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| **Title** | |
| **Principal Investigator** |  |
| **Co-Investigator(s)** |  |
| **All Institutions Collaborating, *if applicable*** |  |
| **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: |
|  |

1. **IMPORTANCE & JUSTIFICATION FOR THE STUDY**

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| Describe the research question you intend to answer with findings from this study: |
|  |
| Explain why the current research question is pertinent, important, interesting, or novel: |
|  |
| Describe what you intend to do with the information you gain from this study and what are any potential next steps: |
|  |

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: |
|  |
| 1. **Available Resources** | |
| 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: | |
|  | |
| Describe availability/access to needed equipment, resources, funding, and access to the population of interest: | |
|  | |

1. **POPULATION**

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| Briefly describe the population of interest: |
|  |
| 1. **Inclusion Criteria** |
| 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.* |
|  |
| 1. **Exclusion Criteria** |
| Describe the exclusion criteria: |
|  |
| 1. **Target Number of Records** |
| 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** | | |
| List the expected period that records will be reviewed and the expected duration of the study: | | |
|  | | |
| 1. **Outcome Measures/Data** | | |
| List all outcome measures/data that will be collected including explanations/definitions of measures as necessary: | | |
|  | | |
| 1. **Data Collection Methods and Instruments Used** | | |
| Describe how data will be collected including a copy of the data collection instrument/data collection form: | | |
|  | Epic Data Pull – DSC Approval Letter Required for IRB Submission | |
|  | Manual Chart Review | |
|  | Already Obtained Patient List – must specify below how list was obtained | |
|  |  | Slicer Dicer |
|  |  | Pharmacy Medication List |
|  |  | Administrative Records |
|  |  | Previous Patient Consent |
|  |  | Other: **Click or tap here to enter text.** |
|  | Pull from Existing Registry/Database | |
|  | Other: **Click or tap here to enter text.** | |
|  | | |
| 1. **Data Storage** | | |
| 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.* | | |
|  | | |
| Will the Data be Stored on a Prisma Server? | | |
|  | yes | |
|  | no – CRMO review will be necessary to determine if data agreement is required | |
|  | | |
| Where will the data be stored? | | |
| *NOTE – anything other than REDCap may not be approved* | | |
|  | REDCap | |
|  | OneDrive | |
|  | Other: **Click or tap here to enter text.** | |
|  | | |
| 1. **Statistical Analysis** | | |
| Describe how the data and samples will be analyzed to achieve all study objectives: | | |
| NOTE – If DSC assistance will be needed for analysis, a DSC approval letter will be required for IRB submission. | | |
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1. **ETHICAL CONSIDERATIONS**
2. **RISKS AND POTENTIAL BENEFITS**

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

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| 1. **Confidentiality of Patient Data** |
| Will data be shared outside of Prisma Health servers? Please specify. |
|  |
| Please describe who will have access to patient data. |
| *NOTE: If investigators, whose primary institutional affiliation is not Prisma Health, will have access to the data, a data agreement may be required through the CRMO department.* |
|  |
| Please explain your process for retention and destruction of project data. Note that all project data must be maintained for three years post study completion and then must be destroyed. If you intend to retain data past this requirement, this must be approved. |
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| 1. **Provisions to Protect the Privacy Interests of Patients** |
| Please describe your plan to monitor and manage the safety and integrity of the data. |
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| 1. **PHI and Waiver of Informed Consent** |
| Please describe the use of PHI in this study. Will be PHI be collected and stored? Will it be used in analysis? Will PHI only be accessed in order to obtain non-PHI data? Please be as specific as possible. |
| *NOTE – De-identified data is different from anonymous data. If data is de-identified, that means that patient identifiers have been collected and either coded or the identifiable information has been destroyed in order to maintain confidentiality. Anonymous data is data that contains no identifiable information.* |
|  |
| Provide a detailed list of the PHI for which use or access is necessary to the research study: |
|  |
| Explain why the research study could not practicably be conducted without access to PHI and the waiver: |
|  |
| 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: |
|  |
| Describe measures that will be taken to ensure the waiver will not adversely affect the rights and welfare of patients: |
|  |

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**