Procedure Title: Training Requirements for Human Subjects Protections

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	04/22/2015	**Executive Lead:**	Chief Research Officer
Effective:	04/22/2015	**Revision History:**	.01 – 2/22/17; .02 – 7/18/17; .03 – 7/24/18; .04 – 3/11/19; .05 – 7/22/19; 06 – 8/28/2019; .07 – 01/28/2020; .08 – 09/10/2020; .09 – 06/29/2021; .10 – 09/27/2021; .11 – 3/22/2022; .12 – 1/10/2023
Approved by:	Institutional Review Board		
Procedure Number:	101.12		
Key Words:	Qualifications; CITI; Training; NIH; IRB Members; Investigators		
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 the investigator educational training in human subjects research protection requirement and the Institutional Review Board (IRB) training and orientation process.

Responsible Parties
The Institutional Review Board (IRB) is responsible for:

- Completing the educational training in human subject research protection.
- Maintaining continuing knowledge of, and complying with, the following:
  - relevant ethical principles.
  - relevant federal, state, and local regulations.
  - other applicable guidance.
- Obtaining input from IRB members on the necessary training and orientation to perform their duties.
- In cooperation with the OSA, members of the IRB evaluate training and orientation materials to ensure IRB members are prepared for their duties.

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

- Obtaining input from investigators.
- Monitoring compliance with this SOP.
- Posting this SOP for the PNWU community.
- Communicating with the IRB to ensure training and orientation processes are adequate.
- Evaluating, reviewing, and providing training and orientation materials to ensure IRB Members are prepared for the IRB.

- Reviewing training and oversight mechanisms to ensure that investigators maintain continuing knowledge of, and comply with, the following:
    - relevant ethical principles.
    - relevant federal, state, and local regulations.
    - other applicable guidance
- Offering educational training in human subjects research protection.
- Assuring the University assigns and maintains an Institutional Official (IO) for Federal-wide Assurances and Signatory Official (SO) for government submissions including but not limited to: NIH, HRSA, SAM.Gov, etc.

The Investigator is responsible for:

- Completing the educational training in human subjects research protection.
- Maintaining continuing knowledge of, and complying with, the following:
    - relevant ethical principles.
    - relevant federal, state, and local regulations.
    - other applicable guidance.
- Advocating a culture of human subjects protections at PNWU via educational training in human subjects research protection.
- Maintaining good standing with PNWU.

Definitions

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

- Consultant
- Family Educational Rights and Privacy Act (FERPA)
- Federal Wide Assurance (FWA)
- Good standing
- Health Information Portability and Accountability Act (HIPAA)
- Human subject
- Investigator
- Institutional Review Board (IRB)
- Institutional Official (IO)
- Principal Investigator (PI)
- Signatory Official (SO)

Procedure:

Investigators:

1. Provide the Office of Scholarly Activity (OSA) with a current CV or Biosketch.

2. Complete educational training in human subjects research protection.
    a. PNWU's educational training in human subjects research protection is provided by the CITI (Collaborative Institutional Training Initiative) Program (citiprogram.org) for social & behavioral and biomedical research. The formal CITI educational training in human subjects research protection certifications are valid for four years from date of certification. If outside the four-year time frame, recertification must be obtained before an IRB application is submitted. Human subjects training certifications must remain current throughout the period of the study.
    b. In rare cases CITI Training from other institutions may be considered at the approval of the Institutional Official (IO) or designee.

i. Collaborating investigators from external R1 institutions will be required to submit a copy of a current curriculum vita (CV) and current human protections training. Training must have been completed in the last four years. The CV and training information will be reviewed by the IRB Chair to ensure that training is appropriate, the investigator resides at an R1 university, and that the investigator is qualified to serve in the requested role. If approved by the IRB Chair, the IRB Administrator will request approval from the IO or his/her designee. Collaborating investigators must maintain current training throughout the period of the study.

c. In some situations, the IRB may request members of the study team complete additional modules specific to the type of research being conducted (e.g., Biomedical Research, or Good Clinical Practices training for clinical studies or the international studies modules when conducting research abroad).
d. Investigators with federally funded research are required to complete conflicts of interest training via CITI Program prior to submitting the IRB application. Renewal is required at least every 4 years. Retraining must be completed immediately when the conflict of interest policies or procedures are revised or when the investigator is not in compliance with the institution's financial conflict of interest policy or management plan. (45 CFR 50.604(b)).
e. Investigators with NIH funding are required to complete the NIH Financial Conflict of Interest Tutorial and Certification prior to submitting an IRB application. Renewal is required at least every 4 years. The training is available at https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html.
f. Investigators with NIH funding are required to complete Responsible Conduct of Research (RCR) Training. RCR training must include substantial face-to-face training (at least 8 hours) and include a combination of didactic and small group discussions (e.g. case studies). More information can be found in Notice NOT-OD-10-019.
g. Investigators with NIH qualifying clinical trials are required to complete training in Good Clinical Practices prior to submitting an IRB application. Renewal is required at least every 3 years.

