The Queens' Medical Center
Research and Institutional Review Committee (RIRC)

CHECKLIST FOR INITIAL SUBMISSION OF ***PROSPECTIVE*** STUDIES

Your application will not be processed without the following:

☐ **Forms**: **1-9, 11-13** (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** –may be separate or combined. (see sample template at http://ord.queens.org/rirc.php)

☐ **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 template at http://ord.queens.org/rirc.php)

☐ **Grant Proposal (if one exists)**

☐ **Investigator's Brochure** (this is for drugs and/or device studies)

☐ **FDA 1572 form** (for all federally regulated studies)

☐ **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)

In parallel to this RIRC submission, follow the instructions (https://ord.queens.org/researchbilling.html) for requesting a Coverage Analysis/Medicare Coverage Analysis (CA/MCA). This is the driver for final negotiation of contract, budget, or informed consent documents.

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[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 (see sample letter). 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 ☐ HUD
   - ☐ 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. It must be in sufficient detail to determine the appropriateness of study-specific statements in the consent documents.
   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), and billing and coding;

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.

USE OF HUMAN SUBJECTS FORM **Form 5**

1. TYPES OF RESEARCH SUBJECTS

Please provide an estimate of the total number of subjects that will be needed to conduct this study as well as an estimated number from the hospital to which this application is being submitted.

	No. From This Hospital	No. From Others	Total Sample
A • Experimental Group Sample Size			
• Control Group Sample Size			

B Number of Participating Hospitals in Hawaii:

C Number of Participating Outpatient Clinics in Hawaii:

D Please describe other relevant characteristics of the sample required (e.g., ages, sex, disease category ...).

2. RISK FACTOR EVALUATION

Any possibility of injury including physical, psychological or social to which a research subject is exposed should be checked under Section II.B of this form, Risk Involvement Inventory. Risk is defined as that possibility of injury greater than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

2A Vulnerable Subjects: Will subjects be selected exclusively from any of the following? (Check all that apply)

☐ Not Applicable	☐ Homeless	☐ Terminally Ill
☐ Minors (less than 18 years)	☐ Pregnant Women	☐ Prisoners/Institutionalized
☐ Cognitively Challenged	☐ Fetuses	☐ Elderly (65+ years)
☐ Physically Challenged	☐ Abortuses	☐ HIV/AIDS
☐ Hospitalized Patients	☐ Non-English Speaking	☐ Non-readers

Explain:

2B Risk Involvement Inventory: Check all foreseeable risks to humans involved in your project.

i. NO RISKS ☐

ii. PHYSICAL

• Death	☐	• Worsening of physical conditions	☐
• Physical trauma or pain	☐	• Side effects of medication(s)	☐
• Contraction of disease(s)	☐	• Experimental diagnostic procedure(s)	☐
• Experimental treatment procedure(s)	☐	• Venipuncture	☐
• Intravenous catheters	☐	• Other (e.g., financial, etc...)	☐

Briefly explain items checked:

iii. PSYCHOLOGICAL/SOCIAL

• Personal material (interviews, opinions, test scores)	☐	• Deception	☐
• Stress or emotional arousal (including but not limited to embarrassment, disappointment or other disagreeable emotion)	☐	• Loss of privacy	☐
• Alteration of self-concept (e.g., through knowledge of test scores)	☐	• Loss of legal rights	☐

- Loss of cognitive functioning ☐
- Other (explain below)

Briefly explain items checked:

2C Risk Protection Procedures: Indicate procedures to protect subjects from risks: (Check all that apply)

i. PHYSICAL

- M.D. or other appropriately trained individual(s) in attendance ☐
- Sterile equipment ☐
- Other (explain below) ☐

Briefly explain items checked:

ii. PSYCHOLOGICAL/SOCIAL

- Precaution in use of stressors or emotional material ☐
- When deception used, subjects fully informed as to nature of research at feasible time ☐
- Procedures to minimize changes in self-concept ☐
- Voluntary participation and withdrawal from study ☐
- Data from protected sources ☐
- Individual data confidentiality and anonymity will be maintained ☐
- No unauthorized use of data ☐
- All data and consent forms kept in a secure place ☐
- Debriefing on experimental purposes ☐
- Other (e.g., legal coverage, financial risks) ☐

Briefly explain items checked:

