Procedure Title: IRB Contingency Planning and Emergency Response Procedures

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:		**Executive Lead:**	Chief Research Officer
Effective:		**Revision History:**	.00 – 2/1/2023
Approved by:	Institutional Review Board		
Procedure Number:	136.00		
Key Words:			
Purpose:	To meet the PNWU's contingency planning and emergency response responsibilities as recommended by the Office for Human Research Protections (OHRP) and the Food and Drug Administration for human subjects' research at institutions holding OHRP-approved Federal Wide Assurances (FWAs)		

Process:

This SOP establishes written procedures for initiating a response to an emergency impacting PNWU's Human Research Protection Program (HRPP) or HRPP operations. An emergency may include, but is not limited to, natural disasters, weather events, man-made disasters, and public health crises. This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU regarding contingency planning and emergency responses to an emergency that may potentially adversely impact the safety of researchers, staff, and/or research participants and impede their ability to comply with IRB approved protocols for the conduct of research. This would also apply if the IRB is unable to continue oversight of research.

This SOP must be used as a guide in parallel with OSA Policy 1.0 to comply with proper reporting of unanticipated problems involving the ability to ensure compliance with IRB approved protocols or risk to subjects or others. This SOP will be invoked once the Institutional Official (IO) or the Chair of the IRB, in consultation with the IO, has indicated an emergency has occurred, or preparations are needed for an imminent emergency, and human research at PNWU (including the IRB or IRB operations) is or is likely to be adversely impacted.

General Information:

In May 2018, the Office of Human Research Protection (OHRP) and the Food and Drug Administration (FDA) finalized guidance (first issued in draft form in August 2016) containing 55 recommendations for what should be included in written procedures for Institutional Review Boards (IRBs) that oversee human subjects' research.

The 51st recommendation is:

> *51. Contingency plans for transferring oversight of one or more studies to another institution or IRB in the event that the IRB is unable to continue oversight of the study (e.g., the IRB closes, suffers loss due to fire, natural disaster). (OHRP & FDA, 2018, p. 13)*

No additional recommendations or discussion were provided on how IRBs should develop contingency plans, and the final guidance omitted any mention of FDA guidance on transferring oversight (FDA, 2014) that had been referenced in the draft guidance (OHRP & FDA, 2016).

This contingency plan was developed with separate consideration of disruptions to electronic records and to personnel. Responses are calibrated to the scope and severity of the disruption, including assuring that electronic records can be reconstructed within one week and incorporating the option of having an independent IRB perform reviews according to PNWU policies and relevant SOPs. The important components of the contingency plan are summarized in the "Responsible Parties and Contingency Plan" section below. This SOP discusses plans for the transfer of oversight as well as processes that respond to disruptions that would not, in fact, require transfer of oversight.

Summary: Responsible Parties and Contingency Plan

Responsible Party	**Responsibility**
IRB Chair	Responsible for implementation of the plan as provided herein.
IRB Vice Chair	Responsible for implementation of the plan in absence of the IRB Chair. There should be a specified hierarchy of responsibility among IRB administrative staff in absence of the IRB Chair and Vice Chair.
Technology Services	Responsible for working with third party vendors to ensure that IRB software connection can be restored in emergency situations.
Technology Services	Responsible for ensuring that the IRB members, IRB staff and investigators can communicate remotely with each other and with research participants in emergency situations.
IRB Chair	Responsible for determining that there will be an acceptable delay of no more than one week in IRB operations in emergency situations.
IRB Chair in consultation with the Assoc. Provost and/or CRO	Responsible for contracts with an independent IRB for transfer of oversight in emergency situations.
IRB Chair	Responsible for the transfer of oversight to an independent IRB if oversight cannot be resumed by PNWU's IRB within a reasonable period of time.
IRB Chair	Determines if and when oversight of any transferred studies will be returned after a disruption caused by an emergency situation is resolved.

IRB Procedures for Contingency Response in Emergency Situations:

1. Procedures for contingency response when IRB is operational, but the emergency may adversely impact the safety of researchers, staff, and/or research participants, or impede their ability to comply with IRB approved protocols for the conduct of research.

