Procedure Title: Functions of the Institutional Review Board

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	6/2/2017	**Executive Lead:**	Chief Research Officer
Effective:	6/2/2017	**Revision History:**	.01 – 6/2/2017; .02 – 10/10/2017; .03 – 10/25/2017; .04 – 12/12/2017; .05 – 10/03/2019; .06 - 4/22/2022; .07 – 3/27/2023
Approved by:	Institutional Review Board		
Procedure Number:	115.07		
Key Words:	Exempt Review, Non-Exempt Review, Expedited Review, Full Board Review, Reviewer System, Exemption Determination, Review Criteria		
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 functions of PNWU IRB.

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

General Information:
The PNWU IRB will apply the criteria for IRB approval described in the PNWU SOPs to research subject to the revised Common Rule for *non-exempt research*.

The PNWU IRB will apply the ethical principles outlined in the Belmont Report and equivalent protections for *exempt research not required to undergo limited IRB review* (e.g., consent, equitable subject selection, safeguards for vulnerable populations). Exempt research required to undergo a limited IRB review (category 2 and category 3 research which include identifiable data) are subject to the revised Common Rule requirements.

Studies approved prior to January 21, 2019, will continue to follow the Pre Revised 2018 Common Rule policies and SOPs until the studies are closed.

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Reviewing process to conduct an IRB meeting.
- Calling a meeting to order (Chair or Vice Chair).
- Leading the IRB meeting (Chair or Vice Chair).
- Facilitating reviews of IRB submitted protocols.
- Monitoring the IRB's decisions for consistency.
- Ensuring that IRB members are free to participate in discussions.
- Providing an acceptable platform for IRB members attending by teleconference to actively and equally participate in all discussions.

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

- Monitoring compliance with this SOP
- Posting this SOP for the PNWU community
- Communicating with the IRB to ensure all the needs are met to operate effectively

The Investigator is responsible for:

- Monitoring the status of exempt studies to ensure that any changes in the study design do not result in the study becoming non-exempt.
- Completing all forms required by the OSA when requesting an exemption or non-emption of determination for an application.
- Providing adequate justification based upon the requested category on which their application request is based (investigators may not make their own determinations).

Definitions

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

- Administrative Hold
- Approved Protocol
- Advertisement
- Bias
- Continuing Non-compliance
- Continuing Review
- Exempt Determination
- Expired Study
- Expedited Review
- Full Board Review
- Tabled

Procedure:

1. The primary function of the IRB is to assist researchers in the protection of the rights and welfare of human subjects. It is necessary for others who are independent of the research to share the responsibility for determining the standards for ethical conduct of research involving human subjects. Investigators, however, carry primary responsibility for assuring that research protocols are carried out according to standards established by the IRB.

2. The OSA is the central administrative office for the PNWU IRB and Human Research Protection Program (HRPP). The OSA serves as the central repository of all information affecting the protection of human subjects in research and is responsible for the management and oversight of the PNWU IRB. In addition, the OSA is responsible for ensuring that all relevant information affecting the safety and welfare of human subjects in research, and noncompliance issues, are reported to the IRBs, and as appropriate to the institutional Official (IO), federal regulatory agencies, and sponsors.

3. PNWU OSA SOP 103.0 defines the institution's process for determining which Health and Human Services (HHS) conducted or supported research studies qualify as exempt from the HHS regulations.

4. The IRB reviews the research relevance of the use of human participants and confirms that ethical issues have been addressed with regard to the study's design and conduct.

5. For sponsored and/or funded studies, the IRB will rely on the peer review process of a federal funded agency. This reliance applies to all protocols that have received a formal peer review from a federal funding agency. In this instance, the PNWU IRB will not be required to consider the research design and scientific merit of sponsored and/or funded protocols.

6. For unfunded research protocols, the PNWU IRB is responsible for assessing the research design and scientific merit in order to determine the risk vs. benefit analysis. In this assessment, the IRB will determine the validity of the research and the nature and degree of risk as well as the nature and level of the anticipated benefits in the research design.
    a. If the research design and scientific merit are not acceptable, the PNWU IRB will defer a decision and refer the study team to the PNWU Research Committee, the OSA, or another designee for further scientific review support.

