

**Study Continuation Request**

**Research Ethics Board**

**Study Continuation - Annual Review Request**

**INSTRUCTIONS**

Please complete this form to request the continuation of Michael Garron Hospital (MGH) Research Ethics Board (REB) approval for your research study. Submission of the form is due one month prior to the study’s expiry date as indicated in the REB initial approval letter/most recent REB continuing approval letter.

**GUIDANCE**

Continuing Review

Tri-Council Policy Statement (TCPS 2, 2022):

* Article 2.8: “Following the initial REB review and approval, the ethics review shall continue to ensure that all stages of a research project are ethically acceptable in accordance with the principles of this Policy.”
* Article 6.14: “Researchers’ responsibilities include monitoring their research to ensure that it is conducted in an ethical manner, reporting unanticipated issues (Article 6.15) or changes to the research (Article 6.16), supervising all team members in the application of the research procedures, and ensuring that they are properly qualified and versed in the conduct of ethical research.”
* Article 6.14: “For research projects lasting longer than one year, researchers shall submit, at minimum, an annual report with sufficient details to enable the REB to make an informed judgment about the continued ethical acceptability of the research. For research lasting less than one year, an end-of-study report may suffice.”

Please also see N2 *SOP007\_09 Research Ethics Board: Submissions and Ongoing Communication*, section 5.6 Annual Re-approval Submission

Fairness and Equity in Research Participation

Tri-Council Policy Statement (TCPS 2, 2022):

* Article 4.1: “Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion.”

**\*For the purposes of this document, “MGH participants” refers to any participant who is enrolled in a research study at MGH, or an institution where the MGH REB is the acting Board of Record (BOR).** **The BOR is the qualified Research Ethics Board that has been delegated authority for the ethics review and ethical oversight of a research study.**

**Study Continuation - Annual Review Request Form**

|  |
| --- |
| SECTION 1 – Study Identification |
| REB Reference Number:  |
| Study Title:  |
| Expiry Date of REB Approval: (DD/MM/YYYY):  |
|  |
| SECTION 2 – Contact Information  |
| Local **MGH** Principal Investigator:  |
| Department/Division/ Program:  |
| Telephone:  |
| Email Address:  |
| Name of Person Completing the Form & Role:  |
| Address:  |
| Telephone:  |
| Email Address:  |
|  |
| SECTION 3 –Enrollment |
| *If your study is a retrospective chart review or using previously collected biological specimens, please skip to section 5.**Please select ONE option from the following four options:*1. [ ]  No enrollment to date

 Explanation:  |
| 1. [ ]  Enrolling Participants
 |
| 1. [ ]  Enrollment complete but study is ongoing (check all boxes that apply below)

 [ ]  Participants receiving study intervention [ ]  Post-Intervention follow-up of participants (e.g., follow-up visits, data collection only) [ ]  Intervention & follow-up complete for all MGH participants – data clarification and/or data transfer ongoing  (e.g., to sponsors or coordinating centers) |
| 1. [ ]  Other:

 Explanation:  |
|  |
| SECTION 4 – Summary of \*MGH Participants (defined above) |
| [ ]  N/A; this study **was** collecting retrospective data or analyzing previously collected biologic specimens; skip to ‘Section 5’. |
|  | Number of MGH participants planned as identified in initial application/REB approved amendments[ ]  Check this box if this number pertains to a Bayesian type adaptive Clinical Trial; indicate the minimum sample size |
| The total of the numbers in the red box must equal the number above | Number of MGH participants who have consented to participate; of these: |
|  | Number who did not meet inclusion criteria and are now excluded |
|  | Number who have withdrawn from study |
|  | Number who are currently active in the study (those receiving the study intervention even if placebo, non-intervention arm, or observation) |
|  | Number who have completed/finished the study intervention/treatment/placebo/non-intervention/observation and continue to be followed |
|  | Number who have completed the study intervention/treatment/placebo/non-intervention/ observation and are no longer being followed |
| Additional Comments: |
|  |
| SECTION 5 – Summary of MGH Retrospective Chart Review/Biological Specimen Studies |
| [ ]  N/A; this study **was not** collecting retrospective data or analyzing previously collected biologic specimens. |
| This summary is for: | [ ]  Retrospective Chart Review | [ ]  Biological Specimens |
|  | Target number of MGH participant charts or biological samples approved by the REB to be reviewed (per original submission and/or amendment) |
|  | Number of charts reviewed/specimens accessed to determine eligibility |
|  | Actual number of MGH participant charts included in the retrospective chart review |
|  | Actual Number of biological samples utilized for this study |
| Additional Comments: |
|  |
| SECTION 6 – Study Summary |
| 1. Please provide a brief summary of the progress of the study since the last REB approval (i.e., recruitment issues, preliminary findings).

