Protocol and Protocol Summary Abstract

Instructions

Protocol or Research Plan

All new research submissions to the IRB must include a protocol or research plan to provide detailed information about the study, particularly the aspects relevant to human subjects.
- Various templates are available at www.pennstatehershey.org/irb, under Investigator Resources.
- Investigators have two submission options based on the complexity of the research.

Research qualifying for expedited or exempt review:

For minimal risk research meeting the expedited or exempt review criteria, investigators may submit the online Protocol Summary Abstract questions as the research plan, provided the responses are written in sufficient detail to describe the research.

Research requiring convened IRB review (i.e., greater than minimal risk research):

- Complete the online questions for the Protocol Summary Abstract **and**
- Submit a Research Protocol* by uploading **one** of the following:
    - Investigator-written research protocol **_or_**
    - Sponsor-written research protocol

*__Note__: *The grant application format is __not__ sufficient to serve as a research plan for this purpose, especially for clinical research, because it lacks the necessary information to adequately evaluate safety and protection issues. However, if your research will be __federally funded__ also include **one** copy of the entire grant application with your IRB submission.*

Protocol Summary Abstract Questions

All new submissions must address the Protocol Summary Abstract questions during the online PRAMS eSubmission process. The next page outlines the headings and descriptions that are included in the abstract questions.   The abstract serves as a reference during initial and future IRB reviews of the research. In addition, for clinical protocols it provides information about the research to medical caregivers of participants who are also patients (a copy of the abstract should be placed in the patient's HMC medical record along with the signed consent form).

- **Abstract completion:**
    - Text may be pasted into the PRAMS eSubmission fields, if needed.
    - Keep responses succinct (e.g., in Purpose summarize only the most important objectives).
    - PRAMS will generate the abstract document. Please do **not** upload print copies of the abstract or create a separate Word version; this will duplicate effort and cause delays.

- **Steps to modify an abstract:**

    - **For PRAMS eSubmissions** – Select *Create eSubmission,* then *Modification/Amendment,* and the study needed. Edit the applicable abstract questions; select *Finish*, then *Submit.*

    - **For non-eSubmission studies** (*not initiated online*) – Revise the currently approved typed abstract using tracked changes.   Submit to IRB Drop Box (instructions on web).

INSTITUTIONAL REVIEW BOARD
Penn State College of Medicine
Penn State Milton S. Hershey Medical Center

PROTOCOL SUMMARY ABSTRACT

Title:

Principal Investigator: **Dept./Div:**

1. Background and Rationale *(Provide background and scientific or scholarly rationale; explain why study hypothesis needs to be addressed; for studies using drugs summarize the drug class and mechanism.)*

2. Purpose(s) of the Research *(List the study's objectives, aims or goals.)*

3. Study Population *(Healthy volunteers or participants with a specific illness? Students? Include the age range of the subjects. Include controls, if any.)*

4. Major Inclusion & Exclusion Criteria *(List the characteristics required to be in the study and those which would cause ineligibility. For studies with a research protocol, describe only the major criteria.)*

5. Method of Identification of Subjects/Samples/Medical Records   (*Indicate how potential subjects samples or medical records will be identified for this research. Describe any recruitment materials.)*

6. Consent Process and Documentation *(Who will provide consent? Who will conduct the consent discussion? Briefly describe the process, e.g., time allotted, waiting period between informing prospective subjects and obtaining the consent, language interpretation, decisionally compromised adults, assent process, etc.)*

7. Study Design *(Describe the study design (e.g., case series, retrospective case-control study, etc.). Include the method of group assignment, including randomization process and study comparison groups if applicable. For case-control studies, provide the criteria used to identify subjects for a control group. For simple research, this section may describe observational methods, medical chart review, etc.)*

8. Summary of Procedures (*Describe the procedures involving the subjects, how they will be done and when and any post-treatment follow-up. Describe the procedures being performed already for diagnostic or treatment purposes. For chart review studies, list the data elements to be recorded for research.)*

9. Outcome Measures (*Describe the endpoints used to answer the aims of the study. For studies with a research protocol, state "See protocol section X".)*

10. Statistical Plan and Sample Size Justification *(Give details of the power analysis used to justify the sample size for the study. Provide a data analysis plan, including statistical methods to be used for each aim of the study. Statistical assistance is available from the Department of Public Health Sciences consultation services with adequate advance notice. See the IRB web site for details. For studies with a research protocol, state "See protocol section X".)*

11. Major Risks & Discomforts (*Describe the risks and discomforts that are reasonably foreseeable*.)

12. Potential Benefits (*Describe the anticipated potential benefits for the subjects and/or others*.)

13. Privacy and Confidentiality (*Indicate measures to protect privacy and to maintain confidentiality of the research data. Indicate whether information or a code will be linkable to subjects in anyway. Who will have access to identifiers, codes or the key; how will information be protected? Will subject identifiers or codes leave the institution?*)

14. Qualifications and Research Experience of Principal Investigator: *(Briefly summarize the PI's qualifications and relevant research experience.)*

15. Study Site Location(s) and Setting(s) in Which the Research is Conducted *(List all sites to be involved and describe the setting(s) in which the research will be conducted.)*

16. References *(List a few most relevant references. For studies with a research protocol, state "See protocol.")*