LIBERTYHEALTH

JERSEY CITY MEDICAL CENTER
Executive Office/Administration

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**POLICY:** **Institutional Review Board (IRB)** **Developed by:** **Chief Medical Officer**

**Effective Date:** **3/1/93** **Approved by:** **Executive Committee, OMDS**

**Revised Dates:** **03/03; 05/05; 04/08; 8/12**

**Distribution:** **Administrative Manual Distribution List**

**POLICY:**
All research conducted at Jersey City Medical Center (JCMC), whether directly involving patients or not, is considered institutional research and, as such, may only be conducted under the auspices and with the approval of the JCMC Institutional Review Board (IRB). Established by the JCMC Medical-Dental Staff Bylaws, the IRB shall:

- Protect the rights and welfare of human subjects involved in research activities conducted at JCMC;
- Ensure that submitted research protocols are scientifically feasible and predicated upon sound research methodology; and
- Provide the Institution with a formal review mechanism to ensure that proposed clinical investigations strictly adhere to all applicable existing federal and state rules and regulations, including the Office for Human Research Protections (OHRP) and the Health Insurance Portability and Accountability Act (HIPAA).

A current list of members of the IRB is attached (Exhibit 1).

PURPOSE

To establish the policies and procedures to be followed in the administration of the Institutional Review Board prescribed by the Medical-Dental Staff Bylaws.

PROCEDURE

I. Responsibilities of the Principal Investigator

The Principal Investigator (PI) shall be a JCMC staff member. If the project involves other institutions as well (as in multi-center trials and collaborative studies), a JCMC staff member shall serve as PI for the JCMC site.

RESEARCH INVESTIGATOR'S PROTOCOL PACKET. The Research Investigator's Protocol Packet is attached (Exhibits 2 through 5). The PI shall complete the Research Investigator's Protocol Packet

(available on the Liberty Intranet Web site (http://lhs2k139), addressing all items on the Research Investigator Submission Checklist (Exhibit 2). Investigators should review and follow the attached Guidelines available to assist with this process (Exhibit 6).

INFORMED CONSENT (EXHIBIT 4). The PI shall incorporate all appropriate elements of Exhibit 4 when creating Consent Forms for research originating from within the institution. Likewise, the Site PI shall ensure that Consent Forms developed by other institutions conform to Exhibit 4.

DEPARTMENT CHAIR/SVP APPROVAL STATEMENT (Exhibit 5). The PI shall submit the packet to the Division Chief (if applicable) and Department Chair for review and approval. The SVP for Patient Care Services will review packets originating from the Department of Nursing. If the research is carried out by more than one Department, the Chair of each department must review and approve the packet. The Chair(s) or SVP indicate approval of the research by signing the Department Chair/SVP Approval Statement included in the packet (Exhibit 5)

The packet shall be forwarded to the Administrative Support Staff of the IRB and examined for completeness. Incomplete packets will be returned to the PI and must be resubmitted after completion. No research proposal will be considered by the IRB until the packet is complete.

The fully completed packet must be received at least one week prior to the IRB meeting at which it will be reviewed. Completed packets that are received less than a week before a meeting will be reviewed at the subsequent scheduled meeting.

PROGRESS REPORTS. The PI shall submit a written progress report to the IRB Chair annually, unless directed to do so more frequently.

ADVERSE EVENTS. The PI shall immediately notify the IRB Chair of any serious adverse event involving a protocol subject, including death, and of other unanticipated problems representing a substantial risk to subjects or others associated with the research.

II. Responsibilities of the Chair of the Institutional Review Board

The IRB Chair shall schedule regular monthly IRB meetings but may change meeting dates to expedite approval of protocols as needed.

The IRB Chair shall ensure that necessary documentation of the IRB's approval of protocols, including but not limited to letters of approval and certificates of concurrence, is appropriately prepared and forwarded to the PI.

