**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 |
|  |  |  |
|  |  |  |
|  |  |  |

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# Objectives

* 1. Describe the purpose, specific aims, or objectives. (There should be one or two primary objectives with additional objectives listed as secondary.)
  2. State the hypotheses to be tested or the study questions that will guide the research.

# Background and Rationale

* 1. Describe the relevant prior experience and gaps in current knowledge.
  2. Describe any relevant preliminary data.
  3. 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.

# Study Procedures

* 1. *Describe and explain the study design to indicate how the objective(s) will be achieved.*
  2. *Describe the data characteristics (data set, from whom, from where, who owns the data)?*
  3. *If the data is obtained from a third-party organization (e.g., via a web portal), a copy of the forms/application that must be submitted to access the data (or a link to the form/application) and any assurances you are asked to provide (e.g., a data use agreement) must be provided to the IRB.*
  4. *Is a person outside PNWU going to be collaborating on this study in any way? Is their IRB going to review their study participation?*
  5. *If there are identifiers associated with the data, will they be removed prior to starting your analysis and who did or will de-identify the data?* Data Storage

# Inclusion and Exclusion Criteria

* 1. Describe the criteria that define the records to be included or excluded in your study.
  2. Describe the criteria that define who will be included or excluded in your final study sample.

# Vulnerable Populations

* 1. *If the research involves records of vulnerable populations, describe additional safeguards included to protect the data.*
  2. *Indicate specifically whether the data will include each of the following special populations: (You may not include members of the special populations as participants 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
     + Cognitively impaired or individuals with impaired decision-making capacity
     + Individuals who are not able to clearly understand English
  3. 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 of the study? Conduct of the study? How will the results of the research be shared with the participants and/or the target community(ies)?

# Statistical Analysis Plan

* 1. *Describe the data analysis plan, including any statistical procedures or power analysis*
  2. *Describe the steps that will be taken to secure*

# Data Sources

* 1. *The source of the data (from whom, from where, who owns the data)?*
  2. *Are there any identifiers associated with the data? If the data have identifiers associated with them, will they be removed prior to starting your analysis: who did or will de-identify the data?*
  3. *Is the data a limited HIPAA data set?*
  4. *Why/where were the data originally collected? Was it collected as part of clinical care? If collected for a research study, provide PNWU IRB number(s) if applicable, and a copy of the informed consent document and the HIPAA authorization (if applicable). [This helps the IRB determine if the new proposed use of the data is within the scope of the original consent/authorization required.]*

# Risks to Participants

*9.1. List the foreseeable risks to privacy and/or confidentiality*

# Vulnerable Populations

*10.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare. Review SOP 128 Vulnerable Populations to ensure that you have provided sufficient information*

# Potential Benefits to Future Participants

* 1. Describe the potential benefits to future participants.

# Data Management and Confidentiality

*11.1 Describe the steps that will be to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use and transmission.*

* 1. *What procedures will be used for quality control of collected data.*
  2. *How data will be managed study-wide*
     + *What information will be included in the data (e.g., will identifiers be present)? If there are codes, where will the key linking the codes to the identifiers be kept?*
     + *How will the data be securely stored? 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?*
     + *What are the plans for disposing of the data once the study is completed?*

# 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

*Do you wish to request a waiver of informed consent for this research? Please address how your request meets the following criteria:*

* 1. *The research involves no more than minimal risk to the participants.*
  2. *The waiver or alteration will not adversely affect the rights and welfare of the subjects.*
  3. *The research could not be practicably carried out without the waiver or alteration of consent (impracticability normally requires justification beyond cost or inconvenience)*
  4. *Whenever appropriate, the subjects will be provided with additional information about their participation in the research (often not necessary)*

# HIPAA

*If you are recording identifiers from subjects who are still living, and it is not practicable to obtain their HIPAA authorization for your study, you will need to request a HIPAA waiver. Please address how your request meets the following criteria:*

* 1. *The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:*
  2. *An adequate plan to protect the identifiers from improper use and disclosure*
  3. *An adequate plan to destroy he identifiers at the earliest opportunity consistent with conduct of research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and*
  4. *Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by this subpart.*
  5. *The research could not practicably be conducted without the waiver or alteration.*
  6. *The research could not practicably be conducted without access to and use of the protected health information.*

# Setting

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

* 1. Identify where research procedures will be performed.

# 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.*

1. **Appendices**

*Examples include:*

* *Schedule of Events*
* *Schematic of Study Design*
* *Case Report Forms (CRFs)*
* *Data Collection Forms*