Procedure Title: Faculty Use of Students as Research Subjects

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	05/01/2020	**Executive Lead:**	Chief Research Officer
Effective:	06/30/2020	**Revision History:**	.00 – 05-01-2020; .01 – 3/22/2023
Approved by:	Institutional Review Board		
Procedure Number:	138.01		
Key Words:	Coercion, Confidential, Privacy, Undue influence		
Purpose:	To meet the responsibilities for protecting human subjects as issued by the Office for Human Research Protections (OHRP) requirement for individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federal Wide Assurances (FWAs)		

Process:
This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU regarding engagement of students as research participants.

This SOP must be used as a guide in parallel with OSA Policy 1.0. SOPs are not intended to supersede existing institutional policies, and local, state, and federal laws and regulations.

General Information
Federal regulations require that consent for research be voluntary. Consent must be obtained under circumstances that eliminate or minimize the possibility of coercion and/or undue influence. Careful consideration must be given to undue influence when an investigator holds a position of authority or power with his/her research participants.

When research is part of a required course activity, a comparable non-research activity must be provided to students not wishing to participate. It is essential that learning experiences and grades not be affected (negatively or positively) when students decide to participate or not participate in research. The IRB may request additional safeguards be put in place to protect the privacy interests of student participants as classroom conditions may make it difficult to keep participation confidential.

The Family Educational and Rights Privacy Act (FERPA) protects the privacy of individual student records. FERPA provides additional protections for students and parents by restricting unauthorized access to student records without written permission from parents of minor children, or permission of students over the age of 18. Proposed use of student education records for research must comply with FERPA requirements.

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Protecting the rights and welfare of human research participants.

- Ensuring that appropriate protections are in place when a researcher's students are the subjects of the research.
- Impartiality when reviewing human subjects research.
- Remaining immune from pressure by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

The Office of Scholarly Activity (OSA) is responsible for:

- Supporting the investigator in the development of research protocols that involve use of investigator's own students.
- Providing the necessary support to the IRB.
- Monitoring compliance with this SOP.
- Overseeing the IRB.
- Posting this SOP for the PNWU community.

The Office of Institutional Effectiveness (OIE) is responsible for:

- Retrieving, compiling, and storing institutional data.
- Ensuring protection of student identities, complying with FERPA laws, and minimizing risk to PNWU when sharing institutional data for the purpose of research.

The Investigator is responsible for:

- Providing justification for including their own enrolled students in their research,.
- Complying with the requests and recommendations of the IRB in the interest of human subject protections.
- Communicating with IRB members in a timely fashion.
- Complying with state laws and federal regulations.
- Seeking support from OSA and the IRB on proper protocol development and submission.
- Filling out the Office of Institutional Effectiveness request form for FERPA data.

Definitions

Please reference the Glossary for complete definitions of the following terms and additional terms not listed.

- Authorized Representative of FERPA
- Coercion
- Confidentiality
- Privacy
- Undue influence
- Institutional data

Investigator Procedure:

1. The IRB Application must include:
    a. a clear and complete description of student participation in the research, and when applicable, justification for including the investigator's students in the research.
    b. a detailed description of consent (who will consent the students, how consent will be conducted, and where consent will be conducted) (Note: it may be necessary to use a third party to conduct consent to reduce the appearance of coercion/undue influence).
    c. an indication of whether student participation will be a required part of a course. (If part of a course, a complete description of the alternative activity or activities that will be offered to students must be provided).

d. a description of how potential risks (e.g., pressure to participate) will be minimized (e.g., blinding instructor investigator to the identity of the participants).
e. a clear description of how participant confidentiality/privacy will be maintained (Note: it may be necessary to blind the identity of the participant from the investigator to maintain confidentiality).
f. proof of approval from/coordination with the Office of Institutional Effectiveness if FERPA or other institutional data will be utilized/requested for the study.

2. Recruitment of Students:
    a. Recruitment strategies that eliminate or minimize the possibility of undue influence must be used.
    b. Participation requests should not be made to individual students, but to a broader base of individuals (e.g., postings, general class or campus-wide announcements).
    c. Recruitment methods that require interested students to initiate contact with the investigator or alternate member of the study team will help to minimize undue influence.

3. Informed Consent Procedures must:
    a. provide subjects with enough information about the risks, required effort, and procedures of the study so that they can make an informed decision as to whether or not to participate in the research.
    b. provide subjects with information about alternate activities (when applicable).
    c. include language in the consent form regarding FERPA and what data will be retrieved/utilized as part of the study unless the research qualifies for an exemption.
    d. describe consent procedures to minimize risk of undue influence when potential participants are an investigator's students (e.g., someone other than the investigator will conduct and document the consent process).
    e. include language notifying the participants of blinding procedures (when applicable).
    f. assess the subject's understanding of their role, time required, and any anticipated risks.
    g. document that subjects voluntarily agree to participate (unless waived).

4. Institutional Data (Student data) Requests:
    a. The investigators requesting PNWU student data are required to complete and submit a Request for Data/Information Form to the PNWU Office of Institutional Effectiveness (or equivalent when utilizing data from an outside entity) ensuring that IRB proposal information provided is complete and specifies the study detail and the study variables for the requested data. Note: When requesting data from partner institutions you will need to verify the process for requesting the data AND determine a secure method for receiving the data from the partner institution.
    b. The approved OIE Request needs to be attached in the appropriate section of the IRB Request for Review in the electronic system.
    c. When the investigator receives documentation of IRB approval or determination, he/she must provide documentation to the director of OIE along with a copy of the final study protocol before any data will be released.

    Please Note: OIE does not store research data.

IRB Procedures:

1. The IRB will review research involving students as participants and assess:
    a. whether involving students/one's own students is warranted by the protocol.
    b. whether the recruitment methods minimize the risks of undue influence.

c. whether the consent process addresses potential problems associated with recruiting students/one's own students (e.g., undue influence, identifying variables collected) and is otherwise adequate.

2. The IRB will ensure that the study is reviewed at a level appropriate to the risks.
3. The IRB chair or designated reviewer(s) have the discretion to require a study to undergo full board review.

References:

1. Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
2. Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
3. The Family Education Rights and Privacy Act of 1974 (FERPA).
4. U.S. Department of Health & Human Services, Office of Human Research Protections website: https://www.hhs.gov/ohrp/
5. The Belmont Report. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html
6. Ball State University SOP Faculty Use of Own Students in Research and Use of FERPA.
7. PNWU FERPA Policy
8. PNWU SOP 121 Quality Improvement Versus Research

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 06-30-2020	C. Case	Original SOP
.01 / 3-22-2023	C. Case	Minor grammar and punctuation revisions; updated the reference links.

Appendices:
None