Investigators at institutions such as PNWU, which have approved Federal Wide Assurances for the conduct of Human Subjects Research, must obtain IRB approval before conducting any activities that meet the definition of research with human subjects. Under most circumstances, except as explained in the section

below, investigators may not make any changes in an approved research protocol without prior IRB approval, must report untoward events such as unanticipated problems and protocol deviations to the IRB, and must provide information for the IRB to re-approve the research protocol annually.

A. CHANGES TO IRB-APPROVED PROTOCOLS

- According to IRB policy, any changes in IRB-approved research procedures must be reported to the IRB and may not be implemented prior to review and approval by the IRB, **except when necessary to eliminate apparent immediate hazards to the subject.** This is permitted by both the Common Rule (38 CFR §16.108(a)(3)(iii)) and by FDA regulations (21 CFR §56.108(a)(4)).
- Beyond the regulation, PNWU and the IRB also have a responsibility to ensure the safety of our research team members and staff. Therefore, interim measures to reduce immediate hazards to research participants and staff may be warranted. This may result in deviations from IRB-approved study procedures prior to securing IRB approval. According to policy, protocol deviations must be reported to the IRB within 5 business days. The PI must also submit these to the IRB as "Reportable New Information (RNI)."
- If apparent immediate hazards will be sustained for a duration that would practicably allow for an amendment covering such changes to be developed, reviewed and IRB-approved, then a protocol modification must be sought.

1. Public Health Emergencies (e.g., pandemic, epidemic)

- During public health emergencies such as a pandemic, it may be necessary for the IRB to require implementation of safety precautions or place a hold on research with in-person interactions in order to protect researchers, employees, and study participants. The PNWU IRB will take into consideration CDC recommendations, Washington State Department of Health recommendations, PNWU recommendations, applicable PNWU emergency plans (e.g., COVID-19 Plan) or emergency policies (e.g., COVID Policy) developed during public health emergencies.
- Safety precautions may include, but are not limited to, telephone screenings prior to scheduled study visits, in-person screening on arrival to the study site for symptoms (e.g., fever, coughing, sneezing, muscle aches), screening for travel to specific locations, protective equipment (e.g., gloves, gowns, face coverings), limiting length of contact, as well as additional hygiene measures such as additional hand washing and frequently wiping down surfaces in high traffic areas).
- A pause or hold may be necessary for research with in-person study interactions. Some studies with direct therapeutic benefit or moderate direct benefit may continue under certain conditions. In general, the specific types below will guide decisions as to whether a study may be allowed to continue during a public health emergency.
    - **Type I** – Direct therapeutic benefit – research protocols that if stopped could cause serious or immediate harm to research participants (e.g., phase clinical trials with no treatment alternatives, protocols that include treatments for acute and/or life-threatening health conditions such as cancer treatments or protocols involving interventional drugs, vaccines, or preventative drug regimens.) Type I research may continue if the IRB agrees that the research can be conducted in a safe manner that protects the subjects, researchers, and the community. PIs must develop a safety plan and pause the enrollment of new subjects unless there are compelling reasons to continue enrollment. PIs may petition the IRB if they have a compelling reason for not following this SOP. Requests will be reviewed in order

of priority. These guidelines must be followed during appeals and until such a time as an appeal is granted.

Type II – Moderate direct benefit to research participants. Type II research can continue if the IRB agrees that the research can be carried out in a safe manner that protects subjects, researchers, and the community. PIs must pause on enrolling new research participants. Examples of Type II research:

- protocols in which the research participants are receiving interventions or clinical care that is interrelated to their research participation (e.g., test results coming back that might have clinical implications for their care);
- protocols evaluating treatments for chronic conditions (e.g., asthma, depressions, hypertension); or
- protocols involving the assessment of safety or efficacy of an intervention in which, if stopped, the potential societal benefit of the science would be significantly and adversely impacted, for example where a research assessment (blood collection or imaging study) is only valuable if collected at a very specific time. This will be measured against the risk to participants, including any risks of exposure.

