CIC#:	Expedited _____ Full Board _____ Exempt _____
Board:	Meeting Date:
Primary Reviewer:	IRB Signature:

Rochester Regional Health System
Institutional Review Board

Application for New Research Project

Instructions

Please complete application, sign, and send hard copy along with submitted enclosures to Renee Capizzi, RN IRB Administrator, G-13 (Ground Floor) Gordon Building or Box 198.

For questions, contact Renee Capizzi at (585) 922-5640 or at Renee.Capizzi@rochestergeneral.org or Ellen Keenan, IRB Coordinator at (585) 922-3543 or at Ellen.Keenan@rochestergeneral.org.

I. GENERAL INFORMATION

Project Title:

Investigator Initiated Project? ☐ YES ☐ NO

Resident Project? ☐ YES ☐ NO

Principal Investigator

Has the PI met the education requirements? ☐ YES ☐ NO

Name:

Title:

Degree:

Dept:

Phone: **Fax:** **Email:**

Work Address:

Primary Contact to IRB? ☐ YES ☐ NO

URMC Faculty? ☐ YES ☐ NO -- **NOTE: If YES, study must be submitted to the RSRB.**

Nursing Research? ☐ YES ☐ NO -- **NOTE: If YES, submit CRN Approval.**

Select the research activities which this person will be involved in and has received training for (Check all that apply)**:**

☐ Screening ☐ Consenting ☐ Data Monitoring ☐ Dispensing Drugs ☐ Conducting Study Visits
☐ Data Analysis ☐ Manuscript Preparation

HSPP Completed? ☐ YES ☐ NO

Department of SOP's on File? ☐ YES ☐ NO

Principal Investigator Interests

1. Does the investigator have a generic conflict of disclosure on file with the Research Institute? ☐ YES ☐ NO
2. Conflict of Interest form submission to CIC. Click here to link to the form.

Co-Principal Investigator (Co-PI)

Has the Co-PI met the education requirements? ☐ YES ☐ NO

Name:

Title:

Degree:

Dept:

Phone: **Fax:** **Email:**

Work Address:

Primary Contact to IRB? ☐ YES ☐ NO

URMC Faculty? ☐ YES ☐ NO -- **NOTE: If YES, study must be submitted to the RSRB.**

Nursing Research? ☐ YES ☐ NO -- **NOTE: If YES, submit CRN Approval.**

Select the research activities which this person will be involved in and has received training for (Check all that apply)**:**

☐ Screening ☐ Consenting ☐ Data Monitoring ☐ Dispensing Drugs ☐ Conducting Study Visits

HSPP Completed? ☐ YES ☐ NO

Department of SOP's on File? ☐ YES ☐ NO

Research Coordinator (if applicable)

Has the Research Coordinator met the education requirements? ☐ YES ☐ NO

Name:

Title:

Degree:

Dept:

Phone: **Fax:** **Email:**

Work Address:

Primary Contact to IRB? ☐ YES ☐ NO

URMC Faculty? ☐ YES ☐ NO -- **NOTE: If YES, study must be submitted to the RSRB.**

Nursing Research? ☐ YES ☐ NO -- **NOTE: If YES, submit CRN Approval.**

Select the research activities which this person will be involved in and has received training for (Check all that apply)**:**

☐ Screening ☐ Consenting ☐ Data Monitoring ☐ Dispensing Drugs ☐Conducting Study Visits

HSPP Completed? ☐ YES ☐ NO

Sub-investigators

(Physician, resident, fellow, research staff, or student specific to the project)

Name:

Title:

Degree:

College/Dept:

Phone: **Fax:** **Email:**

Campus Address:

Primary Contact to IRB? ☐ YES ☐ NO

URMC Faculty? ☐ YES ☐ NO --**NOTE: If YES, study must be submitted to the RSRB.**

Nursing Research? ☐ YES ☐ NO --**NOTE: If YES, submit CRN Approval.**

Select the research activities which this person will be involved in and has received training for:

☐ Screening ☐Consenting ☐ Data Monitoring ☐ Dispensing Drugs ☐ Conducting Study Visits

Has the Sub-investigator met the education requirements? ☐ YES ☐ NO

HSPP Completed? ☐ YES ☐ NO

Sub-investigator Name:

Title:

Degree:

College/Dept:

Phone: **Fax:** **Email:**

Campus Address:

Primary Contact to IRB? ☐ YES ☐ NO

URMC Faculty? ☐ YES ☐ NO -- **NOTE: If YES, study must be submitted to the RSRB.**

Nursing Research? ☐ YES ☐ NO -- **NOTE: If YES, submit CRN Approval.**

Select the research activities which this person will be involved in and has received training for:

☐ Screening ☐ Consenting ☐ Data Monitoring ☐ Dispensing Drugs ☐ Conducting Study Visits

Has the Sub-investigator met the education requirements?

