The Queens' Medical Center
Research and Institutional Review Committee

CHECKLIST FOR INITIAL SUBMISSION OF ***RETROSPECTIVE*** STUDIES

Your application will not be processed without the following:

☐ **Forms**: **1-4, 12-13** (Do not state "see protocol" or "refer to protocol".)

☐ **Budget** (if you need a template, refer to Budget Forms)

☐ **Informed Consent form with HIPAA Authorization, if applicable** –may be separate or combined (http://ord.queens.org/rirc.php for template)

☐ **Surveys, questionnaires, tools, letters, data tools, patient information sheets, or any other pertinent documents**

☐ **Recruitment tools** (ads, flyer, media, etc)

☐ **Complete Scientific Protocol** (see sample templates at http://ord.queens.org/rirc.php)

☐ **Grant Proposal (if one exists)**

☐ **Letter of Agreement with sub/co-investigator(s)[a]**

☐ **Letter of Agreement with QMC Departments and Data Guardians [b]**

☐ **The following for all personnel listed on Form 1:**
- **Curriculum Vitae**
- **Research HIPAA training acknowledgement form** (http://ord.queens.org/education.php)
- **Human subjects training certificate** (http://ord.queens.org/education.php)

[a]- All sub/co-investigators must sign a statement that confirms their intent to participate as the stated position with the investigator on the particular protocol. See sample letter that may be used. http://ord.queens.org/rirc.php

[b] - Any QMC department whose services or data will be used as part of the protocol must have this letter. The principal investigator is responsible to discuss the protocol's requirements and give a copy of the protocol to the supervisor of each QMC department or the data guardian. If the supervisor/data guardian agrees to and is able to fulfill the protocol's requirements, a signed letter of agreement by the supervisor/guardian must be submitted with the application. If there are any costs associated with the use of the department, the letter must show that payment/costs have been agreed upon. See sample letter that may be used. http://ord.queens.org/rirc.php

Form 1

The Queen's Medical Center Research and Institutional Review Committee
RESEARCH PROJECT APPLICATION

1. PROJECT TITLE:

2. PRINCIPAL INVESTIGATOR'S NAME
   Address:
   E-mail Address:
   Specialty:
   Title: Phone:

3. A. SUB-INVESTIGATOR(S):
   B. OTHER RESEARCH PERSONNEL (who will assist with conducting the study and have medical record access)

4. SPONSORING AGENCY/ORGANIZATION:
   Name:
   Address:

5. Secondary Contact Person (cc)
   (Usually the study coordinator; this person will receive a copy of all correspondence.)
   Address:
   E-mail Address:
   Phone:

6. TYPE OF STUDY

Retrospective:
- ☐ Medical Records (documents)
- ☐ Tissue/Blood/Specimens
- ☐ Other, please specify:

Prospective:
- ☐ Investigational New Drug (IND) ☐ Non-IND
- ☐ Investigational Device (IDE) ☐ Non-IDE
- ☐ Investigational Procedure
- ☐ Questionnaire ☐ Tissue/Blood/Specimens
- ☐ Other , please specify:

7. INSTITUTIONS TO WHICH APPLICATION IS BEING SUBMITTED:
   ☐ Kaiser ☐ Kuakini ☐ Saint Francis ☐ Kapiolani ☐ Queen's
   ☐ Straub ☐ University of Hawaii ☐ Other:

8. PROTOCOL SUMMARY: (Write a summary here or attach a summary **as the next page**. Do not refer to protocol. The complete protocol –with version date and page numbers- must accompany the application forms separately.)

