Procedure Title: Review of Exempt Research and Exempt Research Requiring Limited IRB Review

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	3/29/2023	**Executive Lead:**	Chief Research Officer
Effective:	4/13/2023	**Revision History:**	00 – 3/29/2023
Approved by:	Institutional Review Board		
Procedure Number:	140.00		
Key Words:	Review, Actions, Approve, Modifications Required, Major Modification, Minor Modification, Withhold, Tabled, Disapprove, Suspension, Termination, Continuing Review, Closure		
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 review of exempt human subject research.

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

General Information:
Studies may qualify for exempt status if they involve minimal risk and involve activities limited to one or more exempt categories specified by the federal regulations. Exempt studies are reviewed on a rolling basis using expedited review procedures.

The PNWU IRB will apply the ethical principles outlined in the Belmont Report and equivalent protections for participants enrolled in exempt research (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.

Note: Studies determined to be exempt prior to January 21, 2019 will follow Pre Revised 2018 Common Rule policies and SOPs until the studies are closed.

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

- Reviewing applications in a timely fashion.

- Assessing risk and other considerations per federal regulations and guidance.
- Communicating with the investigator as to the application status and modifications needed to ensure protection of human subjects.

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

- Monitoring compliance with this SOP.
- Posting this SOP for the PNWU community.
- Notifying the investigator, no earlier than 60 and no later than 30 days prior to the current IRB approval expiration date and providing them instructions for submitting a request for continuing review, annual check-in, or a study closure report.
- Ensuring all required information is received prior to forwarding a request for continuing review to the convened IRB and IRB Reviewer conducting the review.

The Investigator is responsible for:

- Completing all forms required by the IRB when requesting review and determination of exemption of an initial application or study amendment.
- Providing adequate justification based upon the requested category on which their application request is based (investigators may not make their own determinations).
- Distributing revised consent forms and other revised study documents to collaborators and members of the study team along with relevant instructions from the IRB.
- Reviewing closure reports for impact on any related studies.
- Ensuring no ongoing research activities occur once the study is closed.

Definitions

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

- Exempt
- Expedited
- Health Information Portability and Accountability Act (HIPAA)
- Human Subject
- Principal Investigator (PI)
- Standard Operating Procedure (SOP)

Exempt Research Categories:

The exempt categories of research are found in the revised Common Rule at 45 CFR 46.104. Unless otherwise required by law or a federal agency or department, research activities in which the only involvement of human subjects will be in limited to one or more of the following categories are exempt from the requirements of the revised Common Rule, except that such activities must comply with the requirements of the PNWU IRB and section 45 CFR 46.104 and as specified in each category. *Note: Other than exempt category 6, these categories do not apply to research that is also FDA-regulated.*

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if *at least one of the following criteria is met*:
    i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a ***limited IRB review*** to make the determination required by §__.111(a)(7): "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and *at least one of the following criteria is met*:
    i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
    ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
    iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a ***limited IRB review*** to make the determination required by §__.111(a)(7): "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."

    For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

    Note: If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if *at least one of the following criteria is met*:
    i. The identifiable private information or identifiable biospecimens are publicly available;
    ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be

ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 ['HIPAA'], subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b) (This exemption may only be applied when PHI will not be shared with individuals or organizations who are not part of a covered entity. All data protection standards must still be followed) ; or

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
    i. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:
    i. If wholesome foods without additives are consumed, or
    ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: Exempt categories 7 & 8 - PNWU is not adopting the options for broad consent at this time.

Limitations on Exemptions:

1. **Children:** Exemption #2(i) and (ii) for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children, except for research

involving observations of public behavior when the investigator does not participate in the activities being observed. Exemption #2(iii), where identifiable information is obtained and the IRB conducts a limited IRB review, is NOT applicable to research in children. Exemption #3 does NOT apply to research involving children. [45 CFR 46.104(b)(3)].

2. **Prisoners:** Exemptions do not apply EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners. [45 CFR 46.104(b)(2)].

