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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 research question, objectives, population, design, and outcome measures: |
|  |

1. **INTRODUCTION**
   1. **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 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 (systematic review, randomized controlled trial, other controlled clinical trial, 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. **Resources Available** | |
| List all research team members including contact details (e-mail addresses and telephone numbers): | |
|  | |
| Briefly describe the qualifications (include approximate years of research experience) of the PI and co-investigators as well as their specific roles in the study: | |
|  | |
| Describe availability/access to needed equipment and resources including access to the population of interest: | |
|  | |
| * + 1. **Multi-Site Research** | |
| If applicable, list sites involved in this study that are part of the Prisma Health system. Please indicate which site is the primary (if any) site: | |
|  | |
| Please list all sites involved that are NOT owned by Prisma Health: | |
| *Note – additional information and agreements may be necessary prior to IRB approval.* | |
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1. **PROPOSED INTERVENTION**

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| 1. **Treatment** |
| List the experimental treatment of interest and comparative treatment as applicable: |
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| 1. **Drugs** |
| List the primary drug intervention of interest and any additional drugs used: |
|  |
| 1. **Devices** |
| List the primary device intervention of interest: |
|  |

1. **POPULATION**

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| Briefly describe the population of interest: |
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| 1. **Inclusion Criteria** |
| Describe the inclusion criteria for the population of interest: |
| *NOTE – inclusion criteria should, at a minimum: identify the disease or condition people must have to participate, define the acceptable age range, and delineate all other factors required to be in the study.* |
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| 1. **Exclusion Criteria** |
| Describe the exclusion criteria: |
| *NOTE – exclusion criteria should focus primarily on the protection of participants, with careful consideration of criteria needed to exclude those for whom participation would be unsafe.* |
|  |
| 1. **Sample Size** |
| If applicable, show the power calculation for the estimated sample size: |
|  |
| 1. **Local Number of Participants** |
| List the number of expected participants within Prisma Health: |
|  |
| 1. **Study-Wide Number of Participants** |
| For multi-site studies, list the number of expected participants in total (study-wide): |
|  |
| 1. **Recruitment Methods** |
| Identify how potential participants will be identified and approached (where/when/how): |
| *NOTE –screening procedures must be incorporated into this protocol with a description of the methods and their risks or discomforts. If participants are screened separately from the protocol, the method should be briefly acknowledged.* |
|  |
| If applicable, list and describe recruitment materials: |
| *NOTE – recruitment materials should inform potential participants about the availability and nature of the study. They will need to be attached to the Designer page.* |
|  |
| List any and all recruitment venues (i.e. flyers in a clinic, ads on social media, office visit, etc): |
| *NOTE – mass emailing for recruitment is not permissible* |
|  |
| **7. Remuneration** |
| Describe any compensation for participation in the research, to include amount, how payment is dispersed, and any additional payments that may be included (such as travel, etc.): |
| *NOTE – if the study involves Prisma Health employees, they are not allowed to receive compensation for participation in research while they are being paid to perform their normal job functions per Prisma HR.* |
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1. **SPECIFICS OF STUDY PROCEDURES**

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| Describe **all participant research procedures**, in chronological order and from the participant’s viewpoint. State where procedures will be done and if inpatient admission is required. Identify the required and optional study procedures. Identify the risks discomforts, and inconveniences of each procedure and intervention: |
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| Describe all standard care procedures related to this study, in chronological order and from the participant’s viewpoint: |
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| If applicable, differentiate the procedures or combinations or schedules of the same procedures between study cohorts: |
|  |
| If applicable, describe the plans for the participants’ end of participation, including transfer of care back to their own physicians: |
|  |
| 1. **Study Timelines** |
| List the duration of individual procedures and cumulative time commitment, including number and timing of visits and total duration of participation in the study: |
| *NOTE – the duration of the study should reflect the disease or condition and intervention being studied. Define the frequency of study measurements needed to capture the primary outcome measure.* |
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| 1. **Study Endpoints** |
| For clinical trials, list the study endpoints: |
|  |
| 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 and attach a copy of the data collection instrument/data collection form to the Designer page: |
|  |
| 1. **Data Management** |
| Describe the data safety monitoring procedures to assist in determining trends that affect the integrity of the study or participant safety. Include details on who will monitor, what they review, and how frequently data is reviewed. Also include any policies and procedures if a problem is identified and the study needs to be suspended or stopped: |
|  |
| 1. **Data and Specimen Banking** |
| Describe the storage and management plan of research samples and/or data to assure their integrity and availability for analyses to fulfill the objectives of the study: |
| *NOTE – clearly articulate if samples and data will be retained after the study is complete, whether data and/or samples may be shared with others, the purposes for which they may be used, and any restrictions on use. The protocol management plan must reflect information in the consent form on the additional use of data and samples. If participants are offered options, the participants’ choices as to further use should be outlined.* |
|  |
| 1. **Statistical Analysis** |
| Describe how the data and samples will be analyzed to achieve all study objectives: |
|  |