The IRB Chair shall forward the IRB's final actions on all protocols to the Executive Committee of the Organized Medical-Dental Staff (OMDS). The IRB Chair may utilize IRB Meeting Minutes containing final actions to for this purpose. The President of the OMDS will include summaries of approved protocols in the Executive Committee Report to the Board of Trustees.

III. Responsibilities of the Chief Medical Officer

The Chief Medical Officer is a full voting member of the IRB. Any document requiring the signature of the President and CEO of Liberty Health will be forwarded to the Chief Medical Officer for transmittal.

IV. Responsibilities of the Support Staff

Support Staff shall:

- Facilitate the scheduling of regular IRB meetings and the Annual Meeting, and maintain a calendar for Annual Reports by PIs;
- Distribute agendas, copies of protocols, and other necessary information to IRB members;
- Prepare Minutes of IRB meetings and letters of approval for signature by the IRB Chair;
- Provide Minutes to IRB members and to other appropriate parties;
- Forward approval letters to Pis; and
- Maintain membership lists, minutes, attendance records, and files with copies of research protocols and annual reports.

V. Types of IRB Review

Under Federal Regulations, there are three possible IRB review procedures

- Full/Convened Committee Review
- Expedited Review
- Review of Exempt Status

Full/ Convened Committee Review

A full committee review must be used for the initial review of studies that are not eligible for expedited or exemption status

Expedited Review

Protocols may be reviewed via an expedited process if they meet the following criteria as listed in 45DFR 46.110(b) (1) located in the Code of Federal Regulation Part 46 Protection of Human Subjects

Two main criteria for expedited review are:

- The research poses no more than **"Minimal Risk"** as indicated in ([45 CFR 46.102(i)] and [21 CFR part 56.102(ii)]).

- The entire research project must be consistent with one or more of the following federally defined categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

    a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

    a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

    b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

*3.* Prospective collection of biological specimens for research purposes by noninvasive means.

*4.* Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

*5.* Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

*6.* Collection of data from voice, video, digital, or image recordings made for research purposes.

*7.* Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation,

human factors evaluation, or quality assurance methodologies. Continuing review of research previously approved by the convened IRB as follows:

a. Where the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

b. Where no subjects have been enrolled and no additional risks have been identified; or

c. Where the remaining research activities are limited to data analysis.

*8.* Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

IRB Expedited Review Process

- Investigators are required to submit the complete application.
- IRB support staff member will conduct an initial pre-review for completeness and determine whether submission may qualify for expedited review
- The proposal will be forwarded to the IRB chair and/or co-chair for review
- The reviewers make the final determination of whether initial, continuing review and modification submissions meet the eligibility requirement
- The assigned reviewers may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. The reviewers may choose to consult with another member prior to making any determination. If the reviewers find that the research should not be approved, it must be referred to the full committee for final determinations

Research that is Exempt from Review

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, ***unless***:
    a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects
    b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research not exempt under # 2 above may still qualify for exemption if:

a. The human subjects are elected or appointed public officials or candidates for public office

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate public program
6. Taste and food quality evaluation and consumer acceptance studies

# Exhibit 1

## Institutional Review Board (IRB)

| *NAME* | *EXT* | *DEPT* |
|---|---|---|
| **Ratner, Douglas, MD** | **2430** | **Medicine** |
| **Curci, Michael, RPh** | **2062** | **Pharmacy** |
| **Garay, Kenneth, MD** | **2832** | **Surgery** |
| **Hall, Brenda Ms.** | **2215** | **Administration** |
| **Kaiser, Susan, MD** | **2451** | **Surgery** |
| **LaForgia, Mabel RN** | **3859** | **Nursing** |
| **Micale, Edith Ms** | | **Pharmacy** |
| **Mikkilineni, Rao, MD** | **2524** | **Medicine** |
| **Garzon-Rivera, Claudia RN** | **4149** | **Nursing** |
| **Shu, Joel, MD** | **2271** | **Anesthesia** |
| **Yousry, Ahmed, MD** | **2466** | **Ob/Gyn** |
| **Shaw, Brenda Ms** | **2403** | **Medical Library** |
| **Delapara, Tanishia Ms** | **2403** | |

