 **APPLICATION FOR**

**RESEARCH ETHICS BOARD APPROVAL**

1. Please ensure each section is completed in full. All documentation must be typed. Incomplete applications will be returned before review. **All material must be submitted two weeks prior to the date of the next meeting of the REB, in order that it be distributed for reviewed prior to the next scheduled meeting. A yearly schedule of meetings can be found on our website** [**www.qch.on.ca/REB**](http://www.qch.on.ca/REB)
2. Approval with signature(s) must be obtained from the head of the department(s) at Queensway Carleton Hospital in which the research projects are to be conducted (the principal investigator, or the co-investigator should not be the signatory for departmental approval). For chart review studies, it is imperative that approval be obtained from Health Records (Director, Neman Khokhar nkhokhar@qch.on.ca) .
3. For major studies, commonly those involving multi-centre trials, the principal investigator will have submitted the protocol to other Research Ethics Boards. Copies of such reviews and approvals may be requested as part of the submission for review at Queensway Carleton Hospital.
4. Approval will be for one year, unless otherwise stated. At the completion of the study, the principal investigator is required to notify the committee in writing regarding the current status of the study. If a study requires further REB approval, two months prior to expiration, the principal investigator is required to submit an annual renewal request.
5. The Research Ethics Board reserves the right to examine/review results of all studies conducted at Queensway Carleton Hospital, and must be given appropriate references in all published studies.

**Research Ethics Board Forms Inventory:**

**Form A:** Application for Study Approval

##### TO COMPLETE THIS FORM:

* Please use the “**TAB**” key to move between fields.
* Don’t worry about the boxes being too small. As you type, the text will wrap around, and the boxes will expand.
* There is no need to use “**Enter**” key, as this will create extra space in the form that is not required.
* The form fields will not accept formatting, plain type will be fine.
* If you need additional space, please insert a page where appropriate.

**Form B:** Annual Renewal Request

**Form C:** Protocol Amendment & Deviation Reporting

**Form D:** Study Termination Request

***All material should be submitted to:***

Lindsay Howcroft

Administrative Assistant

Queensway Carleton Hospital

3045 Baseline Rd., Ottawa, ON K2H 8P4

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rev. July 2021

**PROTOCOL CHECKLIST FOR INVESTIGATORS**

*(to be used as a guideline as the application form is being completed)*

[ ]  Background literature review?

[ ]  Hypotheses clearly stated? Study justified?

[ ]  Experimental design outlined? Design valid?

[ ]  Subjects: number, inclusion/exclusion criteria?

[ ]  Number of subjects appropriate? Criteria appropriate?

[ ]  Detailed methodology?

[ ]  Measurements: What is being measured and how?

[ ]  Statistical analysis: Which statistics are being used and why?

 Statistical analysis correct?

[ ]  Risks and benefits to the patient identified for participation in the

 Study?

[ ]  Information/Consent Forms following Tri-Council Guidelines?

[ ]  Patient information sufficient? Clear? Patients competent? On Queensway Carleton Hospital

 letterhead?

[ ]  Application form completed? Each section completed? The phrase “see protocol” not used?

[ ]  All investigators have signed the original copy?

[ ]  (HPB) Health Protection Branch Statement of Investigational New Drug approval, if applicable?

[ ]  QCH Department Manager / Director / VP approval where applicable.

**APPLICATION FOR**

**RESEARCH ETHICS BOARD APPROVAL**

1. **TITLE OF RESEARCH STUDY:**

1. **NAME OF PRINCIPAL INVESTIGATOR:**

 Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **ADDRESS FOR CORRESPONDENCE** *(include email address and phone number)*

1. **HOSPITAL POSITION** *(or hospital collaborator involved in study)*

1. **APPROVAL BY DEPARTMENT CHIEF, VP, DIRECTOR, OR MANAGER:**

|  |  |
| --- | --- |
| ***Q.C.H. Department Chief, VP, Director, and/ or Manager Approval*** |  |
| I have read this application, and I am satisfied that the objective, design, methods and contributions of the proposed research have sufficient validity, quality, and merit to warrant the implementation of this project. I approve the resource impact for this department. |
| ***Signatory #1*** |
| Name: |       | Contact #:      |
| Title: |       | Signature: |
| Date: |       |
| ***Signatory #2 (if appropriate)*** |
| Name: |       | Contact #:      |
| Title: |       | Signature: |
| Date: |       |