3. Acknowledge and accept responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the FWA at the time of the IRB application submission.

4. Maintain good academic standing and/or professional standing. Only faculty or staff members qualified by experience and or training may serve as principal investigators (PI). Only students listed in good academic standing are permitted to participate in any active research study (human subjects, bench, etc.) and/or in the preparation of research studies. Students with an academic standing of "probation", failed COMLEX exam, or remediation in any form are not permitted to be involved in scholarly activity including any aspect of the research spectrum. The PNWU registrar's office will notify the OSA of changes in a student's status. The OSA will notify the PI of the study and complete a change in personnel form in IRB Manager to remove the at-risk student(s) listed on the study. The OSA will notify the student of their removal from the study due to their change in academic standing.

5. Access to human subjects and/or identifiable research data (including de-identified research data that can be re-identified by a member of the study team) cannot be granted to individuals (faculty, staff, or students) who have not completed human subjects research training or who have not been added to the study via an IRB personnel change form.

6. The Principal Investigator (PI) must ensure all research team members have appropriate qualifications and training, and shall ensure records of each are appropriately filed with the IRB (research@pnwu.edu). The IRB and in extreme circumstances the IO have the authority to put a study on hold (stop data collection/enrollment) or suspend a study if any team member is not in compliance with this SOP and overarching policy.

7. Investigators must possess the necessary skills required to conduct human subjects research. The OSA may require additional education based on the type of research being conducted.

8. The PI is responsible and accountable for:
    - conducting the research,
    - protecting the safety and rights of research subjects as well as those of the research team members,
    - the findings of the study,
    - study records and retention of the study records for the appropriate time frame,
    - leading and training the research team,
    - performing all tasks necessary to conduct the study and ensure compliance with policies and regulations.

<u>IRB Members:</u>

1. Once the initial appointment has been made, orientation and training materials will be provided to the new member.

2. New PNWU IRB members are required to:
    - Attend scheduled meetings prior to completion of orientation.
    - Access reference materials via the PNWU IRB shared drive OR check out a printed version of the reference material from the Office of Scholarly Activity
    - Finish orientation and training within three months of appointment to the IRB; exceptions will be made under special circumstances approved by the IO whereby an extension will be offered beyond the three months
    - Complete orientation and training in human subject research protections prior to voting

3. PNWU's educational training in human subject research protection is provided by the CITI (Collaborative Institutional Training Initiative) Program (citiprogram.org) for IRBs. The formal CITI educational training in human subject research protection certifications are valid for four years from the date of certification. Human subject training certifications must remain current throughout the period of the member's appointment.

4. Obtain (either in print or via the IRB shared drive) and review the Pacific Northwest University of Health Sciences IRB Member Information binder from the Office of Scholarly Activity, which contains the following:
    - PNWU Introduction slides for new members of the IRB
    - Accessing the PNWU IRB shared drive for IRB Materials
    - CITI Training Set up instructions.
    - CITI Training Modules for IRB members
    - Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services Part 46, Protection of Human Subjects, Revised and Effective January 21, 2019
    - Department of Health and Human Services, Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection, May 5, 2004.

- Code of Federal Regulations, Title 42 Policies of General Applicability, Department of Health and Human Services, Part 50 Subpart F – Promoting Objectivity in Research
- Code of Federal Regulations, the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. § 1232g; 34 CFR Part 99. https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
- The Belmont Report
- Declaration of Helsinki
- The Nuremburg Code
- Human Subject Regulations Charts
- Categories of Research that may be reviewed by the IRB through the expedited process
- List of Regulations
- Health insurance portability and accountability act (HIPAA) privacy rule
- Free subscriptions (IRB Forum and Journal of Clinical Research Best Practices)
- IRB Meeting Information
- Attend continuing education trainings held at the beginning of IRB meetings.

Note: Non-IRB members (consultants) who perform reviews as a content matter expert for the IRB on an ad hoc basis are not required to meet all the training and orientation requirements

Institutional Official (IO) / Signatory Official (SO):

1. Once the initial appointment has been made, orientation and training materials will be provided to the new IO/SO. If an existing IO/SO, credentials must be maintained.