2D. Procedures: List all procedures or tests to be done for this study which would not ordinarily be performed for the medical care of the patient (Check all that apply)

i. New untested treatment, procedure, or device (Complete FORM 7 if applicable) ☐
ii. Physical examination ☐
iii. Standard laboratory procedures (CBC, Chemistries, etc.) ☐
iv. Administration of drug(s) (Complete FORM 6 as applicable) ☐
v. Administration of blood components ☐
vi. Collection of specimens (blood, tissue, etc.) ☐
vii. Interview or self-administered questionnaire ☐
viii. Other (explain below) ☐

Briefly explain items checked:

2E. Radioactive Materials:

- Will radioactive agents be administered? ☐ Yes ☐ No

If yes, name these radioactive materials and complete the Drug Data Form (FORM 6):

2F. Mechanism for Safety Monitoring:

i. Is there a Data Safety Monitoring Board? ☐ Yes ☐ No

If yes, give a brief description, and frequency they will meet:

ii. **Data Collection**: Describe in detail how and what data will be collected from which data sources. Explain whether store information will be de-identified or subject ID numbers assigned.

iii. **Confidentiality**: Describe in detail how confidentiality of subject(s) information will be maintained.

iv. **Protection Procedures**: Describe in detail the procedures to ensure subject(s) and protected health information safety.

v. **Toxicity Assessment**: Describe in detail how subject(s) will be assessed or treated for any adverse effect(s). What will you do if increased risk is detected?

vi. **Adverse Event Reporting**: Describe in detail how and when adverse events will be reported.

3. BENEFITS OR SIGNIFICANCE OF STUDY

Briefly describe the benefits that will or may accrue to each human subject and/or to humanity in general, as a result of participation in this project:

4. THERAPEUTIC ALTERNATIVES

Describe therapeutic alternatives that are reasonable available to study subjects outside of research context (standard of care):

5 INFORMED CONSENT

Attach consent/assent forms to be signed by each subject for committee review. Use the attached Guidelines for Preparation of an Informed Consent.

A. Indicate how you will obtain informed consent (check the appropriate box):

- Investigator/study representative reads and explains the complete consent form. Subject (or parent/guardian) reads complete consent form and signs ("long" form) ☐
- Oral briefing by researcher or investigator with signing of simple consent form ("short form") ☐

  If the research involve no more than minimal risk to subject, the RIRC may waive traditional written consent requirements in favor of the short form consent. All protocols requesting such procedures are reviewed by RIRC to determine whether the short form process and documentation w ill suffice.

  The short form written consent is a document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there must be a witness to the oral presentation. Also, the RIRC must approve a written summary or script of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject of the representative. However, the witness signs both the short form and a copy fo the summary, and the person actually obtaining consent must sign a copy of the summary. A copy of the summary must be given to the subject or representative, in addition to the copy of the "short form". When appropriate, the obtaining of the short form consent must also be documented in the subject's medical record by the person who obtained the consent; the PI should maintain the original short form.

- Requesting a Waiver of Informed Consent or Waiver of Documentation (complete Form 13) ☐
- Other (explain) ☐

Explain how subject recruitment will be conducted. (Remember that in most cases, prior to approaching patient subject or conducting prescreening of charts, approval from the attending physician must be obtained.)

Describe the process of obtaining informed consent. (i.e. Who will be responsible for what procedure. What steps will be taken.)

If the study will require a pre-screening process on QMC campus, where protected health information will be used/disclosed before obtaining informed consent/HIPAA authorization, you must request a HIPAA waiver of authorization for the prescreening process.

- Will this be needed for this study? ☐ Yes, if yes, complete Form 12. ☐ No

6. OTHER. For further explanation, attach a page with the heading "6 *OTHER"*

Form 6

DRUG FORM FOR CLINICAL INVESTIGATIONS

Please check if not applicable: ☐

Name of Drug: _____ IND/ NDA # _____

1. DRUG STATUS
   - ☐ Investigational New Drug? ☐ Yes ☐ No
   - ☐ If yes, have FDA certification requirements for IND been ☐ Yes ☐ No
   - ☐ If drug is FDA-approved, is it to be administered in a new manner? (e.g., unapproved route or unapproved indication) ? ☐ Yes ☐ No
2. Brand or Trade Name: _____
3. Generic Name: _____
4. Therapeutic Clarification: _____
5. Drug Form: _____
6. Chemical Name (if known) _____
7. Manufacturer/Source: _____
8. Strength: _____

STORAGE REQUIREMENTS

9. Stability/Storage Requirements

☐ Prior to mixing:

