**Office Human Research Protection**

**Research Proposal**

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| **Formatting Guidelines**   * Submit protocol in Microsoft Word. Do not submit a PDF file. * Include Human Subject Protection training certificates for all members involved in the study. * When revisions are submitted do not delete the comments. * When revisions are submitted, assign a new version date to the research proposal. * Text boxes in this form do not accommodate bullet points. If using bullet points, place each bullet point in a separate text box. * Text boxes do not accommodate separate paragraphs or hard returns. One paragraph regardless of length will be accepted for each area.   Contact Renee Capizzi, IRB Administrator with any questions: renee.capizzi@rochesterregional.org |

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| **Research Proposal Title:** Click or tap here to enter text. | |
| Principal Investigator and Credentials | Click or tap here to enter text. |
| Principal Investigator and Credentials | Click or tap here to enter text. |
| Co-PI and Credentials | Click or tap here to enter text. |
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| Co-PI and Credentials | Click or tap here to enter text. |
| Sub-PI and Credentials | Click or tap here to enter text. |
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| Sub-PI and Credentials | Click or tap here to enter text. |
| Research Coordinator | Click or tap here to enter text. |
| Research Coordinator | Click or tap here to enter text. |
| Other: | Click or tap here to enter text. |
| Other: | Click or tap here to enter text. |

**Version Date:** Click or tap to enter a date.

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| **Introduction** Provide a description of the scientific background. Identify the research problem and significance of studying the problem with a description of the rationale and relevance of the problem. Include a brief review of the literature.  Click or tap here to enter text. |
| **Statement of purpose and objectives**  Include the purpose, objectives, or study aims.  Click or tap here to enter text. |
| **Research method and design (quantitative) or tradition (qualitative)**  Discuss the research method and design or tradition (e.g., phenomenology, grounded theory, ethnography) that will be used.  Click or tap here to enter text. |
| **Outcomes**  Clearly define primary and secondary outcome measures.  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text. |
| **Sample Size**  State the sample size and describe how the sample size was calculated.  Click or tap here to enter text. |
| **Fair subject selection – Recruitment of participants**  Description of the population from which participants will be recruited, including details concerning location, recruitment strategies, age groups, gender, ethnicity and whether participants will be recruited from vulnerable groups. Please remember that all recruitment materials must be approved by the Office of Human Research Protection.  Click or tap here to enter text.  Not applicable |
| **Blinding**  Describe whether or not participants, those administering the intervention, and those assessing the outcomes will be blinded to group assignment. When relevant, how the success of blinding will be evaluated  Click or tap here to enter text.  Not applicable |
| **Randomization**  Detail who will generate the sequence. Detail who will enroll and assign participants to their group. Describe the methods used to generate the random sequence, include any details of any restrictions.  Click or tap here to enter text.  Not applicable |
| **Risks to participants** Describe any risks to participate in study including potential disclosure of private health information (PHI)  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text.  Not applicable |
| **Fees** Describe who will be responsible for paying tests (labs, blood tests, diagnostic tests) or other fees (labor, medications).  Click or tap here to enter text.  Not applicable  How are costs being covered?  Click or tap here to enter text.  Not applicable  **Participant Payment** Description of compensation for participants to participate in the study  Click or tap here to enter text.  Not applicable |
| **Plan to maintain confidentiality of participants and/or data** Description of where recruitment will take place. Description of how data will be stored. Details of who will have access to the data.  Click or tap here to enter text. |
| **Trial Monitoring Plan** Description and justification of a formal trial monitoring (safety and efficacy plan) including stopping guidelines for the trial and how they were chosen.  Click or tap here to enter text.  Not applicable |
| **Communication of Protocol changes and Trial Monitoring** Details concerning the methods and timing of reporting protocol changes and trial monitoring results to the Rochester Regional Health Institutional Review Board  Click or tap here to enter text.  Not applicable |
| **Statistical Methods** Describe the statistical method that will be used to analyze the data.  Click or tap here to enter text.  Not applicable |
| **Statistical Analysis**  Detail who will be conducting the statistical analysis and describe their expertise with statistical analysis.  Click or tap here to enter text.  Not applicable |
| **Qualitative Tradition**  Describe the qualitative tradition that will be used to analyze the data.  Click or tap here to enter text.  Not applicable |
| **Qualitative Analysis**  Detail who will be conducting the qualitative analysis and describe their expertise with qualitative analysis.  Click or tap here to enter text.  Not applicable |
| **Public Dissemination of Trial Results** Describe plans for dissemination of results.  Click or tap here to enter text. |
| **Data Use Agreement** If data are being sent outside of Rochester Regional Health, there must be a data use agreement in place which must be approved by the Office for Sponsored Research.  Has the Office for Sponsored Research reviewed and approved the data use agreement?  Yes  Not applicable |
| **Reference List** Include at least three current references to support the study. Use each field for one reference.  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text.  Click or tap here to enter text. |