ROCHESTER REGIONAL HEALTH **Office Human Research Protection**

Elements Required When Writing a Research Proposal

Formatting Guidelines

- Submit protocol in Microsoft Word. Do not submit a PDF file.
- Submit protocol and appendices in one file. Multiple files will not be accepted.
- 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

Research Proposal Title:	
Principal Investigator and Credentials	
Principal Investigator and Credentials	
Co-PI and Credentials	
Co-PI and Credentials	
Co-PI and Credentials	
Sub-PI and Credentials	
Sub-PI and Credentials	
Sub-PI and Credentials	
Sub-PI and Credentials	

Research Coordinator	
Research Coordinator	
Other:	
Other:	

Version Date:

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.
Statement of purpose and objectives Include the purpose, objectives, or study aims.
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.
Outcomes Clearly define primary and secondary outcome measures.
Sample Size State the sample size and describe how the sample size was calculated.

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.

☐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.

☐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.

☐Not applicable

Risks to participants

Describe any risks to participate in study including potential disclosure of private health information (PHI)

☐Not applicable

Fees

Describe who will be responsible for paying tests (labs, blood tests, diagnostic tests) or other fees (labor, medications).

☐Not applicable

How are costs being covered?

☐Not applicable

Participant Payment

Description of compensation for participants to participate in the study

☐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.

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.

☐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.

☐Not applicable

Statistical Methods

Describe the statistical method that will be used to analyze the data.

☐Not applicable

Statistical Analysis

Detail who will be conducting the statistical analysis and describe their expertise with statistical analysis.

☐Not applicable

Qualitative Tradition

Describe the qualitative tradition that will be used to analyze the data.

☐Not applicable

Qualitative Analysis

Detail who will be conducting the qualitative analysis and describe their expertise with qualitative analysis.

☐Not applicable

Public Dissemination of Trial Results

Describe plans for dissemination of results.

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.