- **Type III** - Research with face-to-face (in-person) interactions and low to no direct benefit to participants. Type III research must be paused or placed on hold. For example:
  - cohort and natural history studies where delays in data collection have limited impact on scientific objectives
  - protocols where delays to starting or pausing the research does not substantively impact the research objects
  - protocols in which risk to research participants are higher (e.g., potentially exposing the elderly vulnerable individuals to COVID-19) and benefits of the study to the participants remain minimal
  - Research with healthy volunteers
  - Any minimal risk study that requires research subjects to travel, that involve students, or that are in a community setting and require direct interaction with researchers.
- **Type IV** - Research with online visits or data collection that does not require participant face-to-face (in-person) interactions. Type IV research may continue.

- Investigators are encouraged to contact the IRB with any questions or concerns.
- For externally sponsored studies, it is recommended that the investigator contact the sponsor to determine if safety procedures have been developed.
- Formal notes must be retained documenting all screening questions and answers.
- Given the considerable uncertainty during public health emergencies such as pandemics or epidemics, PNWU strongly encourages its research community to suspend new human subjects research projects involving in-person participant contact and/or domestic or international travel. If delay is not possible, researchers are advised to submit IRB protocols that include study procedures that allow for flexibility/alternatives to in-person participant contact.

B. Examples of Protocol Changes that Require IRB Approval

1. In-person to remote interactions with participants

If you need to make changes to your research to move interactions with participants from in-person to online, check your IRB-approved protocol. If you need to make changes to the protocol to accommodate these types of changes, please submit a modification request to the IRB. We recommend adding procedures, not removing any of the existing procedures, to accommodate this change. This way the protocol still addresses procedures done previously and will allow you revert to in-person procedures at a later date without submitting another modification. When reading through your currently approved protocol to see where modifications are needed, remember to check all sections as modifications may be needed in more than the study scope. Also remember to check your consent forms, consent scripts, recruitment materials, etc. Thoroughly checking all your submission materials and making modifications to all applicable sections will allow the IRB to process the review quicker. Delays occur when incomplete modification requests are submitted, requiring the IRB to send them back for corrections. When conducting research remotely, PNWU recommends:

- Ensure remote access, wherever possible, to files, data, servers, etc. Check that all members of your research team who might need to work remotely have access to computers that are able to connect to research files and meeting software (such as Zoom).
- Privacy and confidentiality provisions remain critically important at all times, even when working remotely. Please note that access to, storage, and treatment of sensitive information, including data governed by HIPAA regulations, **must comply with university and other policies for security of research data.**
- Research teams should obtain contact information for research participants should they need to reach out to them. This information should be accessible remotely yet stored securing following University guidance.
- **Do not use personal email** to conduct human subjects research activities or for correspondence of any kind related to human subjects research.

2. Consent Forms

A revised consent form is not required for urgent changes unless the change fundamentally alters what the participants consented to. You can inform participants via other means. Consent form process changes should be approved by the IRB (e.g., if adding the option to enroll a subject over the phone or with the use of electronic signature).

3. Changes to Participant Payment Methods

If you need to make changes to your research that include changes to the method of payments because of the move of interactions with participants from in-person to online, check your IRB-approved protocol. If you need to make changes to the protocol to accommodate these types of changes, please submit a modification request to the IRB. We recommend adding alternative options, and not removing any of the existing payment methods, to accommodate this change. This way the protocol still addresses payments made previously and will allow you to revert to previous payment methods at a later date without submitting another modification. When reading through your currently approved protocol to see where modifications are needed, remember to check all sections as modifications may be needed in more than the compensation section. Also remember

to check your consent forms, consent scripts, recruitment materials, etc. Thoroughly checking all submission materials and making modifications to all applicable

2. Procedures for contingency response when IRB may be unable to provide necessary oversight and support

Institutions may rely on an IRB other than their own to review research (called "ceding review") by entering into a reliance agreement with an independent reviewing IRB. Independent IRBs can take over IRB functions for institutions temporarily in emergency situations and provide a key resource in contingency planning. The consequences of disruptions to IRB functioning could be delays in the ability of investigators to start new research projects, to make changes to existing projects (including adding study staff), to continue projects that are near the expiration date of annual re-approval, and/or to receive assistance in responding to unforeseen events.

