\*This is a sample protocol template. It is acknowledged that protocol templates may vary. The sections addressed in this template should be addressed in all studies submitted for Mercy Health Regional IRB review. The section titles may not match but content included in this template should be addressed no matter the study type or design.

Study Title

The title should be descriptive and concise.

**Principal Investigator:** Insert full name of the principal investigator and degrees

Provide name of institution the principal investigator represents (i.e. Mercy Health Saint Mary's)

Provide address, phone, email and fax number for principal investigator

**Research Site(s):** Insert the name of site(s) where research will be conducted

Funding Sponsor: Insert name, address and phone number of funding sponsor, or indicate "not funded"

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CONFIDENTIALITY STATEMENT

**This document is confidential and to be distributed for review only to investigators, potential investigators, consultants, study staff, and the applicable independent ethics committees or institutional review boards. The contents of this document shall not be disclosed to others without written authorization from the principal investigator unless it is necessary to obtain informed consent from potential study participants.**

##### 1. Background/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 (FDA Title 21 Part 312).

Describe the background of the study and what is known about the topic you choose to study. Explain the reason(s) for conducting the study and the knowledge you hope to achieve.

# 2. Study 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 statement of the primary objective, secondary objectives may be mentioned.

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

(e.g. to determine whether… to assess whether…)

# 3. Study Design

Describe the study design of the study (e.g. retrospective record review, survey, case study, etc.). Be as complete as possible in your description, and include the expected study duration period.

**4. Study Methodology**

* Describe subject selection. (What is the sampling plan, what are subject and disease characteristics), (if vulnerable population you must also provide justification for including the vulnerable population and the extra precautions being taken to ensure their protection according to the federal regulations).
* Describe the recruitment and screening activities and materials to be used. (Where will recruitment occur? Where and when will consent be obtained? Who will obtain consent? What is the advertising plan, if applicable? What recruitment materials will be provided to the potential participant (brochures/information sheets/video presentation)?
* Describe the study procedures (Describe study specific visits, study specific activities, study specific tools to be used for data collection). (For Drug/device studies: describe active study agents, describe placebo study agents, describe blinding/labeling/preparation of agents, storage, distribution, administration, accountability, toxicities and guidelines for adjustments, return or destruction and the additional federally required elements for investigational drugs and devices).
* Provide a schedule of all study assessments and subject activities, including a tabular representation or timeline as applicable
* Describe the duration of the project. (i.e. how long do you think it will take to conduct the study from start to completion of all data analysis)
* Describe the informed consent method to be used. (i.e. do you propose to use a full informed consent document or will you request a waiver or alteration of informed consent document and/or process)
* Describe scenarios under which a subject may withdraw or be withdrawn from the study prior to completion (e.g. safety reasons, failure of subject to adhere to protocol, subject’s request to withdraw, etc.).
* Describe anticipated problems and ethical concerns.
* Describe the risks involved in the study activity. (i.e. physical, psychological, social, or economic)
* Describe potential benefits for participants that are involved in the study.
* 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.
* Describe study endpoints.

## 5. Statistical Plan

**Sample Size Determination**

Describe how the sample size was determined for this study. The sample size should be based upon the primary outcome variable. If the authors have determined that a sample size estimation was not necessary, please provide rationale.

**Statistical Methods**

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 analysis. (e.g. principal investigator, statistician)

## 6. 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 subject safety? What is the frequency for review of summarized safety information and who will perform the review (e.g., safety monitoring board)? What are the stopping rules with regard to efficacy and safety?)

## 7. Adverse Events/Serious Adverse Events/Unanticipated Problem

Define adverse events and serious adverse events. (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?)

**8. Confidentiality**

Include a statement that advises how information about study participants will be kept confidential. Describe the system for any coding of information. 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.

**9. 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.

**10. Data Management-Records Access, Storage and Retention**

Describe how and where data (both hard copy and electronic) will be stored, how they will be stored, who has access to them, how long they will be kept for and if they will ever be destroyed including 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.

## 11. Study Monitoring, Auditing and Inspecting

Describe the plan for permitting study-related monitoring, audits and inspections by Mercy Health Regional IRB, the sponsor 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.

## 12. Dissemination of Results and Publication Plan

Describe your plan for presentation, publication or sharing of results. (e.g. 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."

## 13. References/Bibliography

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

(i.e. Hughes, Jane C., Elizabeth V. Brestan, and Linda Anne Valle. "Problem-Solving Interactions between Mothers and Children." Child and Family Behavior Therapy 26.1 (2004): 1-16. PsycINFO. Web. 12 Nov. 2006.)