**PURPOSE OF A PROTOCOL**

The protocol is where investigators clarify and document their plan for all aspects of the study. It provides a guide for the research team to reference and follow and ensures the IRB-approved version of the study is implemented. When the study is complete, the protocol will aid in writing an abstract or article for publication.

***DELETE all red and blue INSTRUCTIONS and guidance text before submitting***

* *Use this template to prepare a protocol for minimal risk studies*
* *Complete each section*
* ***Insert version date in footer***

Research Study Protocol for:

The study title should be descriptive and concise and match the title on the IRB Application and any other applicable documents

|  |  |
| --- | --- |
| **Principal Investigator:** | Insert name of the principal investigator and credentials Include the name of the institution the PI represents  Include PI address and phone number |
| **Sub-Investigator(s):** |       Insert name and credentials of each sub-investigator |
| **Research Site(s):** | Insert the name of site(s) where research will be conducted |
| **Sponsor:**  | Insert name, address and phone number of sponsor If investigator is also the sponsor, reflect that information |
| Version Date: |       |

**BACKGROUND and RATIONALE**

      Begin this section by explaining that this document is a research protocol and that your study will be conducted in compliance with the protocol and Good Clinical Practice standards and associated federal regulations.

* Reference the literature searches that confirm or support the hypothesis
* Describe the background of the study and what is known about the topic you choose to study.
* Provide the rationale for conducting the study and the knowledge you hope to achieve.

**PRELIMINARY DATA**

      Discuss what has been done in trials thus far *(i.e., A feasibility study conducted in \_\_\_\_ served as the foundation of a clinical study involving \_\_\_\_\_\_\_\_. This study was a randomized clinical study involving \_\_\_ participants for the treatment of \_\_\_\_. Further confirmation of results was demonstrated in \_\_\_\_.)*

**OTHER RELATED STUDIES**

      *(i.e., A recent case series investigates the use of \_\_\_ for the treatment of \_\_\_\_. This report demonstrated that in these conditions, \_\_\_\_\_ was safe for \_\_\_\_.)*

**PURPOSE and OBJECTIVES** *(Primary endpoints of study, listed and numbered individually)*

**Purpose**
      *(i.e., The purpose of this study is to determine if \_\_\_\_ can safety/effectively be used in \_\_\_\_ in \_\_\_\_\_\_.)*

**Objectives**

      Describe the specific aims for the study. Specific objectives are statements of the research question(s). Objectives should be simple (not complex), specific (not vague), and stated in advance (not after the research is done). After a statement of the primary objective, secondary objectives may be mentioned. Describe study endpoints.

The objectives should align with the overall study purpose but are meant to be direct and measurable goals for the study.

End with a statement of your hypothesis or key question(s)

**STUDY DESIGN**

      Describe the type of study design *(i.e., retrospective record review, multiple case studies, etc.)*. Be as complete as possible in your description and include the expected study duration period. *(i.e., how long do you think it will take to conduct the study from start to completion of all data analysis?)*

Include a description of the date range of the data to be collected: mm/dd/yyyy to mm/dd/yyyy. If this is a retrospective review, the end date **must be before the IRB submission date**):

To qualify as retrospective, the data must exist when the study is submitted to the IRB for initial review. If the data does not exist when the study is submitted to the IRB for initial review, it is defined as prospective.

**STUDY METHODOLOGY**

 **Inclusion & Exclusion Criteria**

* Describe subject selection. (What is the sampling plan, what are subject and disease
 characteristics)
* Describe exclusionary criteria

 **Subject Identification and Recruitment**

* Describe the recruitment and process for identification of records, cases or participants. How will records be identified and accessed?

**Study Procedures**

* Describe the study procedures.
* Describe who will be involved in specific study activities. Describe collaborators.

**Ethical Considerations and Informed Consent**

*

If including a vulnerable population as the focused group of participants (impaired decision making capacity, children, students and employees are in this category), you must also provide justification for including the vulnerable population and the extra precautions that will be taken to ensure their protection according to the federal regulations.

**RISKS AND BENEFITS:** (*modify as needed*)

**Risks:**

* *(e.g. A confidentiality breach is a risk associated with data review research.)* Describe the risks involved in the study activity. *(i.e. physical, psychological, social, or economic).* As applicable, describe why the risks to participants, if any, are reasonable in relation to the anticipated benefits and/or knowledge that might reasonably be expected from the results. **Describe what will be done to minimize any known risks.**

**Benefits:**

* *(e.g. The participants are not likely to receive any benefit from the proposed research; however, society and investigators will benefit from the knowledge gained.)*

Describe potential benefits for participants that are involved in the study. It is acceptable to state that there are no anticipated benefits to subjects.