7. The PNWU IRB identifies and evaluates:
    a. the levels of risk and that everything has been done to minimize risk to the extent possible.
    b. the probable benefits to be derived from the research.
    c. the probability of risk and the stated benefits associated with the research.
    d. the risks /benefits and importance of the knowledge to be gained.
    e. as to whether the protocol is an accurate and fair description of the risks or discomforts and the anticipated benefits.
    f. the research design as it relates directly to the risk assessment and protection of human subjects.
    g. the proposed research design and risk vs. benefit assessment to determine if the risks that will be presented to the subjects are justified.
    h. the adequacy of the provisions to protect subject privacy and maintain data confidentiality.
    i. the undue influence of human subject participation.
    j. that appropriate additional safeguards are in place to protect the rights and welfare of vulnerable populations.
    k. Consent process and documentation.
    l. Recruitment process and equitable selection of subjects.

8. The IRB considers certain groups of human participants to be particularly vulnerable in a research setting and considers additional protections for research activities. Please see the PNWU OSA SOP 128 Vulnerable Populations.

9. The IRB must consider ways to minimize risk by reviewing information in the protocol regarding the experimental design and the scientific rationale underlying the proposed research, which includes the results of previous studies. For protocols above minimal risk, the IRB may request additional information to support its review of research design and scientific merit. This may include justification for inclusion of human subjects, literature review, additional explanations of direct or indirect benefit, and additional explanation of research design.
    a. The review of literature and research design is not required by federal regulation for exempt research; however, equivalent protections will be required, and recommendations

may be made by the IRB (or designee) to better understand the study and/or improve research design in the context of a risk vs. benefit analysis. The IRB has no obligation to disapprove the research on this basis.

10. Where appropriate, the IRB must determine that adequate provisions are in place for monitoring the collection, storage, repository, and disposition of data. See OSA SOP 120 Disposition of IRB Records.

11. A typical list of submission materials for a ***new*** protocol are:
    a. Comprehensive study protocol, as applicable
        - List of personnel involved in the research
        - Certification of any required disclosure/training of the personnel
        - Literature Review
        - Research objectives and hypothesis(es), as applicable
        - Inclusion/exclusion criteria
        - Location of the study (adequacy of the site where the research will be conducted) and to determine applicability of state and local laws
        - Description of the anticipated study population
        - Step by step study procedures
        - Risks/Benefits
        - Confidentiality and Privacy
        - Data collection form/database shell
        - Data and analysis
        - Study budget
        - Dissemination plan
        - Qualifications of the investigator(s) and study staff (training/experience/licensure)
        - Incentives
        - Data and safety monitoring plan, as appropriate
    b. Consent form
    c. Consent form + HIPAA Authorization
    d. Consent form + FERPA Authorization
    e. Study brochure or flyer (approved by PNWU Communications/Marketing), as applicable
    f. Letter/email to clinicians to notify their patients about the study, text for Internet advertisement)
    g. Study instruments, if applicable (e.g., survey, focus group guide, interview script, questionnaire, inclusion/exclusion form, enrollment form, delegation of duties log)
    h. Documented approvals from other institutions, if applicable and available

12. Study applications will first be pre-reviewed by the OSA IRB administrator/coordinator to ensure completeness of the submission packet. Any items missing from the submitted packet as identified in this SOP or other OSA SOPs will be communicated to the investigator or designee prior to moving forward in the IRB approval process. The OSA IRB administrator/coordinator may assist the investigator or designee by correcting file naming, formatting, and versioning of uploaded supportive protocol documents to ensure clarity and processing of the entire protocol prior to the submission packet is distributed to the IRB members/reviewers.

13. IRB members will have access to electronic copies of the submission materials at least one week prior to the next designated IRB meeting for full board reviews and as soon as a submission packet is approved for exempt and expedited reviews.

14. PNWU IRB members are required to use the reviewer checklists provided by within the electronic IRB management system to ensure that all of the required elements of a protocol, consent, HIPAA/FERPA authorization, and any additional elements are included in the study packet.