Procedures for Exempt Research:

1. Please review PNWU OSA SOP 115, which defines the IRB's Function on determining exempt and non-exempt study designations.
2. Determinations regarding whether research subject to the revised Common Rule qualifies for exempt status will be made by a member of the PNWU IRB.
3. Reviewers may make a determination of exemption, require modifications, withhold a determination, or determine that the study is not exempt and requires a higher-level review.
    a. Modifications (Conditions) required to make a determination: Made when the IRB member required specific modifications such that an IRB support staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria. The investigator must address the reviewer's comments.
    b. Withhold: Made when the research does not qualify for exemptions or significant modifications must be made in order for the study to qualify for exemption. All withheld determinations will be returned to the same reviewer.
4. The Principal Investigator will be notified in writing of the IRB's decision.
5. At a convened IRB meeting, the committee will acknowledge and review the list of studies reviewed via expedited process. Any IRB member can call for a full board review of any submitted protocol.
6. Investigators conducting exempt research are required to submit an annual status update (annual check-in). Written notification will be sent to investigators approximately 4 weeks prior to the due date.
8. Closure - The completion, suspension, or termination of a project is a change in study activity and must be reported to the IRB. Thus, the investigator is required to inform the IRB using a closure form when a project is closed or terminated.
    a. If the study is terminated by the IRB Chair, Vice Chair, or IO, a letter will be provided to the investigator indicating that all research must stop and provide the reasoning for this termination.
    b. The principal investigator (PI) and/or the IRB administrators may close approved protocols under certain circumstances. The PI is responsible for promptly closing out an IRB approved study if any of the following conditions exist:
        i. All research/clinical investigation activities including data analysis and reporting are complete.
        ii. The PI never initiated the study.
        iii. Subject accrual is finished, all data collection is complete and the only remaining activity is analysis of the data, the data are de-identified, and there are no identifying links or codes to the de-identified data.
        iv. The PI plans to leave the University and intends to continue the research activities at another institution.
        v. The study has been open for a period of three or more years and the PI has enrolled no subjects in the study, collected no data from records, or collected/received specimens.
    c. The PI cannot close out an active IRB study if:

i. He/she is still following subjects, or
ii. He/she is analyzing identifiable data (including data with codes or links to identifiers).

d. The IRB chair or IRB administrator may notify a PI that IRB approval or active IRB status has expired or that the IRB has inactivated IRB approval after 6-months of non-response from the PI to IRB requests. These requests will be documented in the study files in the electronic IRB management system.
e. If a study has been open for a period of three or more years and the PI has not enrolled subjects in the study, the IRB requires study closure unless there are extenuating circumstances for keeping the project open (e.g., the study is about a rarely seen condition).
f. Procedures for closing a study fall into five categories:
    i. Final review.
    ii. Non-response from PI to IRB requests.
    iii. Closure due to non-enrollmen.t
    iv. Lapse of approval due to non-response to requests for continuation or final review.
    v. PI initiated withdrawal.

Procedures for Exempt Research Requiring Limited IRB Review (Exempt Categories 2 & 3 that include identifiable data):

1. Research requiring limited IRB review **is** subject to the revised Common rule requirements. When the research requires limited IRB review. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications to secure approval, or disapprove all research activities [45 CFR 46.109(a)].
2. For exempt research subject to limited IRB review, categories 2(iii) and 3(iii), the IRB may approve the research when it determines that there are:
    a. adequate provisions to protect the privacy of the subjects, and
    b. adequate provisions to maintain the confidentiality of data.
3. Proposed revisions to studies requiring limited IRB review must be submitted to and approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject(s), in which case the change must be promptly reported to the IRB (i.e., within 10 business days) [45 CFR 46.108(a)(3)(iii)]. (Note: A revision may also be referred to as an "amendment," a "modification," or a "change.")
    a. A change made to correct a typographical or grammatical error in an IRB-approved document is not considered to be a modification and, thus, a modification request is not required. The IRB may administratively approve a request to correct typographical errors and other non-modification changes.
    b. If the study revisions meet the criteria for expedited review, the application will be reviewed under expedited procedures. Proposed changes must not materially:
        i. alter the assessment of risks and potential benefits of the study.
        ii. increase the level of risk to the physical, emotional, or psychological well-being of participants, including loss of confidentiality.
        iii. change the specific aims or design of the study.
    c. Following review of the requested revisions, the IRB will notify the investigator in writing of its decision. Investigators may initiate modifications after they have received final written notice of exempt determination.
4. The Principal Investigator will be notified in writing of the IRB's determination.
5. Continuing review is generally not required for research determined to be exempt, even when that research is subject to limited IRB review. However, the IRB reviewer may feel that the study should undergo annual continuing review. At that point he/she may request to have the review level escalated. Reviewer(s) will document the reason for requiring annual continuing review. The

