**This is only a template, you do not have to use this to submit a protocol to the Pennington Biomedical Research Center IRB; however, this template does reflect the IRB criteria for approval.**

**INSTRUCTIONS:**

Anything indicated in red type should be deleted; the red type is for instructional purposes only.

* Use “TEMPLATE PROTOCOL” to prepare a document with the information from following sections. You may use a different format, order, outline or template provided the necessary information is included.
* Depending on the nature of what you are doing, some sections may not be applicable to your research. **Delete sections that don’t apply to your study.**
* For any items described in the sponsor’s protocol, grant, contract, or other documents submitted with the application, you may reference the title and page numbers of these documents. If you reference page numbers, attach those pages to this protocol. Limit attached pages to those referenced in this protocol.
* When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.

**Protocol Title:** (Include the full protocol title as listed on the application form.)

**PI Name:**

**Sub-Investigator’s Name(s):**

**Protocol Version Date:**

**IRB Review History**

If you have submitted this protocol for review by an external IRB, provide the previous study identification number and provide details of the review including the IRB name, date of review, and IRB contact information.

**Objectives**

Describe the purpose, specific aims, or objectives.

State the hypotheses to be tested.

**Background**

Describe the relevant prior experience and gaps in current knowledge.

Describe any relevant preliminary data.

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.

**Inclusion and Exclusion Criteria**

Describe how individuals will be screened for eligibility.

Describe the criteria that define who will be included or excluded in your final study sample.

Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of the above populations as subjects 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

**Number of Subjects**

Include the number of subjects needed to enroll (IRB authorized number)

If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.

**Recruitment Methods**

Describe when, where, and how potential subjects will be recruited.

Describe the methods that will be used to identify potential subjects.

Describe materials that will be used to recruit subjects. (If developed, 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.)

If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods.

**Study Timelines**

Describe the duration of an individual subject’s participation in the study.

Describe the duration anticipated to enroll all study subjects.

Describe the estimated date for the investigators to complete this study (complete primary analyses)

**Study Endpoints**

Describe the primary and secondary study endpoints.

Describe any primary or secondary safety endpoints.

**Procedures Involved**

Describe and explain the study design. Include a train schedule of procedures.

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

Describe procedures performed to lessen the probability or magnitude of risks.

Describe all drugs and devices used in the research and the purpose of their use, and their regulatory approval status.

Describe the source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)

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

**Data and Specimen Banking**

If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.

List the data to be stored or associated with each specimen.

Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

**Power analysis.**

**Data and Specimen Management**

Describe the data analysis plan, including any statistical procedures.

Describe the steps that will be taken 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.

Describe any procedures that will be used for quality control of collected data.

Describe how data and specimens will be handled study-wide:

What information will be included in that data or associated with the specimens?

Where and how data or specimens will be stored?

How long the data or specimens will be stored?

Who will have access to the data or specimens?

Who is responsible for receipt or transmission of the data or specimens?

How data and specimens will be transported?

**Provisions to Monitor the Data to Ensure the Safety of Subjects**

This is required when research involves more than Minimal Risk to subjects.

The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Describe what data are reviewed, including safety data, untoward events, and efficacy data.

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

Describe the frequency of data collection, including when safety data collection starts.

Describe who will review the data.

Describe the frequency or periodicity of review of cumulative data.

Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Describe any conditions that trigger an immediate suspension of the research.

**Withdrawal of Subjects**

Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.

Describe any procedures for orderly termination.

Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection (example: long-term follow up or planned follow up visits conducted via telephone).

**Risks to Subjects**

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ 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.

If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.

If applicable, describe risks to others who are not subjects.

**Potential Benefits to Subjects**

Describe the potential benefits that individual subjects 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.

Indicate if there is no direct benefit. Do not include benefits to society or others.

**Vulnerable Populations**

If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

**If employees are targeted**, please outline procedures to ensure that the employees will not be subject to undue influence or coercion and to ensure that the employee’s privacy will be respected. Adhere to PBRC Policy 300.00 and HRPP Policy 6.0.

**Multi-Site Research**

If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:

All sites have the most current version of the protocol, consent document, and HIPAA authorization.

All required approvals have been obtained at each site (including approval by the site’s IRB of record).

All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.

All engaged participating sites will safeguard data as required by local information security policies.

All local site investigators conduct the study appropriately.

All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.

Describe the method for communicating to engaged participating sites: problems; interim results; the closure of a study

**Sharing of Results with Subjects**

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how it will be shared.

**Setting**

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

Identify where research procedures will be performed.

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 subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Describe the number and qualifications of your staff, their experience in conducting research, their knowledge of the local study sites, culture, and society.

Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.

Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

**Prior Approvals**

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.)

**Compensation**

Describe the amount and timing of any payments to subjects.

**Confidentiality**

Where and how data or specimens will be stored locally?

How long the data or specimens will be stored locally?

Who will have access to the data or specimens locally?

Who is responsible for receipt or transmission of the data or specimens locally?

How data and specimens will be transported locally?

If this is a multicenter study, describe the local procedures for maintenance of confidentiality.

**Provisions to Protect the Privacy Interests of Subjects**

Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on whom they interact or whom they provide personal information.

Describe what steps you will take to make the subjects 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 subject might experience in response to questions, examinations, and procedures.

Indicate how the research team is permitted to access any sources of information about the subjects.

**Compensation for Research-Related Injury**

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

Provide a copy of contract language, if any, relevant to compensation for research-related injury (if applicable, include contract language in Section 15 of the consent).

**Economic Burden to Subjects**

Describe any costs that subjects may be responsible for because of participation in the research.

**Consent Process**

Indicate whether you will you be obtaining consent, and if so describe:

* Where will the consent process take place
* Any waiting period available between informing the prospective subject and obtaining the consent.
* Any process to ensure ongoing consent.

You must follow the appropriate consent template on the <http://www.pbrc.edu/hrpp/> website.

*Subjects who are not yet adults (infants, children, teenagers)* Refer to PBRC policy, if necessary <http://www.pbrc.edu/hrpp/policies/>

Describe the criteria that will be used to determine whether a prospective subject 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. (Eg. 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*

* Describe the process to determine whether an individual is capable of consent. 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 children to sign assent documents.

*Adults Unable to Consent*

* List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)
* For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research.

Describe the process for assent of the subjects. Indicate whether:

* Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.
* If assent will not be obtained from some or all subjects, an explanation of why not.
* Describe whether assent of the subjects 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 subjects to sign assent documents.

**Drugs or Devices**

If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.