**INSTRUCTIONS:**

*Before submitting to the IRB,* ***remove these instructions from the final protocol.***

*Depending on the nature of what you are doing, some section may not be applicable to your research. If so, retain the section heading and mark the section as N/A.*

*When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes to your study.*

***What template should I use?***

*The Biomedical Template Protocol should be used for studies involving clinical procedures or tests (except for behavioral studies where the only collected sample is obtained via a non-invasive method, for example saliva).*

*For studies involving interviews, surveys, focus groups, or behavioral interventions, please use the Social Behavioral template instead.*

*For studies involving secondary data analysis only, please use the Secondary Analysis Protocol instead.*

*For studies involving only a review retrospective data such as of medical charts, or case series, please use the Records Review template*

**PROTOCOL TITLE:**

*Include the full protocol title.*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**EXTERNAL (NON-PWNU) COLLABORATORS:**

*Name, Title(s), Institution, and Department of External Collaborators*

*(For each entry, please indicate whether that institution’s IRB will review (or has already reviewed) that individual’s engagement in human participants research activities)*

**VERSION NUMBER/DATE:**

*Include the version number and date of this protocol.*

REVISION HISTORY:

|  |  |  |
| --- | --- | --- |
| Revision # | Version Date | Summary of Changes |
|  |  |  |
|  |  |  |
|  |  |  |

Table of Contents

[1.0 Objectives 4](#_Toc108514641)

[2.0 Background and Rationale 4](#_Toc108514642)

[3.0 Study Design/Study Endpoints 4](#_Toc108514643)

[4.0 Study Intervention 4](#_Toc108514644)

[5.0 Study Procedures 4](#_Toc108514645)

[6.0 Inclusion and Exclusion Criteria 5](#_Toc108514646)

[7.0 Statistical Analysis Plan 5](#_Toc108514647)

[8.0 Sharing of Results with Participants 5](#_Toc108514648)

[9.0 Study Timelines 5](#_Toc108514649)

[10.0 Number of Participants 6](#_Toc108514650)

[11.0 Vulnerable Populations 6](#_Toc108514651)

[12.0 Recruitment Methods 6](#_Toc108514652)

[13.0 Withdrawal of Participants 6](#_Toc108514653)

[14.0 Risks to Participants 7](#_Toc108514654)

[15.0 Potential Benefits to Participants 7](#_Toc108514655)

[16.0 Compensation for Participation in Research Activities 7](#_Toc108514656)

[17.0 Data Management and Confidentiality 7](#_Toc108514657)

[18.0 Plans to Monitor the Data to Ensure Safety of Participants and Data Integrity 8](#_Toc108514658)

[19.0 Provisions to Protect the Privacy Interest of Participants 8](#_Toc108514659)

[20.0 Community-Based Participatory Research (if applicable) 8](#_Toc108514660)

[21.0 Compensation for Research Related Injury 9](#_Toc108514661)

[22.0 Economic Burden to Participants 9](#_Toc108514662)

[23.0 Prior Approvals 9](#_Toc108514663)

[24.0 Consent Process 9](#_Toc108514664)

[25.0 Setting 11](#_Toc108514665)

[26.0 Resources Available 11](#_Toc108514666)

[27.0 Multi-site or Collaborative Research 12](#_Toc108514667)

[28.0 References 12](#_Toc108514668)

# Objectives

* 1. Describe the purpose, specific aims, or objectives. (There should be one or two primary objectives with additional objectives listed as secondary.)
	2. Describe the hypotheses to be tested or the study questions that will guide the research. If the study has more than one phase, clearly map out the different phases.

# Background and Rationale

* 1. *Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.*
	2. Describe the relevant prior experience and gaps in current knowledge.
	3. Describe any relevant preliminary data.