9. PROJECT FUNDING:
   ☐ No ☐ Pending ☐ Yes Amt.$ Source:

Form 2

STATEMENT OF GENERAL AGREEMENT

The Principal Investigator must agree:

a. to attend a meeting with the Research & Institutional Review Committee/Board upon request;

b. to obtain hospital-approved and legally effective consent complying with the latest federal regulations from all research subjects prior to commencing research study;

c. upon receipt of approval from institution, to inform the hospital through its appropriate representative and other involved parties, as to when the project will start and end;

d. to abide by professional ethics and hospital policies regarding the conduct of research, physician/patient relationship and the confidentiality of patient information and records (except when proper patient authorization is obtained);

e. to accept primary responsibility and liability for the conduct of this study;

f. to submit a copy of revisions and/or addendums pertaining to human subjects for review and approval;

g. to submit a progress report at least once a year for multi-year projects or mid-way during the course of the project for those lasting no more than one year, or as otherwise required by the hospital reviewing authority;

h. to submit a request for renewal if project extends beyond one year or if protocols are closed but patients are still being followed;

i. to inform the hospital's research administrative authority immediately if research-related unexpected adverse reaction or death occurs;

j. to submit a copy of the study's final report after its completion and any paper derived from the study prior to or at its submission for publication;

k. to withhold the identity of a hospital as the research site, unless prior approval or waiver has been received from the appropriate authority;

l. to allow the Research & Institutional Review Committee or its designee access to all research-related records for monitoring and auditing;

m. that any papers prepared for publication must be presented to the Review Committee/Board for review prior to release and shall include the following statement, "The findings, conclusions, (etc.), of this study do not necessarily represent the views of _____ ";
(name of institution)

n. to assure that all other obligations such as, contract, agreement, set up, billing are finalized prior to initiation of study.

I will comply with the above requirements. I also attest that all information provided in this application and all attachments are true and complete. I understand that non-compliance may result in termination of the study.

Signature of Principal Investigator:	
Date:	

Form 3

USE OF HOSPITAL RESOURCES AND PROJECT BUDGET

1 PERIOD OF INVESTIGATION: From: _____ To: _____
(when the study will be conducted)

2 USE OF HOSPITAL RESOURCES: (Be as specific as possible)

A. Areas of Activity in Hospital: _____

B. Square Footage of Space Required: _____

C. Type and No. Of Hospital Equipment/Furniture Required: _____

D. Review of Medical Records: Years to be reviewed From: _____ To: _____

3 PROJECT BUDGET:

A. Funding organization: _____

B. Institution managing the account: _____

C. Total grant: _____ or per patient allocation: _____

D. Funding period: From: _____ To: _____

E. Number of hospital personnel hours or services* including:

(i) Staff hours for patient interviews or data collection: Number of hours: _____ @ $ _____ /hr

(ii) Technical hours for procedures: _____

(iii) Medical records request (as determined by the hospital): _____

(iv) Pharmacy costs: _____

(v) Central supplies or devices: _____

(vi) Laboratory or diagnostic studies specific to project: _____

(vii) Medications specific to project: _____

F. If applicable, Institutional Review Committee/Board review costs will be determined by hospital.

INVESTIGATORS ARE ENCOURAGED TO INCLUDE REALISTIC BUDGET REQUESTS IN THE GRANT PROPOSAL.

* If paid by the grant, indicate how much is allocated to each item.

** Attach statement by pharmacy representative.

*** Lab or diagnostic studies outlined by study must be quantified even if ordered during "usual medical care".

Form 4

STATEMENT OF CONFIDENTIALITY
Review of Sources of Information for Research Purposes

This statement covers the review of The Queen's Medical Center or The Queen's Healthcare System medical records, databases, listings or other sources of information for research activities.

1 IN ORDER TO MAINTAIN CONFIDENTIALITY OF MEDICAL RECORDS OR RESEARCH RELATED INFORMATION THE FOLLOWING CONDITIONS REQUIRE STRICT COMPLIANCE:

A. Access to information will be limited to persons involved in carrying out the research. **Signing this form is assurance that protected health information will not be reused or disclosed to any other person or entity except as required by law; for authorized oversight; or for other research as would be permitted by federal privacy standards.**