As part of its contingency planning process, in emergency situations when the PNWU IRB is temporarily unable to provide necessary oversight and support, PNWU has entered into a reliance agreement for human subjects research studies to be reviewed by an independent IRB, one of which has established access to PNWU's electronic system.

a. Determining Whether Transfer of IRB Responsibilities Is Necessary

IRB functioning is dependent on whether IRB members and staff have necessary access to IRB records and can communicate appropriately with investigators. Disruptions to IRB functioning can be characterized by their scope and severity. The scope of a disruption depends on whether and to what extent the disruption reduces or prevents access to IRB records and/or makes some or all personnel unavailable to work. The severity of a disruption depends primarily on how long it takes before operations return to normal. In addition to planning for the transfer of IRB oversight, the PNWU contingency plan prioritizes developing ways of responding to disruptions quickly enough so that no transfer is necessary.

b. Identification of Responsibilities

The plan designates the IRB Chair as the individual who will lead the response to a disruption. If the IRB Chair is unavailable, the responsibilities transfer to the IRB Vice Chair, designated IRB Administrators, or to the Institutional Official, in that order. A key responsibility is communicating to investigators about the reasons for, responses to, and anticipated duration of the delays in IRB operations.

c. Response to Disruption of Access to Records

PNWU's IRB uses an electronic system to manage records concerning submission, review, and approval of research. The electronic system (both the software and the data) are backed up on an Amazon AWS Secure hosting site with an open vulnerability assessment system in the cloud by the software vendor in real time. Risks related to continuity of the production environment are mitigated by failover architecture involving real time replication of client data to multiple data centers. Disaster recovery tests and plan updates are performed by the software team on a quarterly basis.

IRB records will be restored within one week after the date that disaster recovery is invoked for restoration of IRB records. The one-week goal was considered appropriate for IRB responsibilities because waiting an additional week for review of new protocols and amendments, while not ideal,

would not be expected to significantly impede research. For annual renewal, investigators are expected to submit progress reports for continuing review to the IRB at least 30 days before the expiration date of the study. Thus, only investigators who had not met this expectation might be forced to cease study interventions (except for those required for the best interest of the already enrolled subjects) until records were restored.

Investigators are also expected to submit initial applications well in advance of any need for IRB approval for funding purposes; again, a funding deadline might be missed if a submission was made less than a week before the funding deadline if records were unavailable. The one-week timeframe could potentially be problematic if an unforeseen event involving a fatal or life-threatening incident occurs during the disruption. However, the immediate response to such events could be accomplished without access to IRB records.

The process for remote backup is for the individual from PNWU responsible for disaster response to make the determination that a disaster requiring recovery has occurred, and for the IRB Chair and IRB staff to coordinate with the PNWU IT department when needed for restoration of connections to the electronic system and access to IRB records. Because under the contingency plan, IRB records will be restored within one week, a disruption of access to records would not require transfer of IRB oversight.

d. Response to Disruption of Availability of Personnel

An unexpected lack of availability of some or all IRB staff and/or IRB members can be caused by multiple resignations, pandemics, and interruptions in electricity and/or internet service to work and/or home. Note that the inability of IRB staff and IRB members to travel to the IRB office location would only constitute a personnel disruption if electricity and internet access were widely unavailable, because IRB staff and IRB members are able to use the electronic system from home and participate in convened meetings via teleconference.

The process for responding is for the IRB Chair to decide whether a personnel disruption is likely to have a significant negative impact on IRB operations without external help, and to identify how soon the disruption is expected to be resolved (e.g., sick IRB members recover, additional staff are hired, new computers are purchased).

OHRP has advised institutions regarding how they handle institutional oversight of ongoing, IRB approved research in emergency situations. OHRP advised that one option is to rely on another institutional review board (IRB) that is not affected by the disaster. OHRP encourages reasonable attempts to rely on another IRB. Accordingly, PNWU's contingency plan follows guidance from OHRP (and the FDA as appropriate) and relies on the services of an independent IRB in emergency situations. The OHRP has also advised on alternatives to transferring oversight to an independent IRB as set forth below.