# Study Design/Study Endpoints

* 1. *Describe and explain the study design to indicate how the objective(s) will be achieved.*
	2. *The type of study to be conducted (i.e., single center or multicenter, randomized crossover, survey study).*
	3. *Describe the primary and secondary study endpoints. Describe any primary or secondary safety endpoints*

# Study Intervention

* 1. *Describe the study intervention that is being evaluated.*

# Study Procedures

*5.1 Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or minimize risks.*

*5.2 Describe procedures performed to lessen the probability of magnitude of risks.*

*5.3 The source records that will be used to collect data about participants*

*5.4 Describe what data will be collected including long-term follow-up.*

*5.5 If your study uses audio/video recordings or photographs:*

*5.6 The type of recording/photographs being used*

*5.7 Why the type of recording is necessary to the research*

*5.8 How the recording/photographs will be utilized in the research (e.g., data analysis only)*

*5.9 How and where the recordings/photographs are stored, who has access to them, and if/when they will be destroyed.*

# Inclusion and Exclusion Criteria

* 1. Describe how individuals will be screened for eligibility.
	2. Describe the criteria that define who will be included or excluded in your final study sample.
	3. Indicate specifically whether you will include or exclude each of the following special populations: (Members in the following populations may not be included in your research unless you indicate this in your inclusion criteria.)
		+ Adults unable to consent
		+ Individuals who are not yet adults (infants, children, teenagers)
		+ Pregnant women
		+ Prisoners
	4. If this study excludes certain populations, explain the rationale for the exclusion in detail.

# Statistical Analysis Plan

* 1. *Describe the data analysis plan, including any statistical procedures or power analysis*

# Sharing of Results with Participants

* 1. Describe whether results (study results or individual participant results, such as results of investigational diagnostic tests, survey results, or incidental findings) will be shared with participants or others (e.g., the participant’s primary care physicians) and if so, describe how it will be shared.
	2. Describe the plan for managing the types of findings that might arise. This should include any secondary findings that are being sought actively, findings that might be anticipated, and findings that might be un-anticipated.
	3. Plan for recognizing, analyzing, and handling incidental findings and how incidental findings will be communicated to the participants during the consent process. If the plan is not to disclose finding, then this should be included. This plan might include the option for participants to opt-out of incidental findings.
	4. Describe the research team’s responsibilities following disclosure of a finding. This should detail educational information about the nature of the finding, how to seek care from a clinician or specialist, obtaining health insurance to secure treatment, and/or referral to a clinical specialist, if one is required.

# Study Timelines

* 1. *Describe:*
		+ *The duration of an individual participant’s participation in the study.*
		+ *The duration anticipated to enroll all study participants.*
		+ *The estimated date for the investigators to complete this study (complete primary analyses)*

# Number of Participants

* 1. Indicate the total number of participants to be accrued. If this is a multicenter study, indicate the total number of participants to be enrolled.
	2. *If applicable, distinguish between the number of participants who are expected to be enrolled and screened, and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures.)*

# Vulnerable Populations

*11.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards that will be included to protect their rights and welfare. (e.g., independent assessment of capacity to consent; reading level of subject documents will be at or below a 6.0 Flesch-Kincaid Scale; Consent form will be read out loud to participants). Review SOP 128 Vulnerable Populations to ensure that you have provided sufficient information*

11.2 *For studies aimed at addressing issues that affect a certain community or group, how, if at all, will this study involve people from the target community in the design and conduct of the study, and how will the results of the research be shared with the participants and/or the target community(ies)?*

# Recruitment Methods

* 1. Describe when, where, and how potential participants will be recruited. Describe the source of participants. If you will recruit from Social Media sites please include the URLs.
	2. Describe the methods that will be used to identify potential participants.
	3. Describe materials that will be used to recruit participants. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)
	4. *Describe how eligibility will be determined and provide a description of any eligibility screening done before enrolling participants (including whether any identifiers will be recorded)*
	5. *If recruiting online, describe how potential participants would be directed to your recruitment information and study description. NOTE research recruitment through social media may not be done via personal social media accounts.* *Explain what will take place if a participant declines participation. For example: “If a participant declines to participate in all portions of the study, the participant will not be assigned a study ID number and the study coordinators/data collects will refrain from collecting any data on the participant. If the participant agrees to participate in some portions of the study by not others, the participant will be assigned a study ID number and the study coordinators/data collectors will be instructed to collect data only on those aspects of the study to which the participant has agreed to participate. These procedures will help prevent unauthorized inclusion of the patient’s data in the database.”*
	6. *Describe the amount and timing of any payments to participants.*
	7. If this is a multicenter study and participants will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

# Withdrawal of Participants

* 1. Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.
	2. Describe any procedures for orderly termination.
	3. Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.