## BIOSPECIMENS

      Explain how specimens will be collected, shipped, processed, stored (and for how long) and any other pertinent information.

## STATISTICAL CONSIDERATIONS:

      Describe how the data will be summarized (i.e., medians and ranges, percentages with 95% confidence intervals, etch). Identify the statistical test for the analysis of the primary outcome variable. Define the tests for the analysis of the secondary outcome variables. Set the level of significance *(i.e., significance will be assessed at p < 0.05)*. If no statistical tests are planned, denote that only summary/descriptive statistics will be used.

Describe any software that will be used for statistical analysis. Describe who will complete the data analysis. *(e.g. principal investigator, statistician)*

Identify the proposed sample size *(the minimum number of records/specimens necessary to carry out the objectives of your study).*

**Data & Safety Monitoring Plan**

      Include a written plan of the measures that will be taken to ensure the safety of participants and protect the validity and integrity of research data. (What procedures will be used to monitor integrity or accuracy of data? Will research mentors review 1 in 10 records to ensure data is being collected correctly? If multiple individuals are involved, how will you ensure all interpret the definition of the data to be collected in the same way?)

**Adverse Events/Serious Adverse Events/Unanticipated ProblemS**

      Define adverse events and serious adverse events, **if applicable** to your type of study. (Include an explanation of how adverse events, serious adverse events and *unanticipated problems* will be recorded, maintained and reported. Who will identify, document, and report any adverse events?)

*It is unlikely that an adverse event will occur in this type of study, however an unanticipated problem is possible.* A UAP is defined as any incident, experience, or outcome that meets **all** of the following criteria:

1. **Unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. **Related or possibly related** to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. Suggests that the research **places subjects or others at a greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

**Examples:** *Theft or loss of USB or laptop with study data resulting in breach of confidentiality, accidental change to protocol without IRB approval, or a complaint from a participant.*

**Confidentiality**

      Include a statement that advises how information about study participants will be kept confidential. Describe the system for any coding of information *(e.g. use of subject ID and correlation tool)*. Include how confidentiality will be ensured throughout the initial study design; identification, recruitment, and consent processes for the study population; security, analysis, and final disposition of data; and publication or dissemination of data and results.

* Describe how data (**both paper and electronic**) will be stored to safe-guard confidentiality *(e.g. in a locked cabinet, password protected computer)*
* Specify who will have access to harvested data
* Clarify how long data will be stored and how it will be destroyed when no longer needed

**Privacy**

      Describe how participants’ protected health information will be accessed and managed according to the requirements of HIPAA (Health Insurance Portability and Accountability Act of 1996). Explain who will have access to the collected data and why, and who will use or disclose any information.

**DATA MANAGEMENT – RECORDS ACCESS, STORAGE and RETENTION**

      Describe how and where data (both hard copy and electronic) will be stored, who has access to them, how long they will be kept for and if they will ever be destroyed including the destruction plan. Please note that it is a requirement of Mercy Health that all study records and data be kept and accessible for review and audit for a minimum of 7 years. Describe any electronic data capture systems that may be used. Describe how access to those systems is assigned and maintained.

**Study Monitoring, Auditing and Inspecting**

      Describe the plan for permitting study-related monitoring, audits and inspections by Mercy Health Regional IRB, the sponsor (if applicable) and government regulatory bodies (FDA, OHRP, ORI) of all study related documents.

*Participation as an investigator in this study implies acceptance of potential inspection by government regulatory authorities and applicable Mercy Health compliance and quality assurance offices.*

*Although it is unlikely that governmental agencies will audit or inspect your research, the IRB may perform an audit at any time. If the IRB is audited by regulatory agencies, your project title may be selected and thus subject to audit. However, this is unlikely.*

**BUDGET**

      As applicable, include a brief summary of estimated expenses for this study. Include the projected funding source, if applicable. You must describe a budget for time and effort of individuals who will be involved in study conduct (i.e. PI, sub-I's, statisticians, research coordinators, information technology data personnel and health information management personnel). You must include a description of the materials needed to conduct the study and their estimated costs (paper, binders, publication costs, poster presentation costs)

**Dissemination of Results and Publication Plan**

      Describe your plan for presentation, publication or sharing of results. Describe how findings will discussed and shared with all of the investigators for the study. Provide an estimated timeline for creation of an abstract. Describe a plan for investigators to create abstract drafts. Describe if authorship has been discussed and determined. Describe what publication the abstract may be submitted to. Describe what meeting an abstract may be presented at. **Please state,** "Investigator acknowledges and agrees that permission for publication must be obtained from Mercy Health and that Mercy Health reserves the right to restrict the use of research data for publication purposes."

**References/Bibliography**

      Identify any literature cited for any information referenced in the protocol. Organize this information like that found in a medical journal.