☐ Room temp. at ____ °C to ____ °C

☐ Refrig. temp. at ____ °C to ____ °C

☐ Freezer temp. at ____ °C to ____ °C

☐ Protect from light

☐ Other (specify): _____

☐ After mixing stable for:

☐ ____ minutes ☐ ____ hours ☐ ____ days

☐ After mixing store at:

☐ Room temp. at ____ °C to ____ °C

☐ Refrig. temp. at ____ °C to ____ °C

DRUG ADMINISTRATION PROCEDURES

10. Administered by ☐ MD ☐ RN ☐ LPN

11. Reconstitution Directions: _____

12. Route of Administration:

☐ P.O. ☐ I.M. ☐ I.T. ☐ I.V. Bolus

☐ I.V. Infusion (indicate rate): _____

☐ Other (specify): _____

13. Usual Dosage Range: _____

14. Special Precautions (including drug interactions and inservice requirements if necessary): _____

DRUG FORM FOR CLINICAL INVESTIGATIONS

15. POTENTIAL SIDE EFFECTS OR TOXICITIES	16. TIME OF ONSET	17. DURATION	18. ANTIDOTES

19 OTHER AUTHORIZED PRESCRIBERS (Other than physicians listed on Form 1)

☐	☐	☐
☐	☐	☐
☐	☐	☐

20 IN CASE OF ADVERSE REACTION, NOTIFY:

☐ Principal Investigator (P.I.) — Phone Number

☐ Designee of P.I. — Phone Number

☐ Medical Director of Manufacturer — Phone Number

Revised 11/99 (msw)

Form 7

DEVICE FORM

Please check if not applicable: ☐

Name of Device: _____ IDE/ 510(k)/ HDE# _____

1. DURATION OF STUDY: From _____ To _____

2. SPONSOR/MANUFACTURER:
   A. Name: _____
   B. Address: _____
   C. Phone Number: _____

3. DEVICE DESCRIPTION:
   A. Name: _____
   B. Use of Device: _____
   C. Device Specifications (e.g., space, temperature, control, storage, electrical needs, etc.): _____

6. STATUS OF DEVICE:
   A. Is device exempt from human subjects regulations? If yes, explain below: ☐ Yes ☐ No
   _____
   B What risks are presented by the device?
   _____
   C. Are the risks presented by the device **significant** ☐ or **nonsignificant** ☐
   D. Has any other IRB reviewed and made decisions regarding this device ?: ☐ Yes ☐ No
   If yes, explain here: _____
   E. What is the status of the device with the Food and Drug Administration (FDA)?
   _____
   F. Has the device been approved for marketing?: ☐ Yes ☐ No
   G. Is the device approved for any other indications? If yes, explain below: ☐ Yes ☐ No
   _____

H. Is the device now being studied for a different indication? If yes, explain: ☐ Yes ☐ No

4. PROTOCOL REQUIREMENTS:

A. New Study? ☐ Yes ☐ No

B. Protocol Revision? ☐ Yes ☐ No

C. Emergency Use? ☐ Yes ☐ No

D. Is device exempt from human subjects regulations? If yes, explain below: ☐ Yes ☐ No

FINANCIAL CONSIDERATIONS

1. INVESTIGATOR PAYMENT FROM SPONSOR

   Will the investigator receive payment for participation in this research? ☐ Yes ☐ No

2. PAYMENT FOR PARTICPATION

   Describe any compensation that will be made to subjects and conditions for receiving full or partial payment. If no payment is planned, please state so.

3. FINANCIAL OBLIGATIONS/COSTS FOR PARTICIPATION

   Describe subject's costs for participation in research, as well as what interventions and/or procedures will be provided at no cost to the subject.

4. EMERGENCY CARE AND COMPENSATION FOR RESEARCH-RELATED INJURY:

   If the research involves more than minimal risk, explain what emergency care will be available in case of research-related injury, how, where and from whom treatment may be obtained, and who will be responsible for costs/charges.

QMC-Specific Research
Significant Financial Interest Disclosure Form for all Potential/Actual Conflicts of Interest

To enable The Queen's Medical Center to monitor all potential and actual conflicts of interest, please answer each of the following questions to the best of your ability. **Each investigator must complete this form.**
This disclosure statement is mandatory and requires that you disclose all potential and actual conflicts of interest even if they are questionable. The Queen's Medical Center reserves the right to make the final determination with regard to all potential and actual conflicts of interest.