This should be completed by the respective Department Chief, VP, Director, or Manager at QCH, who is directly impacted by the proposed research (not the principal investigator, or co-investigator). This approval is **mandatory** prior to REB approval. For chart review studies, approval should be obtained from QCH Health Records. If you need assistance contacting any department heads, please contact the administrative assistant.

1. **PROJECT DESCRIPTION:** *(full summary +/- abstract)*

*Briefly summarize study design, methodology and existing evidence justifying research.*

1. **PURPOSE:**

1. **LITERATURE REVIEW SUMMARY:**

1. **STUDY DURATION:** Start Date:       End Date:
2. **DRUG STATUS:** *(Note that Health Canada Application/Approval must be submitted for*

*new drugs, or approved drugs being used for non-approved indication)*

Is this a new drug trial?  [ ]  YES [ ]  NO [ ]  N/A

Name all drugs to be used:

|  |  |  |
| --- | --- | --- |
| ***Drug*** | ***Dose*** | ***Route*** |
|       |       |       |
|       |       |       |
|       |       |       |

1. **Does the study involve administration of radioisotopes or additional radiation?**

[ ]  YES [ ]  NO

If yes, please attach a letter from the Department of Diagnostic Imaging indicating approval.

1. **Are questionnaires or assessment forms being used?**

[ ]  YES [ ]  NO

1. **Are questionnaires…**

[ ]  Previously published/utilized?

[ ]  Developed by research team for use in this study?

[ ]  Not applicable

Please identify names of all questionnaires used in this study, and if developed specifically for this study, provide a full copy of the questionnaire.

1. **How will the data be tested to determine its scientific validity or test each Hypothesis?**

1. **STUDY DESIGN:**
	1. What is the study design, and describe the methodology? Specify why this particular research design was selected and what are the strengths and weaknesses of the selected design.

* 1. Summarize existing research evidence that justified this research on human subjects.

1. **SAMPLE SIZE:**
	1. Sample size for the entire trial:
	2. Sample size being recruited at the Queensway Carleton Hospital:
	3. Number of centers involved:
	4. Please provide justification for the sample size on scientific grounds

1. **Will the proposal be submitted for peer review?**

[ ]  YES [ ]  NO

If yes, where?

1. **PUBLICATION:**
	1. Please describe plans for publication and dissemination of the findings.

* 1. Are there restrictions on publications?

[ ]  YES [ ]  NO

If yes, please describe in detail

* 1. Does the sponsor retain contractual rights to the initial analysis and interpretation of the resultant data?

[ ]  YES [ ]  NO

* 1. Does the Principal Investigator retain contractual rights to final analysis, interpretation, dissemination and publication of resultant data?

[ ]  YES [ ]  NO

1. **INFORMATION LINKAGE:**

Will the information collected in this study be linked to any other research studies or data bases? E.g. patient names linked to information collected in other databases?

[ ]  YES [ ]  NO

If yes, indicate what information will be linked and for what purpose

1. **Will patients be directly involved?**

[ ]  YES [ ]  NO

If yes, attach the consent form to be used.

1. **Will patients/subjects be compensated?**

[ ]  YES [ ]  NO

If yes, how much?

1. **Describe in detail, the method of recruiting and sampling patients. Indicate who will**

 **contact the patient.**

1. **RISKS:**
	1. Discuss the risks of the proposed research, specifying the particular risks associated with each procedure, drug, test or other aspect of the protocol, including combinations of each.

* 1. Will management of patients be prolonged or delayed as a result of this research study?

[ ]  YES [ ]  NO

* 1. Are there cessation rules for the study?