1. **CONSENT PROCESS**

### **Consent/Assent** **Procedures and Documentation**

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| Provide a detailed description of the consent process, including the following, as applicable: |
| Describe where and when will consent be obtained, including how the privacy of the subjects will be protected during the consent process: |
|  |
| List who will be authorized to obtain consent: |
| *Note – in order to obtain consent, the investigator must be licensed/credentialed/trained to perform all procedures of the protocol.* |
|  |
| List who will answer questions from the participants: |
|  |
| Explain how coercion or undue influence will will be minimized during the consent process: |
|  |
| If the consent process will be take place remotely (via telephone or videoconference), describe this process: |
| *Note – in order to obtain consent remotely, this must be approved by the IRB beforehand and the institutional policy for this procedure must be followed. Please also note that that at this time, Prisma Health does not support the process of eConsenting.* |
|  |
| Explain how much time the potential subject be provided to consider their participation in the study and if they will have the opportunity to consult with others (family, friends, private physician) prior to providing consent: |
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## **CONENT PROCESS FOR MINORS/CHILDREN (UNDER 18 YEARS OF AGE)**

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| For studies involving pediatric participants only: |
| Describe how parental permission will be obtained: |
| *Note – for studies that are determined by the IRB to be “greater than minimal risk” and there is not a prospect of direct benefit to the child, both parent signatures will be required on the consent form.* |
|  |
| If applicable, describe the process for obtaining assent of the pediatric participants: |
| *Note - regulations require that consent information be delivered to prospective participants in a way that they understand.* |
|  |
| Describe the process for consenting participants at age of majority: |
| *Note - when a previously enrolled pediatric subject, who is still enrolled in study participation, reaches the age of majority, they must be formally consented into the study in order to continue their participation.* |
|  |

## **C. CONSENT INVOLVING THE USE OF A LEGALLY AUTHORIZED REPRESENTATIVE, IF APPLICABLE**

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| Describe the process to determine whether an individual is capable of consent: |
| *Note - if an LAR will be used, the IRB must approve this prior to the consent conversation.* |
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| If the individual is not capable of giving consent to participate, indicate who will be authorized to give consent: |
|  |
| Describe the process for consenting the participant if/when they re-gain the ability to provide consent: |
|  |

**VI. ETHICAL CONSIDERATIONS**

1. **RISKS AND POTENTIAL BENEFITS TO PARTICIPANTS**

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| 1. **Risks to Participants** |
| Define the study as “minimal risk” or “more than minimal risk” considering all risks and burdens of participation: |
| *NOTE – If there are multiple study populations and the overall risk and benefit is different for individual populations, then define the risk for each population separately.* |
|  |
| Describe in detail all risks to participants (consider the physical, social, and psychological implications of the research): |
|  |
| 1. **Potential Benefits to Participants** |
| Describe any benefits to participants: |
| *NOTE – the classification of benefit should be weighed based on reasonable expectation of benefit for the individual participant. The possibility of indirect benefit, such as gaining generalizable knowledge may be sufficient depending on the nature and risks of the study.* |
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1. **PARTICIPANT CONFIDENTIALITY AND PRIVACY**

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| 1. **Participant Confidentiality** |
| Describe the plan to protect participant 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 with participants about how their identifiable private information (data) will be handled, managed, and disseminated. It protects the participants’ personally identifying data and records. Confidentiality can be maintained by assigning records, data, and samples 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.* |
|  |
| 1. **Provisions to Protect the Privacy Interests of Participants** |
| Describe the plan to protect participant privacy, including how the investigator(s) will access information from or about participants: |
| *NOTE – privacy refers to a person’s desire to control the access of others to themselves (concerns people). Consider the methods used to identify and contact potential participants, the settings in which an individual will be interacting with an investigator, and the appropriateness of having all personnel present for research activities. 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. **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: |
| *NOTE – for studies enrolling minors, it should also be determined if a “more than minimal risk” study is no more than a minor increment over minimal risk. For minors, the risk level of the study, along with consideration of whether there is direct individual benefit, determines whether the study fits into a category of approvable research.* |
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1. **PARTICIPANT ECONOMIC BURDEN/COMPENSATION & OTHER STUDY DETAILS**

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| 1. **Economic Burden to Participants** |
| If applicable, describe any potential economic burdens to participants: |
|  |
| 1. **Compensation for Research-Related Injury** |
| If applicable, provide details on the amount, method, and timing of compensation: |
| *NOTE – if there are more than one study cohort, include descriptions if they will be compensated differently.* |
|  |
| 1. **Debriefing Participants** |
| If applicable, describe the procedures to debrief participants including what data and information will be released: |
|  |
| 1. **Community-Based Participatory Research** |
| If applicable, describe the details on Community-Based Participatory involvement with this study: |
| *Note – “Community-based Participatory Research (CBPR)” is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.* |
|  |

**VII. BIBLIOGRAPHY**

1. **APPENDICES**

***Please attach all supplemental materials (surveys, consent forms, advertisements, etc.) as separate attachments to the Designer page.***