☐ YES ☐ NO

HSPP Completed? ☐ YES ☐ NO

II. PROJECT INFORMATION

Is this a multi-center study? ☐ YES ☐ NO

If YES, is the PI or this site considered the “lead” or “coordinating” center? ☐ YES ☐ NO

If RGH is the lead or coordinating center, describe the plans for communication among the sites in terms of protocol modifications, unanticipated problems involving risks to participants or others and interim results:

Funding

☐ Federal Funding Source (Specify): Grant Number:

☐ Cooperative Group Involvement: ☐ YES ☐ NO Coop Group #:

☐ State / Non-profit Source (Specify):

☐ Industry Sponsored Project: Industry Sponsor Protocol #:

☐ No External Funding *

If checked, enter PI's department information:

Nature of Study

Study Design (Check all that apply):

☐ Bank of Tissue / Blood / Biological specimens / Data
☐ Social / Behavioral
☐ Genetics
☐ Quality Assurance / Quality Improvement
☐ Use of Clinical Samples, Charts / Records, Database Info w/ No Direct Subject Interaction
☐ Clinical Trial: ☐ Drug ☐ Device(s) ☐ Biologic(s) ☐ Surgical Procedure
☐ Other (i.e., Humanitarian use, treatment use, etc.)
☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☐ N/A

Has Pharmacy approved this study? ☐ YES ☐ NO

Clinical Drug / Biologic / Device Studies: Handling of investigational items for dispensation

Have all staff responsible for the investigative item(s) received training regarding control and dispensation of the investigational item(s)? ☐ YES ☐ NO

If YES, describe when the training occurred and who provided the training (i.e, sponsor site meeting):

If NO, the PI maintains that IRB policies 502 A, B and C have been reviewed with study staff for proper investigational item control.

(Physical documentation of this training is subject to verification through the audit process.)

Is the investigational item being stored and dispensed from a licensed pharmacy? ☐ YES ☐ NO

If YES, indicate the participating pharmacy(ies):

If NO, describe the plan to control the investigational item(s) with regard to storage and dispensation:

If YES, state the pharmacist's name and date of review:

If NO, the IRB Chairperson reviews the above plan for appropriate controls regarding the investigational item.

Request for Exempt / Expedited Status

Are you requesting Exempt Status? ☐ YES ☐ NO

If YES, indicate applicable number:

Are you requesting Expedited Status? ☐ YES ☐ NO

If YES, indicate applicable number:

III. RISKS AND BENEFITS

Does the research involve any of the following risks? (Check all that apply).

☐ Physical ☐ Psychological ☐ Economical ☐ Social ☐ Legal ☐ Other

Describe the nature and degree of all risk or harm associated with participation in the study. This information should be included in the consent form.

Explain what steps will be taken to minimize risks or harms and to protect participant welfare. Describe any anticipated benefits that may result from the research.

Methods of Enrollment

Indicate method for finding potential participants (Check all that apply & attach copies of recruitment materials):

- ☐ Your Practice Referral Where:
- ☐ Outside Practice Referral Where:
- ☐ Chart Review Where:
- ☐ Advertisement Where:
- ☐ Web Listing Where:
- ☐ Other, please describe:

Indicate how potential participants will be approached (Check all that apply):

☐ Direct Contact ☐ Letter ☐ Phone Call ☐ Other, describe:

Data Source Information

Please indicate the source(s) of data for this study (Check all that apply):

☐ Interviews ☐ Focus groups ☐ Medical records ☐ Photos/videos ☐ Registries ☐ Questionnaires / Surveys ☐ Public records ☐ Biological specimens ☐ Voice recordings ☐ Other, please explain:

Will these data be linked to participants / cases or contain any personal identifiers? ☐ YES ☐ NO

If the data are de-identified, will the study personnel have any links / keys to identifiers? ☐ YES ☐ NO

Does this study involve genetic analysis? ☐ YES ☐ NO

V. INFORMED CONSENT / ASSENT / PRIVACY FORMS

Consent Process

Will informed consent be obtained from participants? ☐ YES ☐ NO

If YES, then ***skip*** "Waiver of Consent" section
If NO, the ***complete*** the "Waiver of Consent" section

Who will be consenting to participate in the research?