# Risks to Participants

* 1. List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participants’ participation in the research. Include as may be useful for the IRB’s consideration, describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.
	2. If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable.
	3. If applicable, describe risks to others who are not participants.
	4. Describe any steps that will be taken to minimize the risk to subjects (e.g., will you apply to the NIH for a Certificate of Confidentiality, will you eliminate unnecessary procedures in the protocol, will you hold debriefing sessions for participants)

# Potential Benefits to Participants

* 1. Describe the potential benefits that individual participants may experience from taking part in the research. Include as may be useful for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits.
	2. Indicate if there is no direct benefit. Do not include benefits to society or others.

# Compensation for Participation in Research Activities

* 1. *Describe if/how participants will be compensated for participation in the study.*

*15.2 Describe the amount, timing, and method of any payments to participants. (e.g., gift card, check.)*

*15.3 Describe what tax information will be required (e.g. social security number).*

*15.4 If payments will be pro-rated if a participant withdraws early or does not complete all study procedures.*

*15.5 If the investigator believes that the biologic specimens obtained could be part of or lead to the development of a commercial product, indicate if the participant will have any right to compensation or ownership interest related to such development.)*

# Data Management and Confidentiality

*Describe the data management plan.*

* 1. *What steps will be taken to secure the data/specimens (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and data will be coded and identifiers will be kept separate from the data) during storage, use and transmission.*
	2. *What procedures will be used for quality control of collected data.*
	3. *How data will be handled study-wide*
		+ *What information will be included in the data?*
		+ *Where and how long will the data be stored?*
		+ *Who, in general will have access to the data?*
		+ *Who is responsible for receipt or transmission of the data?*
		+ *How will data be transported?*

# Plans to Monitor the Data to Ensure Safety of Participants and Data Integrity *(for minimal risk research this section may be deleted)*

*This section is required when research involves more than minimal risk to participants. Describe:*

*• The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. The plan might include establishing a data monitoring committee (DSMB/DMC/IDMC) and a plan for reporting data monitoring committee findings to the IRB and the sponsor.*

*• The frequency of DSMB Meeting.*

*• What data are reviewed, including safety data, untoward events, and efficacy data.*

*• How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*

*• The frequency of data collection, including when safety data collection starts.*

*• The individual responsible for safety monitoring.*

*• The frequency or periodicity of review of cumulative data.*

*• The statistical tests for analyzing the safety data to determine whether harm is occurring.*

*• Study stopping rules - under what conditions will the study be modified or stopped and who will make the decision?*

*• Participant stopping rules – under what conditions will a participant be removed from study participation and who will make the decision?*

*• Reporting mechanisms (i.e. Deviations, adverse events, UPs)*

*• Description of the plan for notifying the IRB of reportable events; whether the sponsor requires reporting above and beyond the PNWU IRB reporting requirements, and if so, a description of the requirements and plan for meeting them.*

*If a DSMB is needed, please describe the composition of the board here.*

# Provisions to Protect the Privacy Interest of Participants

* 1. *Describe the steps that will be taken to protect participants’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact with or whom they provide personal information.*
	2. *What steps will be taken to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures.*
	3. *How the research team is permitted to access any sources of information about the participants.*

# Community-Based Participatory Research *(if applicable, if not applicable the section may be deleted)*

* 1. Describe involvement of the community in the design and conduct of the research.