[ ]  YES [ ]  NO

If yes, please describe:

* 1. Is there a data safety monitoring board for the study?

[ ]  YES [ ]  NO

If yes, describe the composition of the board:

1. **Are any standard therapies or diagnostic procedures withheld for the purpose of this**

 **study and what are the risks/benefits to the patients?**

1. **Will the patient be inconvenienced or experience discomfort? How much of the patient’s**

 **time is required?**

1. **Does the sponsor have a policy to compensate the patient in the event that he or she**

 **suffers damage during the protocol?**

[ ]  YES [ ]  NO

If so, please provide details

1. **What are the benefits to the patient?**

1. **CONFIDENTIALITY:**

Discuss in detail the procedures to preserve confidentiality of the patients/results, including how written records, computer discs, recordings, including video, and questionnaires will be kept secure. What is the method of disposal and after which time period? Who will have access? (It is the policy of the Queensway Carleton Hospital Research Ethics Board that no records with the patient’s name leave the Queensway Carleton Hospital.)

1. **SECURITY MEASURES:**
	1. Describe how you will keep information secure

[ ]  Premises will be locked except when one or more of the investigators named in this application are present

[ ]  Access to the premises will be controlled (passcards, security clearances etc.)

[ ]  Access to the information will be restricted to the research team by:

[ ]  Patient Code [ ]  Files/Folders password [ ]  Computer password

[ ]  Other computer security methods that prevent unauthorized access will be used

[ ]  Encryption [ ]  Firewalls [ ]  Identifying Info Scrambled/De-linked

Other (Describe):

[ ]  Staff will be trained regarding privacy

[ ]  Staff will sign a confidentiality agreement

[ ]  Other, explain

* 1. Will information remain within the institution?

[ ]  YES [ ]  NO

If no, please indicate why and how information will be exported outside

* 1. Will system files be backed up automatically?

[ ]  YES [ ]  NO

If yes, please specify provisions that would be made for a private drive that cannot be accessed by anyone other than your research team, or that could not be backed up by computer support staff within your organization

1. **Do you (your spouse or dependents) agree not to buy sell or hold stock (or options) in**

**any of the companies providing or distributing the medication/device under study from the time of the initial discussions concerning the trial until the results are made public?**

YES [ ]  [ ]  NO [ ]  N/A

1. **BUDGET:**
	1. How has this research been funded?

* 1. Name of the agency/sponsor

* 1. Amount of funding received?

* 1. Are any payments and/or benefits made directly to the investigators or physicians for participating in this protocol? (*Please include the amount/benefit and your justification for this remuneration*).

YES [ ]  [ ]  NO [ ]  N/A

* 1. Did you include a budget summary for this protocol?

YES [ ]  [ ]  NO [ ]  N/A

* 1. Do you believe the principal investigators are placed in a conflict of interest or potential conflict of interest by virtue of their involvement with this study?

YES [ ]  [ ]  NO

If yes, please explain:

* 1. Do principal investigators have separate financial agreements with the sponsor of this study?

YES [ ]  [ ]  NO

If yes, please explain:

* 1. Is it understood that this treatment is for research purposes only and that there is no obligation on the part of the investigators to continue this treatment outside the timelines of this study?

YES [ ]  [ ]  NO

1. **IMPACT ON HOSPITAL RESOURCES:**

Complete the attached impact analysis document - Appendix A.

**APPENDX A**

**IMPACT ANALYSIS – RESEARCH IMPACT ON HOSPITAL RESOURCES**

|  |  |
| --- | --- |
| **RESOURCE REQUIREMENTS** | **COST** (FOR HOSPITAL USE ONLY) |
| Hospital Staff*(Specify Role)* | *ROLE:*      |       |
| Nursing |       |       |
| Pharmacy |       |       |
| Rehabilitation |       |       |
| Cardiopulmonary |       |       |
| Radiology |       |       |
| Laboratory |       |       |
| Health Records |       |       |
| Admin Support*(Secretary, etc…)* |       |       |
| Other*(Space, supplies, equipment, etc…)* |       |       |