PROTOCOL TEMPLATE GUIDANCE

1. **TITLE PAGE**
   - Full study title
   - Name, Title(s), and Department of Principal Investigator
   - Collaborators (institutions and departments), if any
   - Sponsor(s), if any
   - Protocol version number and version date

2. **ABSTRACT**
   A brief (usually 400 words or fewer) description of the study objectives, population, design, and outcome measures

3. **INTRODUCTION AND BACKGROUND**
   A summary of the primary hypothesis, purpose, scholarly rationale, and prior literature.

4. **OBJECTIVES**
   The primary and secondary aims and outcome measures.

5. **PARTICIPANT SELECTION**
   - Requested sample size and expected refusal or withdrawal rate;
   - Inclusion/exclusion criteria with justification;
   - Subject recruitment plan;
   - Screening for eligibility process

6. **STUDY DESIGN AND METHODS**
   - The procedures to be performed (distinguish between the procedures performed for diagnostic or treatment purposes and those for research) – include a table of study visits and their procedures, if helpful;
   - Randomization and blinding scheme, if any
   - Wash outs or dose escalations, if any
   - Risks/discomforts and potential benefits if any to subjects - these should be listed in order of probability (most common first) with probabilities quantified to the extent possible;
   - What type of information will be collected;
   - What specimens will be collected, if any;
   - data/samples collected for this study will be saved/banked/archived for future use, describe plans, who may use the material, and for what purposes.
   - Procedures when a subject withdraws from a study

7. INFORMED CONSENT PROCESS

- Describe the process for how will you obtain consent from participants or their legally authorized representatives, if applicable (in person, online, via phone, etc…)
- If you are requesting a waiver of signed documentation of informed consent, describe how will you document consent.
- Interaction consenting:
    - Describe where will the informed consent discussion take place.
    - Indicate who will conduct the discussion and obtain consent.
- Compensation for time and/or discomfort:
    - Describe what the compensation is for, how much the compensation will be, and the method of compensation distribution.

8. STATISTICAL ANALYSIS

Sample size determination and power; interim monitoring and early stopping; analysis plan; and statistical methods.

9. SAFETY AND MONITORING REPORTING

Description of plan for notifying the IRB of reportable events. See PHCIRB policy #6421 and #6422 for reporting requirements for unanticipated problems, deviations and violations.

10. CONFIDENTIALITY

- Describe how you will protect the subjects' privacy during the course of their participation in the study.
- Describe your plans to establish and maintain confidentiality of subjects' identifiable data.
    - Description of any linkages from study data to identifiers
    - If you will destroy identifiers (includes audio/video files) indicate when that will occur during the course of the research.

11. REFERENCES/BIBLIOGRAPHY