1. Use of Independent IRB

   Some disruptions may be so severe that the IRB Chair, in consultation with the Institutional Official and IRB Administrator, will determine that investigators would be best served by transferring oversight to an independent IRB. If additional resources are needed, the IRB Chair will initiate communication with an independent IRB who is willing to perform reviews following the policies and procedures of the PNWU IRB.

In such a situation, the detailed OHRP/FDA recommendations for transferring research oversight will be followed. When transferring IRB review and oversight of research projects from one IRB to another IRB, OHRP recommends that the transfer process be documented in a written agreement between the original and receiving IRBs, if appropriate. [Note: OHRP recognizes that for transfers of oversight between IRBs at the same institution, a written agreement may not be necessary as the process may be addressed by the institution's established procedures (assuming all appropriate steps as identified below are covered).]

The agreement should address the following eight actions, as appropriate. (Note: The following list is not meant to be exhaustive. Additional actions may be necessary and/or appropriate.)

1. Identifying those studies for which IRB oversight is being transferred
2. Ensuring the availability and retention of pertinent records
3. Establishing an effective date for transfer of oversight, including records, for the research project(s)
4. Conducting a review of the study(ies) by the receiving IRB, where appropriate, before it accepts responsibility for the study(ies)
    - Confirming or establishing the date for the next continuing review
5. Determining whether the consent form needs to be revised
6. Notifying the key parties
7. Addressing IRB regulatory issues.

The IRB Chair will monitor the situation to determine when the disruption has been resolved and the services of the independent IRB are no longer required. If oversight of any studies has been transferred to the independent IRB, the IRB Chair will decide whether to leave the studies with the independent IRB for the life of the study, taking into account the burden on investigators and the capacity of the IRB.

OHRP has also provided guidance on alternatives transferring oversight to an independent IRB, which the IRB Chair can consider following.

2. Alternatives to Use of an Independent IRB

If extraordinary circumstances make relying on another IRB untenable, OHRP has advised that it will consider the situation at institutions that are affected by such disasters and will use available flexibility in its decision making if an institution failed to conduct continuing review at least annually. This flexibility will continue during the time that the devastation prevents the IRB from either conducting continuing review or temporarily relying on another IRB to conduct continuing review.

OHRP has stated that in emergency situations it is difficult to provide generalized advice on the steps that affected investigators, IRBs, institutions, and sponsors should take. In some instances, it may be appropriate to terminate the conduct of a study, if doing so would not endanger the subjects. In other instances, it may be appropriate to attempt to find a qualified investigator and IRB outside the affected area to take over the conduct and oversight of the study in order to permit the study to continue, particularly if doing so would be in the best interest of subjects (for example, treatment protocols). Unfortunately, in some instances, studies may be disrupted, subjects and study staff so dispersed, and IRB records and research data so compromised that it may take some time to sort through these issues.

An institution holding an OHRP-approved assurance may extend their assurance to cover two types of collaborating individual investigators: collaborating independent investigators and collaborating institutional investigators (see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html). Another option is to make other individuals "agents" under their FWA for the purpose of carrying out some aspect of a research study on behalf of an engaged institution holding an FWA. Agents can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. The determination of whether an individual or entity is an agent of an FWA-holding institution is generally for the institution and the other individual or entity to determine (see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/determining-when-institutions-are-engaged-in-research/index.html).

Decisions regarding use of alternatives to independent IRBs are within discretion of the IRB Chair, in consultation with the institutional official.

References:

1. U.S. Department of Health and Human Services Effects of Disasters on Human Research Protections Programs Guidance, May 14, 2018
2. U.S. Department of Health and Human Services Extending an FWA to Cover Collaborating Investigators, January 31, 2005.
3. U.S. Department of Health and Human Services Determining When Institutions are Engaged in Research, January 13, 2009.
4. U.S. Department of Health and Human Services Considerations in Transferring a Previously Approved Research Project to a New IRB or Research Institution, May 23, 2012.
5. U.S. Department of Health and Human Services, Office of Research Integrity, ORI Introduction to RCR: Chapter 6. Data Management Practices.
6. U.S. Department of Health and Human Services, The HIPAA Privacy Rule

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 2-9-2023	B. Roach	New SOP