2. New/Current IO/SO is required to:
    - Attend and observe scheduled IRB meetings prior to completion of orientation and attend monthly IRB meetings as needed.
    - Access reference materials via PNWU The IRB shared drive OR check out a printed version of the reference materials from the Office of Scholarly Activity
    - Finish orientation and training within three months of appointment as IO/SO

3. Complete educational training in human subjects research protections for IRBs
    a. PNWU's educational training in human subjects research protection is provided by the CITI (Collaborative Institutional Training Initiative) Program (citiprogram.org). CITI education certificate for IOs and either Social Behavior or Biomedical modules are required. In addition, the IRB member modules are strongly suggested but not required. The formal CITI educational training in human subjects research protection certifications are valid for four years from date of certification. Human subjects training certifications must remain current throughout the period of the IO's appointment.

4. Obtain (either in print or via the IRB shared drive) and review the Pacific Northwest University of Health Sciences IRB Member Information binder from the Office of Scholarly Activity, which contains the following:
    - PNWU Introduction slides for new members of the IRB
    - Accessing the IRB shared drive for IRB Materials
    - CITI Training Set up instructions.
    - CITI Training Modules for IRB members
    - Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services Part 46, Protection of Human Subjects, Revised and Effective January 21, 2019
    - Department of Health and Human Services, Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection, May 5, 2004.

- Code of Federal Regulations, Title 42 Policies of General Applicability, Department of Health and Human Services, Part 50 Subpart F – Promoting Objectivity in Research
- Code of Federal Regulations, the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. § 1232g; 34 CFR Part 99. https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
- The Belmont Report
- Declaration of Helsinki
- The Nuremburg Code
- Human Subject Regulations Charts
- Categories of Research that may be reviewed by the IRB through the expedited process.
- List of Regulations
- Health insurance portability and accountability act (HIPAA) privacy rule
- Free subscriptions
- IRB Meeting Information

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. Code of Federal Regulations, Title 42 Policies of General Applicability, Department of Health and Human Services, Part 50 Subpart F – Promoting Objectivity in Research
4. Code of Federal Regulations, the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. § 1232g; 34 CFR Part 99. https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
5. Responsibilities of Institutions regarding Investigator Financial Conflicts of Interest (45 CFR 50.604)
6. Update on the Requirement for Instruction in the Responsible Conduct of Research. Notice Number NOT-OD-10-019
7. PNWU Conflicts of Interest Policy
8. PNWU Financial Conflicts of Interest Policy
9. PNWU Financial Conflicts of Interest Disclosure Form
10. PNWU Student Handbook accessed 5/26/2021.

Appendices:

1. Attestation Form
2. CITI Program Training Guide
3. PNWU Financial Conflict of Interest Disclosure Form

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 4-22-2015	McCarroll	Previously a policy, now an SOP
.01/2-22-2017	McCarroll	Approved Policy now an SOP
.02 / 07-18-2017	McCarroll	Modified section 6.1 and 6.4
.03 / 07-24-2018	McCarroll	Added student status to section 6.6
.04 / 03-11-2019	McCarroll	Minor changes to the IRB Members section. Item 2 was revised to reflect that new member training materials will be available online or by checkout from the Office of Scholarly Activity
.05 / 7-22-2019	M. McCarroll	Added training for the Institutional Official
.06 / 08-28-19	C. Case	Added signatory designee to item 2b to the Investigator Training section

.07 / 1-28-2020	C. Case	Minor formatting and grammar changes throughout. 2. b. Revised to make CITI Program the required training for human research protections. Remove the alternate training option. Added statement that individuals whose alternate training has been honored will need to complete CITI training upon expiration. 2.c. Added to enable the IRB to request study teams complete training modules specific to the type of research being conducted.
.08 / 09-10-2020	C. Case	Replaced Sharefile with PNWU IRB shared drive as we are moving away from Sharefile to SharePoint.
.09 / 07-22-02021	C. Case	Fixed minor typos. Removed language about alternate training that was honored prior to January 1, 2020, as all of the alternate that was being honored has now expired. Removed information regarding the CITI Training for the Revised Common Rule as all information has now been incorporated into the Biomedical Researcher and Social, Behavioral, and Educational Researcher Training Modules; Added requirement for conflict of interest training for federally funded studies; added responsible conduct of research training for NIH funded studies.
.10 / 10/-1-2021	C. Case	Added institution required NIH Conflicts of Interest Training In item 2e; Added references to the PNWU Financial Conflicts of Interest Policy and the Financial Conflicts of Interest Disclosure Form.
.11 / 4-29-2022	C. Case	Added section 2.b.i. regarding training exceptions for external investigators from R1 institutions.; modified language in the OSA responsibilities regarding assigning an IO to ensuring that the university assigns and maintains and IO.
.12 / 1-18-2023	C. Case	Add section 2g regarding Good Clinical Practice training requirement for qualifying NIH Clinical Trials.