Note: “Community-based Participatory Research” is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

# Compensation for Research Related Injury *(for minimal risk research this section may be deleted)*

*21.1 If the research involves more than Minimal Risk to participants, describe the available compensation in the event of research-related injury.*

*21.2 Provide a copy of contract language, if any, relevant to compensation for research-related injury.*

# Economic Burden to Participants (if applicable)

*22.1 Describe any costs that participants may be responsible for because of participation in the research.*

# Prior Approvals

* 1. Describe any approvals that will be obtained prior to commencing the research. (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety approval.)

# Consent Process

*Review the “SOP 117 Informed Consent & Assent Processes” to ensure you have provided sufficient information for the IRB to make these determinations.*

* 1. Indicate whether you will you be obtaining consent, and if so describe:
		+ where and when the consent process take place
		+ any waiting period available between informing the prospective participant and obtaining the consent.
		+ any process to ensure ongoing consent.
		+ the role of the individuals listed in the application as being involved in the consent process.
		+ the time that will be devoted to the consent discussion.
		+ steps that will be taken to minimize the possibility of coercion or undue influence.
		+ steps that will be taken to ensure the participants’ understanding.

**Non-English Speaking Participants**

* + - Indicate what language(s) other than English are understood by prospective participants or representatives.
		- If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent.

**Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)**

* + - Provide information on the waiver or alteration of consent and the rationale. (e.g., what elements of consent will be altered.)

**Participants who are not yet adults (infants, children, teenagers)**

* + - Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)
		- Describe whether parental permission will be obtained from:
			* Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
			* One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
			* Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.
		- Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.
		- When assent of children is obtained describe whether and how it will be documented.

**Cognitively Impaired Adults/Adults Unable to Consent**

Describe:

* + - the process to determine whether an individual is capable of consent.
		- the individuals from whom permission will be obtained in the order of priority. (e.g., durable power of attorney for health care, a court-appointed guardian for health care decisions, spouse, or adult child). Provide information about which individual(s) are authorized under applicable state law to consent on behalf of a prospective participants to their participation in the procedure(s) involved in this research. if assent will be required of all, some, or none of the participants. If some or all are indicated, which participants will be required to provide assent and which will not.
		- if assent will not be obtained from some or all participants, an explanation of why not.
		- whether the assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents.

# Setting

Describe the study sites or locations where your research team will conduct the research.

* 1. Identify where your research team will identify and recruit potential participants.
	2. Identify where research procedures will be performed.
	3. Describe the composition and involvement of any community advisory board.
	4. For research conducted outside of the organization and its affiliates describe:
		+ Site-specific regulations or customs affecting the research for research outside the organization.
		+ Local scientific and ethical review structure outside the organization.

# Resources Available

*Describe the resources available to conduct the research: For example, as appropriate:*

* *Justify the feasibility of recruiting the required number of suitable participants within the agreed recruitment period. For example, how many potential participants do you have access to? What percentage of those potential participants do you need to recruit?*
* *Describe the time that you will devote to conducting and completing the research.*
* *Describe your facilities.*
* *Describe the availability of medical or psychological resources that participants might need as a result of anticipated consequences of the human research.*
* *Describe your process to ensure that all persons assisting with the research are adequately informed/trained about the protocol, the research procedures, and their duties and functions.*

# Multi-site or Collaborative Research *(this section may be deleted for single site studies)*

*Multi-site and collaborative research occurs when researchers from PNWU and external institutions, or individual external investigators, are involved in carrying out the research. Provide the following information:*

*• Which institutions or individuals are participating in the research?*

*• What activities will institutions or individuals participate in?*

*• Will each institution or individual’s IRB review their own activities, or will one IRB serve as the IRB of Record?*

*If your research involves non-exempt, federally funded, human research, happening at multiple research sites you may be required to establish a Single IRB via reliance agreements.*

# Literature References

*Include a list of relevant literature in this section. Use a consistent, standard, modern format, which might be dependent upon the required format for an anticipated journal publication.* [*The preferred format is ICMJE*](https://umc.libguides.com/citations/nlm)*.*

# Appendices

Examples include:

* Schedule of Events
* Schematic of Study Design
* DSMB Charter
* Case Report Forms (CRFs)
* Data Collection Forms
* Laboratory Handling
* Manual of Operations