B. Patient's identity will be concealed in any results obtained and/or published unless formal patient authorization for the release of medical information has been obtained. Personal identity information includes: Names; all geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes; all elements of dates (except year) and all ages over 89; telephone numbers; Fax numbers; Electronic mail addresses; Social security numbers; Medical record numbers; Health plan beneficiary numbers; Account numbers; Certificate/license numbers; Vehicle identifiers and serial numbers, including license plate numbers; Device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; Biometric identifiers, including finger and voice prints; Full face photographic images and any comparable images; and Any other unique identifying number, characteristic, or code; individually or in combination

C. Patient identity information will not be made available to any "third party" (persons not involved in the study).

D. Raw data will be kept in a secure, locked place.

E. Federal and State rules and regulations pertaining to the disclosure of information regarding alcohol and drug abuse cases, human immunodeficiency virus, acquired immune deficiency syndrome (AIDS) related complex or AIDS cases require strict compliance.

2 PRIVACY SAFEGUARDS (also include what you and your study staff will do, and what the sponsor will do.)

A. Describe your plan to protect identifiers from improper use and disclosure:

B. Describe your plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. And if there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, please explain.

I HEREBY ACKNOWLEDGE the restrictions imposed upon me with regard to the disclosure of information in connection with working with patient's charts or information, and with my signature on Form 2, do accept the responsibility for myself and my designees of treating information as completely confidential for myself and my designees.

Co-investigators and other research personnel listed on Form 1 are authorized to request research information.

Form 12, version initial appl only

Request for HIPAA Waiver of Authorization
For the use/disclosure of existing data OR for subject recruitment/prescreening

Please check if not applicable: ☐

Check the appropriate box you are requesting:

- Use/disclosure of existing data for entire study (for example, record review, specimen) ☐
- For subject recruitment/prescreening purposes only ☐

Check the box that describes what PHI will be used/disclosed for this study:

☐	Medical Records/personal health information**:**	☐	Reviewing records only, OR	☐	Obtaining copies of records
☐	Diagnostic imaging**:**	☐	Reviewing records only, OR	☐	Obtaining copies of records
☐	Photographs **:**	☐	Reviewing records only, OR	☐	Obtaining copies of records
☐	Existing specimens/biologic material				
☐	Registry information				
☐	Database information				
☐	Other				

3. Please complete the following:

Explain why research could not practicably be conducted without the waiver:

Explain why the research could not practicably be conducted without access to the protected health information (PHI).

Explain that rights or welfare of subject will not be adversely affected by the waiver.

4. What data fields are the minimum necessary that will be used under a HIPAA waiver?

Request for Either a Waiver of Informed Consent OR Waiver of Documenting Informed Consent

Please check if not applicable: ☐

Criteria for Waiver of Informed Consent

Use this section if the research does not plan to obtain informed consent. The QMC RIRC may waive the requirement for informed consent if all of the following criteria are met. Please provide justification for each item.

1. Explain why study involves no more than minimal risk to subjects:

2. Explain why the waiver or alternation will not adversely affect subjects' rights and welfare:

3. Explain why the research could not practicably be conducted without the waiver or alteration:

4. Whenever appropriate, explain how the subjects will be provided additional pertinent information and what information will be provided:

5. IF the research involves using identifiable private information or identifiable biospecimens, explain why the use of such information/biospecimens in an identifiable format is necessary to carry out the research.

Criteria for Waiver of Documenting Informed Consent

Use this section if the research plans to provide information about informed consent without obtaining the subject's signature, such as an anonymous surveys/questionnaires, or when signing a consent that might be negative for the subject. This waiver still requires the investigator to provide information about the research to each subject. A written script/information sheet of what will be read or given to subjects must accompany the RIRC submission. The script/sheet must contain basic elements of informed consent. Please provide justification for at least one of the 2 criteria; note that each criteria has 2 items to address.

1. Explain how the only record linking the subject and the research would be the consent document AND the principle risk would be potential harm resulting from a breach of confidentiality. Note: Each subject must be asked whether the subject wants documentation linking the subject with research, and the subject's wishes must govern.

2. Explain why research presents no more than minimal risk of harm to subjects AND involves no procedures for which consent is normally required outside of the research context.