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| **Title** |
| **Principal Investigator** |  |
| **Co-Investigator(s)** |  |
| **Study Location(s)** |  |

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| *Provide a concise summary (a few sentences) that includes objectives, population, design, and outcome measures:* |
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1. **INTRODUCTION**
2. **BACKGROUND**

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| *Describe the rationale for the study, including the disease or condition being studied, citations, and synthesized earlier preclinical and clinical research on the topic of the study:* |
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1. **IMPORTANCE & JUSTIFICATION FOR THE STUDY**

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| *Describe the research question you intend to answer with findings from this study:* |
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| *Explain why the current research question is pertinent, important, interesting, or novel:* |
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1. **HYPOTHESIS & OBJECTIVES**
2. **HYPOTHESIS**

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| *Describe the hypothesis/hypotheses that your study is intended to demonstrate, and your objectives are based:* |
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1. **OBJECTIVES**

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| *Describe the details of each objective that will lead to the achievement of the study goal including a summary of the outcome measures:* |
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1. **DESIGN & METHODS**
2. **STUDY DESIGN**

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| *Briefly describe the study design (observational [cohort, case-control, cross-sectional] or case study):* |
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1. **SETTING**

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| *List the locations, with descriptions, of where procedures will be performed:* |
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| 1. **Available Resources**
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| *List all research team members including contact details (e-mail addresses and telephone numbers) as well as a brief description of qualifications (approximate years of research experience) and specific roles in the study:* |
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| *Describe availability/access to needed equipment, resources, funding, and access to the population of interest:* |
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1. **POPULATION**

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| *Briefly describe the population of interest:* |
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| 1. **Inclusion Criteria**
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| *Describe the inclusion criteria for the population of interest:* |
| *NOTE – inclusion criteria should, at a minimum: identify the disease or condition patients must have for record review, define the acceptable age range, and delineate all other factors required to be in the study.* |
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| 1. **Exclusion Criteria**
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| *Describe the exclusion criteria:* |
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| 1. **Target Number of Records**
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| *List the number of expected records to be reviewed within Prisma Health:* |
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1. **SPECIFICS OF STUDY PROCEDURES**

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| *Describe all research procedures:* |
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| 1. **Study Timelines**
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| *List the expected period that records will be reviewed and the expected duration of the study:* |
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| 1. **Outcome Measures/Data**
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| *List all outcome measures/data that will be collected including explanations/definitions of measures as necessary:* |
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| 1. **Data Collection Methods and Instruments Used**
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| *Describe how data will be collected including a copy of the data collection instrument/data collection form:* |
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| 1. **Data Banking**
 |
| *Describe the storage and management plan of collected data to assure their integrity and availability for analyses to fulfill the objectives of the study:* |
| *NOTE – clearly articulate if data will be retained after the study is complete, whether data may be shared with others, the purposes for which they may be used, and any restrictions on use.* |
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| 1. **Statistical Analysis**
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| *Describe how the data and samples will be analyzed to achieve all study objectives:* |
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1. **ETHICAL CONSIDERATIONS**
2. **RISKS AND POTENTIAL BENEFITS**

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| 1. **Risks to Patients’ Data**
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| *Describe in detail all risks to patients’ data:* |
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| 1. **Potential Benefits to Future Patients**
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| *Describe any benefits to future patients:* |
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1. **PATIENT CONFIDENTIALITY AND PRIVACY**

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| 1. **Confidentiality of Patient Data**
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| *Describe the plan to protect patient confidentiality including controls on storage, handling, and sharing of data.**If applicable, include a schedule for destruction of identifiers associated with the data:* |
| *NOTE – confidentiality is the researcher’s agreement regarding how identifiable private information will be handled, managed, and disseminated. It protects patients’ personally identifying data and records (concerns data). Confidentiality can be maintained by assigning records and data a code that does not embed personal identifiers and keeping the key to the code separately and securely. Further protections may include limiting access to identifiable data and the key to the code, and keeping records secured in double-locked storage and on secure, protected servers and computers.* |
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| 1. **Provisions to Protect the Privacy Interests of Patients**
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| *Describe the plan to protect patient privacy, including how the investigator(s) will access information about patients:* |
| *NOTE – privacy refers to a person’s desire to control the access of others to themselves (concerns people). Consider the methods used to obtain information about participants, the nature of the requested information, and how to access the minimum amount of information necessary to complete the study.* |
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| 1. **PHI and Waiver of Informed Consent**
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| *Provide a detailed list of the PHI for which use, or access is necessary to the research study:* |
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| *Explain why the research study could not practicably be conducted without access/use to PHI and the waiver:* |
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| *Explain why the use or disclosure of PHI involves no more than minimal risk to the privacy of patients and why the risks are reasonable in relation to the expected benefits of the research as well as the importance of the knowledge that may be reasonably expected to result from the research:* |
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| *Describe measures that will be taken to ensure the waiver will not adversely affect the rights and welfare of patients:* |
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1. **VULNERABLE POPULATIONS**

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| *Describe any vulnerable populations required to complete the study objectives as well as the plan to offer extra protection of confidentiality and privacy:* |
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1. **BIBLIOGRAPHY**