

**Study Closure Request**

**Research Ethics Board**

**Study Closure Request**

**INSTRUCTIONS**

Please complete this form to formally close a Michael Garron Hospital (MGH) Research Ethics Board (REB) approved research study. Note research activities including recruitment and data collection cannot occur after REB approval has expired or the study is closed. However data clarification, transfer, and analysis may continue between coordinating centres, sponsors, study team members. Once the MGH REB approves study closure, the study cannot be reopened.

**GUIDANCE**

Your study must be closed in accordance with N2 *SOP016\_09 Study Close-Out* (see References and Resources below)

**\*For the purposes of this document, “MGH participants” refers to any participant who is enrolled in a research study at MGH, or 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 Closure Request Form**

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| --- |
| 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 –Study/Trial Status |
| All participant recruitment at this site is complete:  | [ ]  Yes [ ]  No [ ]  N/A |
| All participant follow-up is complete: | [ ]  Yes [ ]  No [ ]  N/A |
| All data collection and analyses using identifiable data are complete; no further access to participant records is required: | [ ]  Yes [ ]  No [ ]  N/A |
| The sponsor has conducted a close-out visit (industry-sponsored studies): | [ ]  Yes [ ]  No [ ]  N/A |
| If “No” to any of the above, then this study should remain open. Please complete an Annual Renewal Form instead or provide an explanation below. |
| Explanation:  |
|  |
| All data clarification, transfer, and analyses using de-identified data are ongoing; no further access to identifiable participant records is required: | [ ]  Yes [ ]  No [ ]  N/A |
| If you answered “Yes” to the question above, then this study can be closed. If further access to participant records is required, please complete an Annual Renewal Form instead or provide an explanation below. |
| Explanation:  |
|  |
| SECTION 4 – Reason for Closure |
| [ ]  Study completed; completion date:  [ ]  Final report attached [ ]  Final report pending; will submit as soon as it is available Total number of participants recruited at all sites (if known):  |
| [ ]  Study never received funding |
| [ ]  Insufficient participant accrual |
| [ ]  Withdrawn by [ ]  Investigator [ ]  Regulatory authority [ ]  Sponsor Explain:  |
| [ ]  Study closed due to safety reasons  Explain:  |
| [ ]  Other; identify:  Explain:  |
|  |
| SECTION 5 – Summary of \*MGH Participants |
| [ ]  N/A; this study **was** collecting retrospective data or analyzing previously collected biologic specimens; skip to ‘Section 6’. |
|  | Number of participants planned as identified in initial application or REB approved amendment[ ]  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 participants who consented to participate; of these: |
|  | Number who did not meet inclusion criteria and were excluded |
|  | Number who withdrew from study |
|  | Number who have completed the study intervention/treatment/placebo/non-intervention/ observation and are no longer being followed |
|  | Other, please describe:  |
| Additional Comments: |
|  |
| SECTION 6 – Retrospective Chart Review/Biological Specimens Studies |
| [ ]  N/A; this study **was not** collecting retrospective data or analyzing previously collected biologic specimens. |
| This summary is for: | [ ]  Retrospective Chart Reviews | [ ]  Biological Specimens |
|  | Target number of 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 |
|  | Number of participant charts included in the retrospective chart review |
|  | Number of biological samples utilized for this study |
| Additional Comments: |
|  |
| SECTION 7 – General Information |
| 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. If applicable, please describe any experiences/procedures through which the study successfully engaged diverse representation from the community. |
| Have there been any participant complaints or feedback about the research? [ ]  Yes [ ]  No [ ]  N/AIf “Yes”, please describe: |
| Did the study team provide research participants with a lay summary/letter of appreciation? [ ]  Yes [ ]  No [ ]  N/AIf “Yes”, attach a copy to this form.If “No”, please explain why: |
| Current consent form(s) attached? [ ]  Yes [ ]  No [ ]  N/AIf “No”, please explain why: |
|  |
| SECTION 8 – Publication/Dissemination of Results |
| Have there been any new publications or presentations of the study/study data since the initial/most recent REB review?[ ]  Yes [ ]  No  |
| If “Yes”, please submit a copy of the abstract(s)/presentation(s) or provide a list of references: |
| If “No”, please explain: |
|  |
| SECTION 9 – Storage of Study Data |
| [ ]  Study data and essential documents will be stored in a secure/confidential manner in accordance with applicable agreements, guidelines and regulations including, but not limited to: Canada *Food and Drugs Act*, N2 SOP015\_09 Investigator Study Files and Essential Documents, MGH Record Retention and Destruction Policy & Records Retention Index. |
| Study data will be retained for (please select one): |
| [ ]  15 years (for drug, medical device, biologic, and natural health product regulated clinical trials) |
| [ ]  7 years minimum (for non-clinical trials) |
|  |
| 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 confirm that all participant recruitment and follow-up is complete, including data collection and clarification, and no other analyses using identifiable or de-identified data will be conducted unless previously approved by the REB. Further, I confirm that I have implemented the safe retention and/or disposal plans for all study data as per the REB approved submission, study agreements, and in compliance with policies of the Toronto East Health Network.I warrant that this study was 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 to formally close this study.** |
|  |  |  |  |  |
| Print Name |  | Signature |  | Date (DD/MM/YYYY) |

**Submission Instructions:**

**One (1)** electronic copy of this signed and dated form.

**Return to**:

Email: ResearchEthicsBoard@tehn.ca

**References and Resources:**

* N2 SOP016\_09 Study Close-Out (*available on iCare*)
* N2 SOP015\_09 Investigator Study Files and Essential Documents (*available on iCare*)
* MGH Record Retention and Destruction Policy (*available in PolicyTech*)
* MGH Records Retention Index (*available in PolicyTech*)
* Holland Bloorview Research Ethics Board, Study Closure Form, V2: February 2012
* Unity Health Toronto Research Ethics Board (Unity Health REB), Study Closure Report Form, Ver. 01-Nov-2019
* McGill University, Research Ethics Board Office (REB-1, 2, 3, 4), Renewal Request/Study Closure Form (UpdatedApril-17-2019)