**RETROSPECTIVE PROTOCOL TEMPLATE**

***Guidance for using this template:***

*The template contains some sample text and instructions as to the type of information that needs to be included in a retrospective study protocol.*

* *Language in italics should be used as a guide for development of your protocol and should be replaced.*
* *Remove any template language that is not applicable to your study prior to submitting to the IRB.*
1. **Protocol Title:**
2. **IRB Manager Study #:**
3. **Investigator(s):**
4. **Version Date:** (Eg. mm/dd/yyyy Version 1)
5. **Research Site(s):** Insert the name of the site(s) where data is being collected (Eg. Butterworth, Blodgett, Helen DeVos, etc)
6. **Introduction: (Background and Rationale including references)**

*Three to four paragraph section outlining the research study. Paragraph one begins with a broad introductory sentence. Last sentence outlines the GAP or NEED in research. Paragraph one and two provides scientific or scholarly background and rationale for the research based on the existing literature (include references). Paragraph 3 (optional) describes any relevant preliminary data. The last paragraph outlines the significance of the research. This paragraph should contact a clear significant statement: This research is significant because …*

1. **Objectives: (Primary endpoints of study, listed and numbered individually)**

*Overall Goal: (State the overall goal of the study.)*

*Research Hypothesis: Next state the research hypothesis (when applicable). The hypothesis should align with the overall goal of the study.*

*List the specific aims for the study. Specific aims are distinct statements of the research to test the above hypothesis and accomplish the study goal. Aims should be simple (not complex), specific (not vague), and stated in advance (not after the research is done).*

1. *Specific Aim 1*
	1. *Primary Objective (main goal/focus of aim)* *The study is powered to achieve the primary objective.*
	2. *Secondary Objective (if needed)* *List any other secondary objectives*
2. *Specific Aim 2 (if needed)*
3. **Study Design:**

*Describe the type of study (e.g. 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: mm/dd/yyyy to mm/dd/yyyy.*

*To qualify as retrospective, the* ***data must exist when the study is approved*** *by 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.*

1. **Study Methodology:**

**Inclusion & Exclusion Criteria**

*Describe subject selection. (What is the sampling plan? What are subject and disease characteristics? etc.)*

*Please list the inclusion and/or exclusion of the vulnerable populations (pediatrics, pregnancy, adults who are unable to consent, and prisoners)*

*Remember to consider and include any study specific details of inclusion and exclusion*

 *criteria that might be different for cases versus controls if two differing populations are being*

 *reviewed retrospectively.*

1. *Inclusion Criteria*
	* *List inclusionary criteria*
2. *Exclusion Criteria*
	* *List exclusionary criteria*
3. **Subject Identification and Recruitment**

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

1. **Study Procedures:**

*Describe the study procedures (Describe what data will be collected, who will collect it, from where it will be collected, when it will be collected, how it will be collected and describe the tool(s) that will be used for data collection).*

*Consider the use of a data correlation tool to manage private (protected) health information. If additional information is requested during manuscript review or data needs to be clarified during data analysis, individuals who do not use a data correlation tool may have to return to all reviewed records to respond to the data in question. This effort is time consuming and burdensome. Below are two options:*

* + *Excel*

*If you are going to use Excel, the correlation tool is a separate data sheet, which contains, for each subject, the patient study identification number, along with other PHI such as patient name and MRN. You may also wish to have other information, such as the actual birthdate, FIN, and SSN. The correlation tool has its own password, which should be different from the password used for the data in the file to which it is linked via the patient study number. Use of a correlation tool is an easy and acceptable method to ensure patient identifiers are separated from the health information but still readily accessible to you ( as the approved investigator for the project) in the event you need to revisit subjects records for missed information or clarification . If you have no use for identifiable information for the purpose of your project, this would not be applicable. If you will find it beneficial, a copy of the tool should be included as an appendix.*

*Describe who will be involved in subject identification and data collection. How are these individuals involved in the care of the subject population? Are they employees of Spectrum Health? Describe collaborators.*

1. **Ethical Considerations and Informed Consent**

*Describe justification for waiver of informed consent.*

* *Explain why the research could not be conducted without the waiver granted (note: time, inconvenience and limited resources are not considered justifiable reasons).*
* *Will the waiver of informed consent adversely affect the rights and the welfare of the participant(s)?* *Explain (example: procedures have already been completed; therefore, results will not affect clinical decisions about the participants' care).*

*Examples could include:*

* *Since this is a retrospective review of existing data from the period of time described above, we will request a waiver of informed consent. This is a minimal risk study, which will not require any interaction with or prescribe any intervention for the subjects involved in the study.*
* *This study will only involve the collection of existing data where measures will be taken to maintain individual confidentiality, as described in following sections. For these reasons, the request for the waiver will not adversely affect the rights and welfare of the study subjects.*
* *Given the nature of patients with said diagnosis, it is possible that not all eligible subjects have survived \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and thus obtaining informed consent could not practicably be carried out.*

*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 to be taken to ensure their protection according to the federal regulations.*

1. **Risks and Benefits (modify as needed)**

*Risks: 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: The participants are not likely to receive any benefit from the proposed research; however, others may 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 the subject.*
1. **Statistical Plan**

*Sample size determination (The minimum number of records necessary to carry out the objectives of your study).*

*Describe how the data will be summarized (i.e., means and standard deviations, medians and ranges, percentages). 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. (i.e. statistical analysis will be done using SAS, R, or SPSS, etc.)*

1. 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.*

1. Unanticipated Problem

*It is possible that an Unanticipated Problem (UAP) may occur. A UAP is defined as any incident, experience, or outcome that meets all of the following criteria:*

* *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;*
* *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*
* *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 include theft or loss of USB or laptop with study data resulting in breach of confidentiality, accidental change to protocol without IRB approval or complaint from participant).*

1. Provisions to Maintain the Confidentiality of Data

*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 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 Spectrum Health computer, individually password protected files stored on the M drive, no portable devices, REDCap)*

*Specify who will have access to harvested data*

*Clarify how long data will be stored and where (both hard copy and electronic), who has access to it and how it will be protected. Please note that it is a requirement of Spectrum Health that all study records and data be kept and accessible for review and audit for a minimum of 11 years. Include how data will be destroyed when no longer needed and include the destruction plan.*

*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.*

1. Study Monitoring, Auditing and Inspecting

Describe the plan for study-related monitoring, audits and inspections by Spectrum Health IRB.

1. **References/Bibliography**

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

1. **Appendices: Appendix A and B must be completed and included in the protocol.**

**Instructions:**

**Appendix A: Data Collection Tool** (This document should list the data elements that will be collected. It should not contain any direct or indirect identifiers except for a unique participant code.)

**Appendix B: Correlation Tool** (This document will serve as the link between the unique participant code and any identifiers you need to conduct this review study [e.g., name, medical record number, date of birth, address, telephone number])