

The Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board

Submitting a Research Study for the First Time?

All research that is conducted within the Faculty of Health Sciences and requires the participation of human subjects must be initially approved by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (REB) prior to commencement of the study. There are two types of REB review: *Expedited Review* and *Full Review*.

Expedited Review

A research project may be considered for expedited review if requested by a researcher or if deemed by the REB Chair, prior to a REB meeting, to be of low ethical concern or a chart review, survey and/or questionnaire type project. Conditions of low ethical concern include, but are not limited to, protocols that meet the requirements for free and informed consent, protect privacy and confidentiality, adhere to guidelines of conflict of interest and inclusion, and are of minimal risk. Minimal risk means that potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in his or her everyday life.

Researchers who believe that their research project meets the guidelines mentioned above for expedited review can submit directly to the REB Chair at anytime. However it is encouraged that researchers submit their documents several days in advance of a REB full review deadline in case the Chair decides that the study should go for full board review and therefore more copies would be required. If the REB Chair reviews the research project and grants approval, the Chair will report the decision to the REB at its next meeting. The REB Chair can also deem a research project submitted for expedited review to undergo a full review by the REB, if risk to potential participants is not considered minimal.

Documents required to be submitted for an expedited review are identical to the documents required to be submitted for a full review. The *only exception* is that only *one (1) Original document plus 1 copy* is required for each of the documents listed below under the full review.

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Full Review

The REB Committee meets once monthly and researchers wishing for their submission packages to be reviewed need to submit all required documentation at least two weeks prior to the scheduled meeting date. A schedule of the meeting dates can be found on the REB website (<http://www.queensu.ca/ors/researchethics/REB.html>). In order to submit a study for consideration at a REB meeting, the following documentation needs to be completed and submitted:

- ***REB Submission Form***

The REB Submission Form is an electronic document that can be downloaded on the REB's website (<http://www.queensu.ca/ors/researchethics/REB.html>). This document periodically changes so it is important that researchers or research staff completing the form download the latest version each time they are submitting to the REB committee for review. The Principal Investigator's Signature and the Department Head or Dean's Signature is required on the form.

When submitting a clinical drug research trial to the REB, a copy of the submission documents is automatically forwarded to the KGH/HDH Pharmaceuticals & Therapeutics Committee by the REB. This Committee is responsible for the review of clinical drug research trials in order to ensure that there is adequate pharmacologic rationale for conducting a new clinical drug research trial at KGH/HDH, that the clinical trial drugs are prescribed, dispensed and administered in a safe and appropriate manner, and there is adequate information in the clinical drug research trial's protocol regarding the storage, preparation, administration, and side effects of the drugs being used in the clinical drug research trial.

The REB requires one (1) Original and seventeen (17) copies of the completed REB Submission form.

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- ***Information and Informed Consent Form***

The information sheet and consent form distributed to subjects participating in research studies should be combined into one form called "*The Information and Informed Consent Form*". This form must use lay terminology and define any clinical terms that may not been known to the general public, as the majority of the individuals reading the form are not fluent in medical terminology. *The Information and Informed Consent Form* should indicate the date of the version of the form in the upper right hand or bottom section on each page: ensuring that any amended versions are kept current in the REB office. *The Information and Informed Consent Form* must be signed by all subjects prior to any study-related procedures performed. Subjects should have ample time to read over the *Information and Informed Consent Form* and all questions/queries should be addressed and answered to their satisfaction prior to signing the *Information and Informed Consent Form* such that they completely understand and comprehended the form. The consent process should occur in a quiet and private setting and subjects should be given a copy of the signed document for their personal records.

It can be useful to put the information of the *Information and Informed Consent Form* into sections, such that statements and issues can be addressed as appropriately:

- ✓ Title of Study: the title should be consistent on all documentation submitted to the REB Committee;
- ✓ Background Information: an overview of the research study is addressed in this section
- ✓ Details of the Study: this section should list:
 - the purpose/aims of the study;
 - a description of study visits (when? how often?);
 - a description of the drug dosage administered (if a clinical drug trial);

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- the tests/procedures to be performed as part of the study;
 - an explanation of any special research techniques to be used (e.g. randomization, blinding, placebo control);
 - a list of available alternative therapies for medical conditions should subjects wish not to participate in this study;
 - the benefits, risks and side-effects associated with participating in study;
 - the inclusion/exclusion criteria for participating in the study;
 - a statement indicating that participation in the study is voluntary and that subjects may freely withdraw from this study at any time; including an explanation of when a subject may be withdrawn from the study by a sponsor (if applicable), investigator or REB;
 - a statement regarding liability;
 - a statement regarding subject compensation;
 - a statement regarding confidentiality and privacy of personal information;
- ✓ Statement of Consent: to be signed by subject, investigator and the person conducting the consent process.
- ✓ Statement of Investigator: a statement included that is signed by the Investigator indicating that the Investigator has carefully explained to the subject the nature of the above research study and that they certify that, to the best of their knowledge, the subject understands clearly the nature of the study and demands, benefits, and risks involved to participant in this study.