Investigator: _____

Project Title _____

Before checking boxes and printing descriptions on this form, please make a separate photocopy of it for each Business and review definitions in Investigator Significant Financial Interest Disclosure Policy.

Section A

Have you or any other person responsible for the design, conduct, or reports of this research has an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by, the research?

Yes ☐ — If YES, please also describe in Section F.

No ☐ — Go to Section B.

Section B

Have you directly or indirectly accepted any compensation or benefit (regardless of monetary amount) from a Business which relates, in any way, to your professional activities on behalf of The Queen's Medical Center?

Yes ☐ — If YES, did this compensation or benefit constitute a Significant Financial Interest in the Business (> $10,000 or 5% equity)?

- Yes ☐ — If YES, please fill out a separate form for each Business.
- No ☐ — If NO, please briefly describe the compensation or benefit in Section F below, and confirm whether this was received in accordance with QMC Investigator Significant Financial Interest Disclosure Policy.

No ☐ — If NO, skip to Section G.

Business Name: _____
Address: _____

Section C

Your Significant Financial Interest in this Business (check each applicable box and describe at Section F):

☐ Salary ☐ Consulting Fees ☐ Honoraria
☐ Compensation for services on Boards of Directors/Advisors
☐ Equity Interest ☐ Intellectual property interests
☐ Other items of value: _____

Section D

Your QMC activities that might relate to the activities of the Business (check each applicable box and describe at Section F):

☐ Research (including Clinical or Basic Research)

☐ Clinical care including referral of patients and specimens

☐ Make or influence administrative or supervisory decisions regarding purchasing by, or contracting on behalf of, QMC

☐ Service on body with jurisdiction to review activities of the Business (e.g., committee of NIH, FDA, or other governmental agencies, private professional or regulatory body or private insurer)

Section E

Range of your total Significant Financial Interest in the Business (in thousands of dollars):

	5-15	16-25	26-50	>50
Income/Year	☐	☐	☐	☐

	YES	NO	Not Sure
Publicly Traded	☐	☐	☐

	YES	NO
For Profit	☐	☐

Section F

Please print any descriptions ☐ or questions ☐ on blank lines below and reference each to an above number (use additional pages if needed).

Section G

I acknowledge that I have been provided with a copy of QMC's Investigator Significant Financial Interest Policy and agree to comply with its terms. I have answered fully and to the best of my ability circumstances related to Significant Financial Interest in a Business. I agree that I shall notify the Research Regulatory Office immediately to complete an additional form to update any changes in my circumstances. I understand that my failure to provide and/or update this Disclosure Statement in a timely, complete and accurate manner may subject me to disciplinary action, which may include severance of my professional relationship with QMC.

Signature _____ Date _____

Application for Accessing CareLink Report to Identify Potential Research Candidates
The Queen's Medical Center
Research and Institutional Review Committee (RIRC)

Please check if not applicable: ☐

The PI may be given special CareLink access to limited, de-identified, inpatient information to identify potential research subjects. Data provided, if approved by RIRC, is limited to patient admitted in the last 24 hours and to the following information only: age, gender, admitting diagnosis and name of attending physician. The investigator must contact the attending physician for permission to approach subject for inclusion in a study. (see Administrative Policies and Procedures 610-03-209)

Are you a QMC employee or do you have medical staff privileges?	☐	Yes	☐	No
Do you currently have CareLink access privileges?	☐	Yes	☐	No
Will study participants potentially come from the QMC inpatient population? If yes, please explain how below:	☐	Yes	☐	No

Conditions of use:

- All answers must be "Yes", and may be subject to verification.
- The study must have RIRC approval under the same Principal Investigator AND the Principal Investigator must have CareLink access privileges.
- The Principal Investigator must agree to comply with procedures for special CareLink access privileges, as outlined under Administrative Policy and Procedure 610-02-209.
- Approval for this use is solely for the Principal Investigator and is not transferable to another person.
- This process will not allow a PI to review a patient's medical record nor contact potential candidates without approval of the attending physician and the patient.
- Special access privilege will be revoked at the end of the accrual period or if QMC CareLink terminates approval of the study, or if revocation is necessary due to inappropriate use.

You must sign a Limited Data Use Agreement, which is available through the Privacy Officer or RIRC office. Once RIRC has granted approval for the study and this privilege, the signed agreement is received, and all other requirements have been met to conduct the study, CareLink will be informed of the PI to be added for special CareLink access privilege report.

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:

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.