ROCHESTER REGIONAL HEALTH

Standard Operating Procedure

Clinical Investigation Committee

Rochester Regional Health

Title: **Procedures for Internal/External IRB Minimal Risk Studies**	
SOP#:	Document Status:
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Supersedes: **None**	Approval:

Scope:
This Standard Operating Procedure (SOP) describes the process the Rochester Regional Health (RRH) Clinical Investigation Committee (CIC) uses to assess risk & scientific merit of minimal risk studies overseen by the CIC or an external Institutional Review Board (IRB).

Purpose:
The assessment of risk and scientific merit 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 is responsible for providing the CIC an application, comprehensive research protocol and consent form. 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 the application, protocol, CIC review fee of $800, transfer of funds paperwork, and consent form.

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

4. Th**e CIC Chairperson will assess Scientific Merit**
   The scientific reviewer will attest to the scientific merit of the proposed research, which includes the following elements:
   - 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
- There are no additional burdens to nursing/hospital resources

The CIC Chairperson will also assess Risk Identification and Management
The scientific reviewer will assess risk which includes assessment of the balance of potential benefit to potential risk to human subjects:

- Foreseeable risks to research subjects have been identified and described
- Reasonable means to mitigate risks have been employed
- Data and safety monitoring procedures are appropriate to the design, specific risks and risk level of the study, and are adequate to safeguard the rights and welfare of study subjects

The CIC Chairperson may consult with members of the Clinical Investigation Committee as needed.

If the CIC Chairperson does not approve of the study, it will be sent to one of the full boards for their review and decision.

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 chairperson reviews the study, it will be sent to the CIC IRB Coordinator to prepare a letter that will be sent to the investigator with a decision. The investigator can contest a negative CIC decision.