The REB requires eighteen (18) copies of the Information and Informed Consent Form. Samples of successful Information and Informed Consent Forms used by KGH investigators are available through the KGH Clinical Research Centre.

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- ***Study Protocol***

The REB requires three (3) copies of your study protocol; four (4) copies if it is a clinical drug study).

- ***Investigator Brochure or Product Monograph (if applicable)***

The REB requires two (2) copies of each investigator brochure or product monograph for all clinical drug studies.

- ***Office of Research Services Data Summary and Signature Sheet***

Researchers are required to complete online a Data Summary and Signature Sheet (DSS). If research is being conducted in a Queen's affiliated teaching hospital (Kingston General Hospital, Hotel Dieu Hospital, Providence Care), it is important that researchers or research staff completing the application indicate which hospital department(s) that their research will be impacting. Impact is defined as any procedure or research protocol which uses hospital resources above those normally required for practice and care. This may include, but not limited to, extra tests or procedures, preparation and dispensing of special medications used in drug trials, additional nursing time, educational preparation or other ancillary costs covered by the hospital. The hospital will not normally absorb research costs associated with projects. Extra costs must be clearly indicated and researchers are advised to seek early consultation with the appropriate departments/or programs to ensure that a feasible proposal is prepared.

All required signatures are completed electronically by the Researcher, Department Head/Dean, Operational Directors of hospital departments, and Queen's University Office of Research Services.

For Hospital Staff who are not Queen's employees, researchers can sponsor their staff to obtain a username (NETID) and password in order to allow them the opportunity to create DSS applications for the researcher: simply contact your

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Departmental IT Representative for further details
(<http://www.queensu.ca/its/itadmin/itadmin-list.html>).

- ***Budget Information***

A detailed budget needs to be included ensuring that all foreseen costs are included. Researchers need to also include the amount of funding received and to include an explanation as how expenses not covered by the funding provided will be absorbed. Some key points to consider when creating a budget are the following:

- Salary and benefits for researcher to carry out research?
- Salary and benefits for graduate students, post-doctoral fellows, research associates, technicians, administrative support, etc. to carry out the research?
- Infrastructure costs (equipment, collection of data (computer software, databases), housing/installation, warranties, and contracts for servicing or training)?
- Travel to conferences to present data?
- Publication costs?
- Overhead (utilities, phone/data, occupancy costs, building use, central administration, central computing services, library costs)?
- Supplies for study?
- Hospital/Departmental costs
 - Laboratory costs (i.e. laboratory analysis of specimens and storage of samples)?
 - Imaging and diagnostic costs (i.e. CT scans, x-rays, MRI, technician's salary/benefits for performing imaging and diagnostic procedures)?
 - Pharmacy costs (i.e. storage and dispensing of drugs)?
 - Medical records costs (i.e. extracting charts from storage for researchers and industry-sponsored monitors, access to electronic database)?

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- Nursing costs (use of research nurses to recruit potential subjects or perform procedures on inpatients and outpatients)? Etc...

- *Curriculum Vitae*

One copy of current curriculum vitae for each principal and co-investigator(s) participating in the study needs to be submitted. Each investigator should sign and date the front copy of the curriculum vitae to confirm that the version submitted is up-to-date.

- *Additional Documentation*

Throughout the study, additional documentation may be needed to be distributed to the public or potential and enrolled subjects. The REB needs to review and approval all documents prior to disbursement, especially when it comes to industry-sponsored trials. These include, but not limited to:

- ✓ Advertisements for recruitment (i.e. newspaper, radio, television, telephone script, email);
- ✓ Letters of correspondence (i.e. letter of invite to potential subjects, appointment letters to subjects, letters to family physicians/specialists informing of subject's participation, letter to be placed in subject's medical records at hospital at study entry and discharge from study);
- ✓ Questionnaires utilized in study;
- ✓ Subject diaries, instruction letters sent home, pamphlets, etc...

Please note: Researchers should be aware that the major granting funding agencies (SSHRC, CIHR and NSERC) now require institutions to withhold the release of funds until appropriate REB review has been conducted and approved. It is strongly recommended that researchers submit their REB submission packages within 30 days of submitting their grant application to the appropriate agency.

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For more information regarding the REB, please consult the REB policies on "How to Apply to the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (REB)" (<http://www.queensu.ca/ors/researchethics/REB.html>) and the "Human Ethics Procedural Guidelines (REB Guidelines)" (<http://www.queensu.ca/ors/researchethics/REB.html>) or contact directly Kathy Reed, REB Coordinator, at (613) 533-6000 ext. 77000 or reedk@queensu.ca.