☐ Participant ☐ Child ☐ Parent of child ☐ Guardian ☐ Legally authorized representative

Describe measures instituted to minimize undue influence and/or coercion:

Is the primary language of the consent process English? ☐ YES ☐ NO

If NO, submit appropriately translated consent document(s).

Does your study involve children? ☐ YES ☐ NO

If YES, child assent is required by regulation if the child is capable of providing such assent (typically, ages 7 to 17).

Does your study involve the collection, use or sharing of Protected Health Information? ☐ YES ☐ NO
(Protected Health Information (PHI) is individually identifiable health information that is transmitted by electronic media, maintained in any medium that falls within the definition of electronic media, or transmitted or maintained in any other form or medium.)

If YES, a HIPAA Form must be included with this application.

Waiver of Consent

Participants will not be required to sign a consent document when a waiver of signed written consent is reviewed and approved by the IRB. If the IRB waives the requirement of documentation of informed consent, the IRB may require the investigator to provide a written statement of the research to the participant. The IRB shall review and approve the written statement prior to the investigator providing the statement to the participant. The consent form reviewed and approved by the IRB may also serve as the written statement.

Is the waiver of consent requested? ☐ YES ☐ NO

If YES:

1. Explain the reason for the waiver
2. Category 1 OR 2 below must be indicated as "**YES.**"

Category 1
The only record linking the participant and the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether they want documentation linking them with the research and their wishes will govern. The research is not subject to FDA regulations. ☐ YES ☐ NO

Category 2
The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of research context. ◯ YES ◯ NO

Explain:

VI. PRIVACY AND CONFIDENTIALITY

Describe how information will be accessed from or about participants and the provisions used to protect the privacy interests of participants (e.g., Participant interactions are conducted in a private room, discussions are held in a private exam room, only designated personnel are present during discussions):
("Privacy" refers to a person's desire to control the access over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Describe the instituted measures to protect the confidentiality of identifiable private data of study participants (e.g., PHI kept in locking storage cabinets, use of password protected computer files containing PHI, limited access to PHI, use of identifiers, processes for appropriate data destruction):
("Confidentiality" refers to how the participant's individually identifiable private information will be handled, managed and disseminated by the investigator).

VII. ENCLOSURES SUBMITTED

Check all that apply:

- ☐ IRB Application, hard copy
- ☐ HIPAA Form
- ☐ Abstract (Original, plus 20 copies)
- ☐ Application fee - $1,800
- ☐ Advertisements
- ☐ Letters of Support
- ☐ Package Insert (1 copy) (for Investigator Initiated Drug/Device Studies)
- ☐ Protocol * (3 copies)
- ☐ Informed Consent (Original, plus 20 copies)
- ☐ HSPP (for each research team member if not previously filed with the CIC)
- ☐ Questionnaire / Survey (3 copies)
- ☐ Investigator's Brochure (1 copy)
- ☐ Conflict of Interest Form
- ☐ Other (please specify):

VIII. APPROVAL LETTER REQUIREMENTS

Note any specific information related to the protocol which needs to be included in the approval letter (i.e., version dates, consents, protocol, etc.)

IX. Required Signatures

Research Study Title:

By signing this application form:

- I agree to accept responsibility for the rights and welfare of the research participants involved with this study.
- I agree that the benefits outweigh the risks to the participants in the study.
- I agree to comply with the Rochester General Health System's Guidelines of the use of Human Studies in Research.
- I certify that, to the best of my knowledge, I am in compliance with the Department of Health and Human Services and Federal Drug Administration policies and procedures regarding the protection of human subjects.

Principal Investigator_____ **Date**_____

By signing this application form:

time and resources to meet the study design requirements and complete the study as proposed in this application form.

Department Chair_____ **Date**_____

Print Department Chair Name _____

Will faculty or staff from other departments or units participate in this project or will resources of another department, unit or office be used? ☐ YES ☐ NO

If YES, which departments?:

If YES, the following information requires completion by the Chair or Unit Director

I have read the protocol	_____ initial	_____ initial	_____ initial
I have no concerns with the protocol	_____ initial	_____ initial	_____ initial
I approve the study to be conducted	_____ initial	_____ initial	_____ initial

Signature(s) of Department, Unit Director or Manager

Signature _____ Title _____

Signature _____ Title _____

Signature _____ Title _____