Procedure Title: Suspensions and Terminations of Approved Research

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	08/12/2021	**Executive Lead:**	Chief Research Officer
Effective:		**Revision History:**	.00 – 8/12/2021; .01 – 3/27/2023
Approved by:	Institutional Review Board		
Procedure Number:	154.01		
Key Words:	Administrative Hold, Suspension, Termination		
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 IRB procedures for suspension and termination of approved research.

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:
The federal regulations give the Institutional Review Board (IRB) the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to subjects (45 CFR 46.113, 21 CFR 56.113). The IRB's authority to suspend or terminate research applies to all research that requires IRB approval, including exempt research, research for which continuing review is no longer required, and human subjects research that has not undergone IRB review.

Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and will be promptly reported to the principal investigator in writing. The institutional official (IO) will be notified of any incident resulting in unexpected harm to human research participants or any incident deemed serious or continuing noncompliance.

The sponsor, principal investigator, IRB chair or their designee may place a voluntary administrative hold on a study to temporarily stop some or all research activities in order to protect the welfare and safety of human participants. Administrative holds are not suspensions or terminations.

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Protecting the rights and welfare of human research participants;
- 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:

- Overseeing and providing the necessary support to the IRB;
- Monitoring compliance with this SOP;
- Posting this SOP for the PNWU community.

The Investigator is responsible for:

- Being a steward of a research environment that promotes the responsible conduct of research;
- Ensuring compliance with the IRB-approved protocol, federal regulations, state laws, good clinical practice, and applicable FDA guidance;
- Reporting problems, voluntary administrative holds, or possible issues of noncompliance to the IRB;
- Reporting to the IRB if an outside entity with proper authority suspends or directs early termination of a study;
- Seeking support from OSA and the IRB when questions arise.

The Institutional Official (IO) is responsible for:

Reporting suspensions and terminations to federal funding agencies if applicable, and when appropriate, filing required incident reports with the Office of Human Research Protections

Definitions

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

- Administrative hold
- Suspension
- Termination

Incident Reporting:

1. Suspected incidents of research not being conducted in accordance with IRB requirements may be reported to the IRB chair, IRB vice chair, institutional official (IO), IRB administrator or via the Human Resources confidential reporting form within 10 business days. This process is outlined in SOP 134 Required Reporting: Unanticipated Problems and Adverse Events.

2. Voluntary administrative holds, suspensions, or terminations initiated by the investigator must be reported to the IRB within 7 days via the IRB electronic submission system as some suspensions or early terminations may have adverse effects on currently enrolled or past subjects.

IRB Procedures:

1. Incidents reported to the IRB are reviewed by the IRB chair, vice chair, or designee. The reviewer will make a determination of no additional actions needed, or additional review needed.

2. Events receiving a determination of no additional actions needed will be reported to members of the IRB at the next regularly scheduled meeting.

3. If the IRB chair, vice chair, or designee determines that additional review is needed, the event will be placed on the agenda for the next regularly scheduled IRB meeting. The IRB will review the event/incident and make a determination of no additional actions needed, modifications needed, suspension, or termination.

4. The IRB committee will consider whether additional procedures are needed to protect the rights and welfare of study participants. These procedures may include, but are not limited to:
    - Suspending the study pending further action by the investigator;
    - Terminating the study;
    - Making arrangements for clinical care outside of the study;
    - Transferring participants to another investigator;
    - Allowing continuation of some research activities under the supervision of an independent monitor;
    - Requiring follow up of participants for safety reasons;
    - Requiring unanticipated problems or outcomes be reported to the IRB and/or the sponsor;
    - Notification of former and/or enrolled participants.

5. The IRB chair, vice chair, or designee may suspend or terminate a study outside of a convened IRB meeting when there is reason to believe that the event poses increased or unacceptable risk to the safety and welfare of human subjects, or when the incident or events appear to represent serious or continuing noncompliance.

6. Before a study is suspended or terminated outside of a convened meeting, the IRB chair or designee will consult with at least one of the following: IRB administrator, vice chair, or IO and may make a decision to immediately suspend or terminate a study.

7. Research suspended outside of a convened meeting will be reported at the next regularly scheduled IRB meeting. When applicable, the IRB will determine whether to continue the suspension, reinstate IRB approval, or terminate approval of research.

8. A study may be suspended or terminated for many reasons, including but not limited to:
    - Serious adverse event(s) or unanticipated problems posing risk to subjects;
    - Noncompliance, including serious or continuing noncompliance;
    - Significant change in the risk-benefit ratio of the study;
    - Failure of the investigator to complete required training;
    - Failure of the investigator to complete annual check-in;
    - Failure to obtain appropriate consent;
    - Failure by the investigator to respond to IRB requests (e.g., noncompliance, study suspension, requested modifications, and requested event reporting) or when remedial action plans are not submitted and/or implemented;
    - Conduct of research activities without IRB Approval.

