report: Ethical principles and guidelines for research