

LIBERTYHEALTH

Jersey City Medical Center
Department of Patient Care Services

GUIDELINE: Nursing Research Approval process **Developed by:** Nursing Research Council

Approved by _____
Rita Smith, DNP
Senior Vice President
Patient Care Services

Approved by Policy Committee: _____

Effective Date: 6/8/2010

Revised Date: 8/8/2012

Reviewed Date:

Distribution: Nursing Units, Institutional Review Board

Purpose: To provide guidelines for Investigators conducting research at Jersey City Medical Center

GUIDELINE: All Research studies involving nurses in roles such as investigators, subjects, caregivers, or data collectors must be reviewed by the JCMC Nursing Research Council. The functions of the Research Council are to review, approve, obtain progress updates for nursing research, and facilitate collaboration and mentorship with nurse researchers. Written permission must be granted prior to submission to the Institutional Review Board (IRB).

PROCESS

I. The Investigator:

- A. Will contact the Nursing Research council Chair Mabel LaForgia mlaforgia@libertyhcs.org during the stages of proposal development.
- B. A packet containing the following will be given to the investigator:
 - 1. Nursing Research Approval policy
 - 2. A Cover letter with instructions (Attachment A)
 - 3. Notification of Intent form (Attachment B)
 - 4. An IRB Application check list (Attachment C)
 - 5. Guideline for Research Proposal (Attachment D)

- C. The investigator will submit written Notification of Intent and if necessary, presents verbally to the Research Council.

II. **The Nursing Research Council:**

- A. Will review the letter of Intent and the application packet documents within two weeks of receiving materials, and make recommendations.
- B. Notification of approval or denial will be given to the investigator in writing within 30 days (Attachment E)
- C. Approval of research proposals will be dependent on the following:
 - 1. The problem is relevant and timely
 - 2. The research design is appropriate and logical
 - 3. The rights and safety of patients, staff, or the nursing profession, are protected
 - 4. The study will not interfere with or compromise existing nursing care
 - 5. The study is feasible in terms of staff time, space and/or materials required
 - 6. Results will be shared with Nursing Research Council, nursing staff, and nursing leadership
- D. If the primary researcher is not employed at JCMC, a Nursing Research member will be assigned to assist with facilitating the of research project as well as update the Nursing Research council of investigators progress

III. **Human Subject Review:**

- A. All Nursing Research should be approved/evaluated by the IRB.
- B. After approval by the Nursing research council, the Approval Letter and Proposal must be submitted to the IRB by the primary investigator. The investigator should contact Tanishia Delapara via email at tdelapara@libertyhcs.org to be placed on the IRB schedule. All documents must be submitted two weeks prior to IRB meeting date.
- C. In some circumstances a research project may not meet the definition of “human subjects” as defined by Department of Health and Human Services regulations. In those situations an expedited review process may occur. Only the Chair of the IRB is authorized to make this determination
- D. The Letter of Approval, along with a copy of the Study Protocol should be submitted to the Director/Manager of any unit, which the study will take place

IV. Research Study Status Reporting:

- A. It is the responsibility of the Investigator to keep the Nursing Research Council updated every six months from the study start date

- B. Upon completion (or termination), the researcher will present the following:
 - 1. Study outcomes
 - 2. Implication for nursing practice
 - 3. Implication for future nursing research
 - 4. Publication plans

Reference:

Kaktins, Nina. Faculty Guide to the Institutional Review board Process. *Nurse Educator* 2009; 34(6) 244-248

Latimer, R., Kimbell, J. Nursing Research Fellowship: Building Nursing Research Infrastructure in a Hospital, *Journal of Nursing Administration* 2010; 40(2) 92-98