15. The type of reviewer system utilized by the PNWU IRB include:
    a. Exempt Studies
    1) Investigators must submit an application to the IRB requesting for exemption determination from IRB review on research activities that are in one or more of the categories listed in 45 CFR 46.104 or 21 CFR 56.104. Note: Per the Revised Common Rule exempt studies that include identifiable information are required to undergo a limited IRB review, are subject to the Revised Common Rule, and may be required to undergo annual continuing review requirements.
    2) Per the Human Research Protection Policy, exempt research is subject to review for determination of exemption status. At PNWU exempt studies are reviewed and granted by appropriately qualified members of the Institutional Review Board. Exempt study reviews are assigned to members on a rotating basis by the IRB administrator/coordinator based on the content expertise of the member.
    3) The IRB Chair, Vice Chair, and/or other designated members of the IRB make exempt determinations based on the review of items submitted. Members of the IRB have the authority to bump the review to a higher level (e.g., expedited or full board).
    4) The designated/assigned reviewer reviews the application for:
        - Sound and ethical research design.
        - Reasonable background, objectives, description, data management plan, and dissemination plan.
        - Participation of subjects to be adequate to permit a determination regarding the request for exemption.
        - Risks are minimal.
    5) Once the IRB Chair, Vice Chair, and/or other designated members of the IRB member review the study they can either implement a range of possible actions (e.g., approve, require modifications to secure approval, or if not approvable, referral to the full board for review).
    6) If any portion of the exemption application is unclear, the designated reviewer will not make a determination. Instead, the designated reviewer documents the items requiring clarification and returns it to the IRB administrator/coordinator. The designated/assigned reviewer can either request clarification from the investigator or defer the review back to the IRB Chair or Vice Chair.
    7) Informed consent will be sought from each prospective subject or the subject's legally authorized representative (LAR) or an appropriate alteration or waiver of consent will be requested.
    8) If the designated reviewer has any doubt and determines that the research has associated risk that:
        - Is greater than minimal risk
        - Has ethical issues
        - Contains identifiable HIPPA/FERPA data needing authorization, and/or
        - Additional concerns outlined in the OSA Policy 1.0 even if all other criteria for exemption are met,

    An exempt determination will not be made by the reviewer. The project will be deferred back to the IRB administrator/coordinator, the IRB Chair or Vice Chair, returned to the investigator with recommendations or bumped to a higher level of review. The

investigator's application will not move forward, and a new/modified application will be requested.

9) The IRB Chair or Vice Chair may defer the final exemption determination to a convened IRB meeting. The application will then be scheduled at the next regularly scheduled IRB meeting.
10) A list of exempt studies is provided in the monthly IRB meeting minutes.
11) Submitted exempt study materials are accessible to all IRB members via the electronic IRB management system.

b. **Non-Exempt Studies**

Procedures for Expedited Review

a. Per the Human Research Protections Policy non-exempt research is subject to review for determination of non-exemption status.
b. Investigators do not make the determination of non-exemption.
c. The IRB Chair, Vice Chair, assigned reviewers and/or Institutional Official (IO) have the prerogative to route any study for full board review, regardless of whether it is eligible for exempt or expedited review per the federal regulations.
d. Primary and secondary reviewers are assigned by the IRB administrator/coordinator based on the content expertise of the IRB member. The reviewers must determine that the following requirements are satisfied before non-exempt research can be approved. These criteria, as defined in 45 CFR 46.111 and 21 CFR 56.111, will be considered during the review process for each non-exempt study submitted for review.
    - Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
    - Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result from the study. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (i.e., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
    - Selection of subjects is equitable: In making this assessment, the IRB should consider the purpose of the research, the setting where the research will occur, and the local context in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
    - Informed consent will be sought from each prospective subject or the subject's legally authorized representative (LAR), in accordance with, and to the extent required by, 45 CFR 46.116.
    - Informed consent will be appropriately documented, in accordance with, and to the extent required by, 45 CFR 46.117 and 21 CFR 50.27.

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- In addition, IRB review will consider the following, as applicable:
  - Recruitment methods and advertising material are appropriate (See OSA SOP 107).
  - Additional protections are in place for vulnerable subjects.
  - Potential conflict of interest of investigators is eliminated, mitigated, or managed.
- For expedited studies, the assigned primary and secondary reviewers can implement a range of possible actions (e.g., approve, require modifications to secure approval, or if not approvable, referral to the full board for review).
  - A list of expedited studies is provided in the monthly meeting and recorded in the meeting minutes.
  - Submitted expedited study materials are accessible to all IRB members via the electronic IRB management system.