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| 1. MGH serves one of Canada’s most diverse neighbourhoods, and is committed to fostering an inclusive culture that embraces diversity in the delivery of medical and support services. Briefly describe any challenges or barriers the study team has encountered achieving equitable access to the study (including communication issues, technological barriers, lack of transparency and scarcity, structural barriers and biases); and how this has been or will be addressed.

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| 1. Is there any new information in the literature or from other recent studies that would change the rationale or risk/benefit ratio for this study (e.g., changes in standard of care, new information about side effects, approval of another drug for this indication)?

Has this influenced participants' willingness to continue in the study? [ ]  Yes [ ]  No [ ]  N/A If “Yes”, explain:  |
| 1. Do the informed consent processes continue to be appropriate and documented? [ ]  Yes [ ]  No [ ]  N/A

If “No”, please explain:**Version number of current ICF:** **Version date of current ICF:**   |
| 1. If any participants have been removed from the study prematurely or have withdrawn their consent, please provide the reasons for participant removal/withdrawal. [ ]  N/A

 |
| 1. Have there been any participant complaints or feedback about the research? [ ]  Yes [ ]  No [ ]  N/A

If “Yes”, please describe the complaint/feedback and the follow-up actions: |
| 1. If applicable, are there are there any outstanding Serious Adverse Event (SAE) Annual/Six-Monthly Reports from the sponsor not yet submitted to the REB? [ ]  Yes [ ]  No [ ]  N/A

If yes, please attach all outstanding reports. [ ]  Attached  |
| 1. If applicable, has there been a report from the Data Safety Monitoring Board (DSMB) since the initial submission or last continuing review? [ ]  Yes [ ]  No [ ]  N/A

If yes, please include a copy of the most recent report. [ ]  Attached Date of Report:  |
| 1. Since the last renewal, has there been any change in the Conflict of Interest information provided to the REB for Investigators involved in this study? (Potential Conflicts of Interest can include functioning as an employee or consultant to the study sponsor, direct or indirect financial interest in the drug/device or technology involved in the study or receiving honorarium or other benefits from the sponsor.)

 |
| 1. Is the contact information on the consent form current? [ ]  Yes [ ]  No [ ]  No consent form(s) for this study

If “No”, please update the contact information and submit the revision with this form. |
| 1. Has there been a change or addition to the financial support for this study? [ ]  Yes [ ]  No

If “Yes”, please specify the changes/additions: |
| 1. Have there been any new publications or presentations of the study/study data since the initial submission or last continuing review? [ ]  Yes [ ]  No

If “Yes”, please attach to this form. [ ]  Attached |
|  |
| SECTION 10 – MGH Local Principal Investigator Attestation |
| My signature attests that I as the **MGH Local Principal Investigator** confirm that I have reviewed any adverse events, if applicable, in a timely fashion during the course of the study and these have been reported to the REB. All revisions to the study protocol and consent form have been submitted. I am not aware of any new information that may affect the continuation of the study or require change in the study protocol or associated study documents. I warrant that this study is being conducted in accordance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS 2), the Ontario Personal Health Information Protection Act (PHIPA) 2004, and other relevant laws, regulations or guidelines including, but not limited to: the Canada *Food and Drugs Act,* Health Canada’s Therapeutic Products Directorate Guidelines, the ICH Harmonised Tripartite Good Clinical Practice Consolidated Guideline, and the Declaration of Helsinki, as applicable.**I request continuing REB approval for this study.** |
|  |  |  |  |  |
| Print Name |  | Signature |  | Date (DD/MM/YYYY) |

**Submission Instructions:**

* **One (1)** electronic copy of this signed and dated form.
* If your study is industry sponsored, an administrative fee for REB review will apply. Please complete the [*Research Administrative Fees Invoice*](https://www.tehn.ca/documents/document/research-reb-administrative-fees-invoice) and submit it to the sponsor. A copy of the invoice and fee payment must accompany this application for continuing review.

**Return to**:

Email: ResearchEthicsBoard@tehn.ca

**References and Resources:**

* N2 SOP007\_09 Research Ethics Board: Submissions and Ongoing Communication (*available on iCare*)
* N2 REB SOP 405.003 Continuing Review
* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7551738/>
* McGill University, Institutional Review Board – Continuing Review Form
* Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2022 (referred to as TCPS 2, 2022).