*****NOW ONLINE*****

Queen's students and researchers are now able to utilize an online tutorial about the practical application of Canada's national standard of ethics for research involving human subjects. The Course in Human Research Participant Protection (CHRPP) is intended for a wide audience including research administrators and educators, graduate students, research assistants, and active investigators. For more information, please consult the CHRPP brochure (<http://www.queensu.ca/ors/researchethics/CHRPP.pdf>). The online tutorial consists of eight modules that you can complete at your own pace (<https://webapp.queensu.ca/chrpp/>). At the completion of the course, a certificate can be printed off for your personal records. The content of the course is based on our national standard of human research ethics, *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.

Renewing a Research Study Already Approved?

Researchers are required to complete an "Annual Renewal & Amendment Form for Approved Studies" annually. The REB office forwards this form automatically to each researcher in advance of their actual annual renewal due date. For the annual renewal, the researcher should briefly indicate progress including:

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- ✓ the number of subjects required and recruited for the study both locally and nationally/internationally (for multiple institution trials);
- ✓ any major changes to the protocol or REB approved *Information and Informed Consent Form* that is on file at the REB office;
- ✓ the funding expected and received to date for the study;
- ✓ any challenges faced for the recruitment of subjects and the study in general;
- ✓ study completion date (if study ended) or expected completion date for study;
- ✓ any adverse events (for clinical trials) that have occurred throughout the study.

Once the form is completed, researchers need to sign the form and return it to the REB office prior to their annual renewal due date. For continuing projects without significant changes, there will be a detailed review that will occur every three years, if the study is still running. Once the form has been received by the REB office, a one-year renewal letter of approval will be sent to the researcher for their records.

Amending a Research Study Already Approved?

Throughout the duration of a study, researchers may need to amend a portion of the documentation (i.e. protocol, consent form) that was previously submitted and approved by the REB. In any instance when a researcher amends a portion of their REB approved documentation, the REB needs to be notified immediately, and supporting documentation for the amendment needs to be provided for the REB to review and approve the changes requested. In the amendment letter, researchers should clearly explain where the changes occurred, include any background information or rationale for the change, and explain any new risks associated to the subjects, if applicable. If an amendment involves changing the preapproved *Information and Informed Consent Form*, a copy of the revised *Information and Informed Consent Form* needs to be included, with a new updated version date. Any amendments to an existing pre-approved protocol require a new protocol to be forwarded to the REB for review. The REB must approve any amendment prior to any changes being implemented into a pre-approved study.

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The Chair of the REB has some discretionary ability to approve minor amendments without the amendment going through a full committee review; however, major amendments will require full review and should be handled by the same process as the Initial Review. Any minor amendments in which the Chair of the REB approved will be reported to the committee at the next scheduled meeting.

Serious Adverse Events?

In compliance with regulatory guidelines, the REB must be informed of expected (previously recorded or known) and unexpected (unknown) serious adverse events (SAE's) occurring during any clinical study that arises both locally (within this institution) and externally (other institutions). A SAE is defined as any event or change in the health status or side effect or symptom that a subject participating in a clinical trial may experience that results in death, disability, hospitalization, deformity, is life-threatening or in the opinion of an investigator warrants being classified as serious. SAE's are recorded and captured immediately following the signing of the *Information and Informed Consent Form* by the subject, through the screening and treatment phases of the study, and usually within a pre-specified period of time after treatment has been completed for the subject.

For local SAE's only, the researcher must provide a summary of the event and include any information regarding any changes to the *Information and Informed Consent Form* or protocol which might be necessary due to the SAE. For both internal and external SAE's, researchers are required to complete a SAE form (<http://www.queensu.ca/ors/researchethics/REB.html>) and for external SAE's attach a copy of any documentation received regarding the SAE: usually with industry-sponsored clinical trials, a regular *Expedited Safety Report from Sponsor* or SAE reports are received by the site from the sponsor reporting all new SAE's that have occurred at all sites nationally and world-wide.

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Unexpected SAEs occurring locally must be reported to the REB within 2 working days of becoming aware of the SAE or earlier if the sponsor or any regulatory agency has such a requirement. Expected SAEs occurring locally must be reported within 5 working days of becoming aware of the SAE. All SAEs (unexpected and expected) occurring at other sites must be reported within 15 working days of becoming aware of the SAE's. The REB will review the information and may re-evaluate the ethical aspects of the trial, particularly how the study will likely affect the safety of subjects or the conduct of the trial. A copy of the completed SAE form will be signed by the REB and returned to the researcher as acknowledgement of receipt. In some cases, more detail or follow-up may be requested by the REB.