Professional Practice	Y_7/7/10__	N/A _____
Research Committee	Y_6/9/10, 8/8/12__	
JCMC Investigational Review Board (IRB)	Y 6/30/10	
Cardiac Care	Y_____	N/A __x__
Emergency Dept	Y_____	N/A __x__
Peri-Op	Y_____	N/A __x__
Maternal Child Health	Y_____	N/A __x__
Behavioral Health	Y_____	N/A __x__
Cardiac Cath Lab	Y_____	N/A __x__
Interventional Radiology	Y_____	N/A __x__
Med Exec	Y_____	N/A __x__
Pharmacy/ P&T	Y_____	N/A __x__

The Nursing Research council

RE: Request to conduct nursing research

Thank you for considering Jersey City Medical Center for your research study. As a preliminary step, we require an application of Intent to conduct Nursing Research and copies of the documents listed in the application packet. The purpose of this application is to determine if your proposal is suitable for Jersey City Medical Center.

Please complete and email this application packet to Mabel LaForgia at mlaforgia@libertyhcs.org, prior to scheduling your appointment with the IRB.

Upon receipt of your information, the research council will have the information reviewed and notify you of approval, acceptance with changes or rejection within 30 days of review. In some circumstances we may ask that you present your project to the council.

The Nursing Research Council will also serve as a mentor to you if needed in preparation for the IRB review process. A member of the Research council will be assigned to assist you with your research

A formal written approval of your research must be granted prior to IRB approval and initiation of your project

If you have any questions, please contact Mabel LaForgia, 201-978-6423

Thank you

The Nursing Research Council

Application of Intent to Conduct Nursing Research at Jersey City Medical Center

If you have completed a similar application of intent to an IRB, please indicate that and attach a copy of your documents, you do not need to duplicate your answers

Date: _____

Primary Researcher _____ Contact
Info: _____

Institution Affiliation _____

Additional Researcher(s): _____ Contact Info:

_____ Contact Info:

_____ Contact Info:

_____ Contact Info:

Title of Research Project:

Research Question:

Where will the project take place?

What procedure will be followed?

What is the sample size and population being researched?

Will consent be required? If Yes Please attach copy of consent form _____

How will your research finding enhance Nursing Practice at JCMC?

Date reviewed by Nursing Research Council: _____

Investigator's Packet

Clinical Research Proposal to the
Jersey City Medical Center Review Board

Research Investigator Submission Checklist

Principal Investigator _____

Date of Submission _____

Co-Investigators

Title of Proposal

Return the completed packet (with this Checklist as the top sheet, and items in the order listed on this Checklist) to Linda Gerson, Administrative Support to the IRB.

Address any questions to Dr. Kirk McMurtry (915-2525) or Brenda Shaw (915-2403).

Include the following in your submission:

- Detailed description of
 - Research project and its objectives
 - Methodology to be used, including type of study, number of subjects, subject inclusion and exclusion criteria, tests, and statistical analyses.
 - Appropriateness of research methodology to the field of study and the objectives of the research.
 - Appropriateness of subject selection criteria and techniques.
 - Risks to research subjects and how risks, if any, will be minimized
 - How consent will be obtained, and by whom.
 - How treatment and/or compensation will be provided to research subjects if harm occurs.
 - How costs of the research are to be funded. Specify possible costs to subjects or to Jersey City Medical Center
- Summary discussion of expected results.
- A copy of the proposed Consent form, completed except for signatures;
- Completed Chair/SVP Approval Statement
- A statement indicating that a report will be submitted to the IRB annually, or more often if required
- Investigator credentials;

Identification of all co-investigators, including their institutions and possible conflicts of interest

Name and address of the individual or institution to be notified if the proposal is approved by the IRB, requires modification, or is not approved.

- Copies of completed Assurance Training Certificate. Visit website to obtain certification through brief modular training: <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>

Attachment D

To:

FROM: Nursing Research council

Date:

Subject:

Your application of intent to conduct formal research at Jersey City Medical Center has been approved. The Nursing Research council has assigned a Mentor to assist you with the JCMC IRB approval process. The name of your Nursing Research Representative is _____ . He/she will contact you to see how they may be of assistance. In addition you're your Mentor will keep the Nursing Research council updated on your progress

Thank you

The Nursing Research council