ROCHESTER REGIONAL HEALTH

Standard Operating Procedure

Clinical Investigation Committee

Rochester Regional Health

Title: **Procedures for Review of External IRB Greater than Minimal Risk Studies**	
SOP#:	Document Status:
Date Issued: **3/21/2017**	Written by: James R. Cronmiller
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Scope:
This Standard Operating Procedure (SOP) describes the process the Rochester Regional Health (RRH) Clinical Investigation Committee (CIC) uses to assess greater than minimal risk studies overseen by the CIC and an external Institutional Review Board (IRB).

Purpose:
The assessment will ensure that research being conducted at RRH is warranted.

Applicability:
This SOP applies to all investigators performing research at RRH, including any of its affiliates.

Procedures:

1. The investigator should have adequate qualifications, training, experience, time and resources to conduct the study (See SOP on Investigator Qualifications).

2. The investigator will provide the administrator of the CIC:
   - CIC new study application
   - Comprehensive research protocol
   - Investigator brochure
   - Original plus 20 copies of the consent form
   - Original plus 20 copies of the abstract
   - CIC review fee of $1,600 and transfer of funds paperwork

3. The CIC administrator will:
   - Assess whether the application is appropriately filled-out, signed and dated
   - Ensure the investigator and all study personnel have an up-to-date HSPP on file
   - Compare the consent form against the RRH boilerplate checklist and protocol
   - Communicate any missing information to the investigator

4. The protocol and all accompanying paperwork will go to one of the two CIC Boards for review.
   - All documents will be given to a Scientific Primary Reviewer. The reviewer will complete a scientific reviewer form which includes risk and benefits analysis, research design, approach to subjects, recruitment of subjects, privacy and confidentiality, and assessment of the consent form.
   - Each member of the CIC will be provided a synopsis of the protocol and consent form.
   - The scientific reviewer will present the study to a Board at a scheduled meeting of the CIC.
   - The investigator is required to be present to answer questions.
   - The board will assess whether:
     - The consent form contains all the necessary boilerplate language

- There is adequate background support for the proposed study
- The protocol provides well-framed, testable hypotheses and/or well-framed study aims
- Study design and strategies are adequate to test the hypothesis and/or to achieve study aims
- The analysis plan and methods are adequate to test the hypothesis and/or achieve study aims
- The proposed research may provide benefits
- The proposed research creates a burden to nursing/hospital resources
- The language of the consent form is adequate

Definitions:
Risk Category – Under the federal regulations, research is categorized as either "greater than minimal risk" or "minimal risk." This category is based on the potential harm associated with the research that a reasonable person would likely consider to cause injury or discomfort.

Greater Than Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in everyday life or during the performance of routine physical or psychological examinations or tests as defined by the Code of Federal Regulations, Department of Health and Human Services (45 CFR 46-102).

Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains:

- Data through intervention or interaction with the individual, or
- Identifiable private information

Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations as defined by the Code of Federal Regulations, Department of Health and Human Services (45 CFR 46-102).

After the board reviews the study, it will be sent to the CIC administrative coordinator to prepare a letter that will be sent to the investigator with a decision. The investigator can contest a negative CIC decision.