9. The IRB may require additional actions, for suspended or terminated studies, to protect the rights and welfare of the study participants. These actions may include, but are not limited to:
    - Written notification of current and previously enrolled subjects (e.g., certified mail with return receipt);
    - Protocol modifications;
    - Independent monitoring in order to continue the study;
    - Transfer of PI study responsibilities to another qualified investigator;

- Withdrawal of current study subjects from the research;
- Arrangement of care for subjects outside of the research;
- Follow-up care for safety of study subjects;
- Re-consent of study participants;
- Additional training for members of the study team.

10. When a study is suspended or terminated, the IRB administrator will place the study in a suspended or terminated state in the electronic IRB system.

11. The IRB chair, vice chair, or designee will compose a formal written notification to the principal investigator. The written notification will be sent to the principal investigator within 48 hours of the determination. The IRB administrator will save a copy to the electronic IRB system. The notification may include the following:
    - A statement as to if the study is suspended or terminated and the reason(s) for the decision;
    - An explanation of the extent of the suspension/termination in regards to study enrollment, recruitment, interventions, interactions, and data analysis;
    - As appropriate, a request for an investigator initiated corrective action plan to protect the rights and welfare of current participants and others;
    - As appropriate, a description of any IRB proposed corrective actions (including requiring study amendment and event reporting);
    - When appropriate, a deadline for receipt of proposed corrective actions;
    - Notice that the investigator may make an appeal to the IRB determination.

12. The IRB will report study terminations and suspected serious or continuing noncompliance to the IO within four working days when feasible.

13. Events that are deemed noncompliance will be placed on the agenda for the next regularly scheduled IRB Meeting for review and determination. The IRB will determine whether the noncompliance is serious and whether or not it is continuing noncompliance. *(See SOP 134 for more information about protocol deviations, violations and noncompliance.)*

14. The IRB chair or the convened IRB may restore IRB approval for suspended studies when issues and concerns have been resolved and sufficiently documented in the IRB records. All determinations made by the convened IRB will be clearly documented in the IRB meeting minutes. A formal written notification from the IRB office will be sent to the principal investigator, and a copy will be included with the study file in the electronic IRB system.

Principal Investigator Procedures:

1. Upon IRB notification the investigator is responsible for taking action to stop enrollment and research procedures as directed by the IRB.

2. Investigators are required to cooperate with any investigation directed by the IRB or the institutional official and assist with carrying out actions required to protect the rights and welfare of study participants.

3. Study modifications made as a result of suspension must undergo review prior to implementation.

4. The investigator must resolve all pending issues with the IRB in order to reinstate a suspended study.

a. The investigator must provide the IRB with a detailed plan to ensure that the study will be conducted in compliance with applicable laws and regulations, and that events leading to suspension will not occur again. The plan must be reviewed and approved by the IRB prior to implementation. Any participant communication (email, letters, and telephone scripts) must be reviewed and approved by the IRB.
b. If adequate progress has not been made on the pending issues by the deadline given, or within 90 days when no deadline has been given, then the IRB may administratively close the protocol. The principal investigator will be notified in writing of the study closure.

5. The investigator is responsible for reporting voluntary administrative holds, suspensions, or early terminations via the IRB electronic submission system in a timely manner to reduce the risk of harm to study participants and others.

6. Approved research in a suspended state remains open. The principal investigator must complete continuing review, annual check-in, or study closure as directed by the PNWU IRB or sponsor.

7. Additional reporting may be required if outside sponsors, regulatory agencies, and/or organizational officials are involved in the research. It is highly recommended that you consult with the IRB office prior to making a report to outside entities.

Investigator Appeal:
A principal investigator may appeal a decision to suspend or terminate their study. Appeals must be submitted in writing to the IRB within 30 days of being notified of the determination. *(See SOP 108 Appeal of IRB Decisions.)*

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. US Department of Health and Human Services Guidance on Reporting Incidents to OHRP https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html
4. PNWU SOP 108 Appeal of IRB decisions
5. PNWU SOP 129 Required reporting of protocol violations, deviations, and noncompliance
6. PNWU SOP 134 Required reporting: Unanticipated Problems and Adverse Events

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 8-27-2021	C. Case	Original SOP
.01 / 4-4-2023	C. Case	Minor punctuation corrections; added SOP 134 name and link to the SOP under Incident Reporting #1; Added Vice chair to #1, #3, #5, & #11 under IRB procedures; Add link to SOP 134 under IRB procedure #13; Added Institutional Official regarding PI cooperation for any investigation in #2 under

		Principal Investigator Procedures; Added study closure to Principal Investigator procedures in item #6; Added link to SOP 108 under investigator appeal; changed appeals must be submitted in writing to the IRB chair within 30 days TO submitted in writing to the IRB within 30 days.

Appendices:
None