<u>Procedures for Full Board Review</u>

1) Investigators do not make the determination of non-exemption.
2) The IRB Chair, Vice Chair, assigned reviewers, and/or Institutional Official (IO) have the prerogative to route any study for full board review, regardless of whether it is eligible for exempt or expedited review per the federal regulations.
3) The primary and secondary reviewers are assigned by the IRB administrator/coordinator based on the content expertise of the IRB members. The reviewers must determine that the following requirements are satisfied before non-exempt research can be approved. These criteria, as defined in 45 CFR 46.111 and 21 CFR 56.111, will be considered during the review process for each non-exempt study submitted for review.
   - Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
   - Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result from the study. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (i.e., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
   - Selection of subjects is equitable: In making this assessment, the IRB should take into account the purposes of the research. the setting in which the research will be conducted, as well as the local context, and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
   - Informed consent will be sought from each prospective subject or the subject's legally authorized representative (LAR), in accordance with, and to the extent required by, 45 CFR 46.116.

- Informed consent will be appropriately documented, in accordance with, and to the extent required by, 45 CFR 46.117 and 21 CFR 50.27.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- In addition, IRB review will consider the following, as applicable:
  - Recruitment methods and advertising material are appropriate (See OSA SOP 107.0).
  - Additional protections are in place for vulnerable subjects.
  - Potential conflict of interest of investigators is eliminated, mitigated, or managed.
- Full board studies will be scheduled for a full board review meeting once the assigned primary and secondary reviewers have completed their review/reviewer checklist. The IRB can vote to implement a range of possible actions (e.g., approve, require modification to secure approval, defer, or disapprove the research).
  - Submitted full board study materials are accessible to all IRB members via the electronic IRB management system.

References:

1. Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services Part 46, Protection of Human Subjects, Revised January 15, 2009, Effective July 14, 2009
2. Department of Health and Human Services, Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection, May 5, 2004.
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

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 06-02-2017	M. McCarroll	New Standard Operating Procedure
.01 / 6-2-17	M. McCarroll	Modified bullets under 6.8, 6.9, and 6.15
.02 / 10-10-2017	M. McCarroll	Modified bullets under 5.0, 6.9, and 6.15
.03 / 10-25-2017	M. McCarroll	6.5 changed federally funded to sponsored or funded studies. 6.7 added bullets for consent process & documentation as well as recruitment process and equitable selection of subjects. Renumbered section 6 (6.10 - 6.12). Section 6.15.2 Added separate language for an expedited review for exempt studies and the procedure for full board review
.04 / 12-12-2017	M. McCarroll	Section 6.12 Added language that enables the IRB Administrator/coordinator to assist the investigator or designee by correcting file naming, formatting, and versioning of uploaded supportive protocol documents to ensure clarity of processing.

.05 / 10-03-2019	C. Case	Put into new PNWU SOP format
.06 /04-22-2022	C. Case	Fixed so type font throughout the document is the same; corrected citation of regulations #15 Exempt studies
.07 / 3-23-2023	C. Case	Minor punctuation fixed; removed the L: Drive information from the footer of the SOP as all SOPs are now stored in the electronic IRB system; Added Investigator training/experience/licensure to qualifications bullet in #11a; Added additional study instruments to the examples provided in 11g; changed encouraged to use the reviewer checklist to required to use the reviewer checklist in #14; Added a note about limited IRB review for exempt studies that include identifiable information #15a; removed statement (with chair or vice chair knowledge) from a3, b4 and IRB procedures #3; also added on 15 a3 that the members of the IRB have the authority to bump the study up to a higher level of review(from SOP 150 Revised Common Rule & SOP 124 Review and Approval of Studies); added language about returning a study to the investigator in 15, a7; Changed PNWU IRB Manager to the electronic IRB management system throughout the SOP; added assigned reviewers can route a study to full board to b3 and procedures for full board #2; added local context to #b4.

Appendices:
None