Enhancing Life
Jersey City Medical Center

Department of Patient Care Services

GUIDELINE: Nursing Research Approval process	**DEVELOPED BY:** Nursing Research Council
POLICY COMMITTEE: _____ Cheryl Owens DNP(c) Policy Committee Chair ❑ N/A	**APPROVED BY:** _____ Rita Smith, DNP, RN CNO, Senior Vice President Patient Care Services _____ Name: Mabel LaForgia Title: Nursing Research Council Chair Dept: Nursing Chair/Designee of Developing Committee

Effective Date:	**Revised Date:**	**Reviewed Date:**
6/8/2010	8/8/12	8/8/12

Distribution: Nursing Units, Institutional Review Board

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

Approvals:

Professional Practice	Y ☐	N/A ☐
Nursing Education	Y ☐	N/A ☐
Critical Care	Y ☐	N/A ☐
Emergency Dept	Y ☐	N/A ☐
Peri-Op	Y ☐	N/A ☐
Trauma	Y ☐	N/A ☐
Maternal Child Health	Y ☐	N/A ☐
Behavioral Health	Y ☐	N/A ☐
Cardiac Cath Lab	Y ☐	N/A ☐
Interventional Radiology	Y ☐	N/A ☐
Med Exec	Y ☐	N/A ☐
Pharmacy/ P&T	Y ☐	N/A ☐
Pathology/Blood Bank	Y ☐	N/A ☐
Other:	Y ☐	N/A ☐
Other:	Y ☐	N/A ☐

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

GUIDELINE:
Research involving nurses in roles such as investigators, subjects, care givers, 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

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

Attachment B

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: _____

Attachment C

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 Tanishia Delapara, Administrative Support to the IRB.

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

Guideline for Research Proposal

The primary responsibility of the Institutional Review Board (IRB) is to safeguard the rights and welfare of human research participants. For that reason, the principal investigator must provide sufficient information for the IRB to determine that research participants will be adequately protected and that the research will be conducted in full compliance with Jersey City Medical Center IRB standards. In order to approve a research activity, the IRB must assure that **all** of the following requirements are satisfied:

1. **Introduction/Literature Review:**
    - Identify the problem and provide background information on the problem
    - Discuss the importance of your research
    - Discuss current research findings as it relates to the problem or research question
    - Describe how your research will add to the knowledge in this area
    - If applicable include a discussion of the conceptual or theoretical framework you will use
    - Use references and citations

2. **Research project and its objectives:**
    - State the purpose/objective/aims of your research.
    - State your research questions

3. **Methodology to be used, including type of study, number of subjects, subject inclusion and exclusion criteria, tests, and statistical analyses**
    - Describe Methodology
    - Appropriateness of research methodology to the field of study and the objectives of the research
    - Study Design
        - Describe in detail how the study will be conducted
        - Indicate the steps taken to answer identified research questions
        - Indicate inclusion and exclusion criteria
    - Sampling:
        - Describe how sample will be selected (i.e. random sample, convenience sample etc)
        - If applicable, describe characteristics of the sample by gender, race/ethnicity, socioeconomic status, or other relevant group membership
        - Expected sample size and justification
    - Instruments:
        - Outline instruments to be used (surveys, scales, interview protocols, observation grids)
        - If instruments have previously been used, identify previous studies and findings related to reliability and validity
        - If instruments have not previously been used, outline procedures you will follow to develop and test their reliability and validity
        - Written permission by author to use tool

- Data Collection
    - Outline the general plan for collecting the data. This may include survey administration procedures, interview, medical record review or observation procedures
    - Describe your plans for maintenance and disposal of the data in a way that keeps the data private
    - Discuss how patient confidentiality will be maintained
- Data Analysis
    - Specify the procedures to be used, and label them accurately (e.g., ANOVA, ethnography, case study, grounded theory).
    - Describe how the data will be evaluated in relation to each of the objectives
    - Communicate precise intentions and reasons for these intentions
    - Discuss how results will be interpreted

4. Appropriateness of subject selection criteria and techniques.

- How will you assure that participants are not in any way coerced to participate
- Describe how you will recruit participants. Include any information about the use of incentives if relevant
- If your research includes vulnerable participants, state the rationale for their inclusion
    - (Vulnerable participant populations include children, prisoners, people with developmental disabilities, members of politically disadvantaged groups and anyone else who might not be completely free or able to refuse participation in your research)

5. Risks to research subjects and how risks, if any, will be minimized

- Describe any potential risks of physical, emotional, financial or social harm to participants
- Describe your methods for minimizing the risk of harm
- Specify any factors that would cause you to stop your research due to physical or emotional stress on the part of participants
- Discuss how treatment will be provided if harm should occur
- If there are no risks of harm, this must be stated and explained
- Anticipated Benefits
    - State any anticipated direct benefits to these participants.
    - State any anticipated benefits to society-at-large or others (e.g., the academic literature)

6. How consent will be obtained, and by whom

- Attach any relevant forms
- Discuss process for obtaining consent
    - All participants obtaining consent must obtain NIH training. Provide copies of training certificates
- Use the template provided in the IRB packet, modify to included specific information regarding the study

- Discuss how patient confidentiality will be maintained

7. **How treatment and/or compensation will be provided to research subjects if harm occurs**
    - Discuss process
    - If there are no risks of harm, this must be stated and explained

8. **How costs of the research are to be funded. Specify possible costs to subjects, Jersey City Medical Center, or to Liberty Health**

9. **Summary discussion of expected results**
    - Predict the significance of the study and expected outcomes. This may closely relate to aims

10. **Completed Chair/SVP Approval Statement**
    - Use form provided
    - Must be signed

11. **A statement indicating that a report will be submitted to the IRB annually, or more often if required**

12. **Investigator credential**
    - Identification of all co-investigators
    - including their institutions and possible conflicts of interest

13. **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.**

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

    Copies must be provided for Investigators and Co-investigators

Attachment E

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