Research Protocol Template Instructions

The following is a suggested template for a research protocol.

- As stated above, a research plan must be included with the IRB submission to provide detailed information about the study, particularly those aspects relevant to human subjects.
- This template is provided to help investigators prepare a protocol that includes the necessary information for the IRB to review a submission from the human subject participation perspective.
- The grant application format is not sufficient 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.)
- All guidance language appears in blue and should be deleted from the final version of the protocol.
Protocol Title

Principal Investigator’s name and department
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Appendix A  Study Procedure Flow Sheet
1.0 Introduction

Describe the background, including human participant or animal research and references that are relevant to the design and conduct of the study.

Provide a rationale for the current study.

2.0 Objectives

State clear, concise objectives for the study.

3.0 Study Design and Methods

Describe the design of the research.

Include the method of group assignment, including randomization process and frequency of allocation to different groups, if applicable.

For simple research, this section may describe observational methods, medical chart reviews, etc.

4.0 Inclusion and Exclusion Criteria

List the characteristics required of subjects to be in the study and those which would make an individual ineligible.

- Use bullets or number the criteria for easy identification

Explain the rationale for the involvement of special classes of participants, if any, such as fetuses, pregnant women, children, cognitively impaired adults, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. Discuss what, if any, procedures or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risks as research participants.

5.0 Recruitment and Consent Process

Explain how participants will be identified for this study, and if applicable, how potential participants will be approached about participation and who will approach them.

Describe any recruitment procedures that will be used for this study, e.g., advertisements, flyers, brochures, letters to potential participants, etc.

Explain the consent process, including who will obtain informed consent, and where and when the informed consent discussion will occur. Explain if a waiver of informed consent or a waiver of a signed consent document will be requested.
6.0 Study Procedures

List the procedures involving the participants, including initial evaluation procedures and screening tests, procedures and sequence of the study and any post-treatment follow-up.

List the days and time frame of the study. Describe any wash out period if applicable. Provide a description of what the participants will experience. Separate standard and experimental aspects of the study as much as possible.

Give detailed procedures for treatment, dose adjustments, etc. Include all interventions, experimental manipulations, data collection procedures, and measurements.

7.0 Risks and Discomforts

Provide a description and assessment of the study risks. List the risks and discomforts associated with any drugs, biologics, devices or procedures that are used or performed solely for research. List their likelihood and seriousness and provide the grading mechanism, if applicable. Types of risks include physical, psychological, social, legal or other risks.

Describe alternatives to experimental therapy, if they exist, that might be advantageous to the participants.

Describe the procedures for protecting against or minimizing any potential risks and assess their likely effectiveness. Provide the procedures (e.g. lab tests, evaluations, observations and their frequency) which will be utilized to monitor participant safety.

Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the participants.

8.0 Benefits

Describe the anticipated benefits to participants or to others that may reasonably be expected from the research.

Discuss why the risks to participants are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to result.

9.0 Reporting of Adverse Events and Unanticipated Problems Involving Risks to Participants or Others

List the process for reporting adverse events or unanticipated problems.

Indicate where and how to submit adverse events and the timeframe in which to submit. List the regulatory authorities and their contact information for reporting.
Identify the person(s) responsible for identification, documentation and reporting adverse events and unanticipated problems.

10.0 Study Withdrawal/Discontinuation

List the process for withdrawing from the study. List the process for being withdrawn from the study and the indications for withdrawal.

11.0 Statistical Analysis of the Study

Delineate the precise outcomes to be measured and analyzed.

Describe the statistical power of the study and the confidence intervals or explain how the sample size was determined.

Provide a data analysis plan, including statistical methods to be used for each aim of the study.

12.0 Privacy and Confidentiality Considerations

Describe the procedures for ensuring privacy of participants and confidentiality of the data collected.

13.0 Data and Safety Monitoring Plan

Required for all research studies involving greater than minimal risk. Information about data and safety monitoring plans and what needs to be included can be found on the IRB website at www.hmc.psu.edu/irb under Forms and Instructions.

In this section of the protocol:
- Describe the provisions for monitoring the data collected to ensure the safety of the participants and to protect the study’s integrity and validity;

- Define the frequency of review for summarized safety and aggregate analysis of adverse event information and for the research data;

- Provide any study stopping rules which define critical thresholds for stopping or modifying the study, if applicable; and

- Specify who will perform the review (e.g., principal investigator, medical monitor, clinical trial team, data and safety monitoring board, sponsor’s medical monitor)

14.0 Compensation

Describe any payments or compensation to participants.
15.0 **Drugs, Biologics, or Devices**

List the source(s) of all drugs/devices used in the research.

Describe the U.S. Food and Drug Administration status of the drugs, biologics and/or devices used in the research, including Investigational New Drug (IND) or Investigational Device Exemption (IDE) numbers, if applicable.

Describe the drug/device storage monitoring accountability and dispensing plan.

16.0 **Records and Study Monitoring**

List the records to be kept and the data submission schedule if applicable.

Describe the study monitoring, including site monitoring for multi-center studies.

Describe measures used for quality control and assurance.

17.0 **Facilities**

Describe where the research will be conducted.

If applicable, describe how the facilities are appropriate to ensure participants’ privacy and whether continuous emergency medical care is available.

18.0 **References**

List relevant references in the literature which highlight methods, controversies, and study outcomes.