requirement for annual continuing review will be communicated to the investigator in the IRB determination letter. [45 CFR 46.109(f)(ii), 45 CFR 46.115(a)(3)].

6. Studies not required to submit annual continuing review are still required to submit an annual status update (annual Check-in). Written notification will be sent to investigators approximately 4 weeks prior to the due date.
   a. If continuing review is not completed prior to the expiration of the current approval period, there is an automatic lapse of IRB approval. All research must stop unless the IRB Chair or Vice Chair determines that it is in the best interests of individual participants to continue the research interventions or interactions.
   b. If the investigator wants to re-open a study that lapsed for more than 30 days a new application must be submitted or the investigator can consult with the IRB Chair or Vice Chair and the Institutional Official (IO) regarding any documentation that may be required, in addition to the continuing review application, for the review to take place.
7. At a convened IRB meeting, the committee will acknowledge and review the list of studies reviewed via expedited process. Any IRB member can call for a full board review of any submitted protocol.
8. Closure – The completion, suspension, or termination of a project is a change in study activity and must be reported to the IRB. Thus, the investigator is required to inform the IRB using a closure form when a project is closed or terminated.
   a. If the study is terminated by the IRB Chair, Vice Chair, or IO, a letter will be provided to the investigator indicating that all research must stop and provide the reasoning for this termination.
   b. The principal investigator (PI) and/or the IRB administrators may close approved protocols under certain circumstances. The PI is responsible for promptly closing out an IRB approved study if any of the following conditions exist:
      i. All research/clinical investigation activities including data analysis and reporting are complete.
      ii. The PI never initiated the study.
      iii. Subject accrual is finished, all data collection is complete, and the only remaining activity is analysis of the data, the data are de-identified, and there are no identifying links or codes to the de-identified data.
      iv. The PI plans to leave the University and intends to continue the research activities at another institution.
      v. The study has been open for a period of three or more years and the PI has enrolled no subjects in the study, collected no data from records, or collected/received specimens.
   c. The PI cannot close out an active IRB study if:
      i. He/she is still following subjects, or
      ii. He/she is analyzing identifiable data (including data with codes or links to identifiers).
   d. The IRB chair or IRB administrator may notify a PI that IRB approval or active IRB status has expired or that the IRB has inactivated IRB approval after 6-months of non-response from the PI to IRB requests. These requests will be documented in the study files in the electronic IRB management system.
   e. If a study has been open for a period of three or more years and the PI has not enrolled subjects in the study, the IRB requires study closure unless there are extenuating circumstances for keeping the project open (e.g., the study is about a rarely seen condition).
   f. Procedures for closing a study fall into five categories:
      i. Final review.
      ii. Non-response from PI to IRB requests.
      iii. Closure due to non-enrollment.
      iv. Lapse of approval due to non-response to requests for continuation or final review.
      v. PI initiated withdrawal.

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. The Belmont Report, Office of the Secretary, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 19, 1979.
5. PNWU SOP 103 Activities Subject to Human Protections
6. PNWU SOP 115 Functions of the IRB
7. PNWU SOP 124 Review and Approval of Non-Exempt Human Subjects Research
8. PNWU Human Research Protections Policy

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 4-13-2023	C. Case	Original SOP

Appendices:

None