Exhibit 2

**Investigator's Packet**

**Clinical Research Proposal to the**
**Jersey City Medical Center Institutional 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 Brenda Shaw, 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 modular training:** http://phrp.nihtraining.com/users/login.php.
- ❑

**PROPOSALS WILL NOT BE REVIEWED UNTIL THEY ARE COMPLETE. THE PRINCIPAL INVESTIGATOR OR A CO-INVESTIGATOR MUST PERSONALLY PRESENT THE PROPOSAL AT THE IRB MEETING.**

Protocols must be consistent with applicable federal, state and local laws and regulations as well as with Jersey City

Minimum Requirements for Uniform Consent for Research Protocols

I. Introduction

This paper is an informed consent form which will explain in every day language what the project you are being asked to participate in is about.

II. This project was studied and approved by the Institutional Review Board (IRB). The Committee consists of doctors, nurses, clergy, scientists, lawyers and members of the community who review every research proposal and approve those which seem to offer help to the ill and have limited risk to people who participate in the research. If you do not take part in this research you will not be penalized and will receive treatment for your illness. If you wish to stop being part of this research, you can stop at any time and your doctor will continue to treat you. All the people who will be in this project will do so as volunteers and can stop at any time.

III. In accordance with Federal regulations, we are obliged to inform you about Jersey City Medical Center's policy in the event physical injury occurs. If, as a result of your participation, you experience physical injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization if necessary, will be available. No monetary compensation, however, will be available and you will be responsible for the costs of such medical treatment, either directly or through your medical insurance and/or other forms of medical coverage. Further information can be obtained by calling _____. If you have any questions regarding your rights as a research subject or concerning a research-related injury, please call, Kirk McMurtry, MD, the Chair of the IRB, at (201)915-2525, or Brenda Shaw, at (201)915-2403.

IV. This research has the following aims and purposes (Investigator will include procedures designed to provide direct benefit to you, the patient, and available alternate ways to pursue any such benefit[s]):_____

V. The investigator will tell you what will happen in this study and what you will be expected to do: _____

VI. The investigator will discuss with you what risks and dangers may occur during this research and whether treatment or compensation is available if harm occurs.

This study is being conducted by: _____

This study is paid for by: _____

If any harm occurs or if you have any complaints during this study you should contact the principal investigator,

Name: _____ Phone_____

VII. There will be the following additional costs to you or your insurance company which might result from taking part in this research project _____

VIII. This consent form has been fully explained to me by the investigator whose name appears below, and the investigator has answered any questions which I have concerning this consent to my satisfaction.

_____

Investigator Obtaining Consent

_____

Subject

**Department Chair/SVP Approval Statement**

Principal Investigator_____

Department _____

_

Protocol Title _____

_____

Amount of Funds Allocated/Requested

_____

_____

_____

**Summary of Research Project**

_____

_____

_____

_____

**Approved Budget**

_____

_____

**Approvals:**

_____ _____

Division Chief (if applicable) Date

_____ _____

Department Chair or Senior Vice President Date

POLICIES AND PROCEDURES

# MEDICAL RECORDS DEPARTMENT

**TOPIC:** Providing Medical Records for Research Purposes

POLICY: Upon approval of IRB research protocols requiring access to medical records, a copy of the IRB protocol must be submitted and placed on file.

**PROCEDURE:**

1. Person who will be doing the record review must meet with the Medical Record Director or her Designee.

2. Confidentiality agreement must be signed.

3. Portions of Medical Records may be copied only if the patients' identification is obliterated.

4. Medical Records can be reviewed by appointment only.

5. Funding to retrieve off-site medical records must be allocated.

Exhibit **6**

## 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