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| **For REB Use Only** |  | http://callaway.smh.smhroot.net/web-assets/images/logos/2019/UHT_Logo_Sites_RGB.png |
| Form Version Nov 2019 |

**Unity Health Toronto Research Ethics Board (Unity Health REB)**

**Study Closure Report Form**

**Complete this form electronically (i.e. not handwritten) and submit two (2) signed hard copies to the REB.**

Note: In this form, Providence Healthcare is referred to as “PHC”, St. Joseph’s Health Centre as “SJHC”, and St. Michael’s Hospital as “SMH”

Use this form **ONLY** if you are requesting closure of the REB study file.

**Date:**       **REB #:**

**Study Title:**

**Unity Health Lead Applicant:**

**Study Approval Date:**       **Study Approval Expiry Date:**

1. **Completion Summary**

If you answer ‘NO’ to any of the following, then this study should remain OPEN.

|  |  |
| --- | --- |
| Is all participant involvement complete for all Unity Health sites? | [ ] Yes [ ] No [ ] N/A |
| Is all data collection complete for all Unity Health sites? | [ ] Yes [ ] No [ ] N/A |
| Is all data clarification complete for all Unity Health sites? | [ ] Yes [ ] No [ ] N/A |
| Is all data transfer complete for all Unity Health sites? | [ ] Yes [ ] No [ ] N/A |
| Is all access to participants’ health records complete for all Unity Health sites? | [ ] Yes [ ] No [ ] N/A |
| Has the clinicaltrials.gov registration been updated and will summary results be posted within the [required timelines](http://stmichaelshospitalresearch.ca/staff-services/research-ethics/research-ethics-board/guidelines-for-clinical-trial-registration-and-results-reporting/)? | [ ] Yes [ ] No [ ] N/A |

1. Reason for Closure

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| [ ] Study completed |
| [ ] Principal Investigator left/leaving institution |
| [ ] Study never received funding |
| [ ] Insufficient participant accrual |
| [ ] No enrollment at site (e.g. competitive enrollment) |
| [ ] Withdrawn by Investigator. Explain:       |
| [ ] Withdrawn by Regulatory Authority. Explain:       |
| [ ] Withdrawn by Sponsor. Explain:       |
| [ ] Study closed due to safety reasons. Explain:       |
| [ ] Other. Explain:       |

1. Summary of Cumulative Study Participant Enrollment

[ ] No enrollment

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| **Explain why there was no enrollment in the study:**       |

1. **Retrospective Data / Biological Specimens** (e.g. Retrospective Chart Review/Biological Specimens Studies)

[ ] N/A, this study was not collecting retrospective data or analyzing previously collected biologic specimens

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| **Complete each line** |
|       | 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 |
| Number of charts included / biological samples utilized **at each Unity Health site** | **PHC** | **SJHC** | **SMH** |
|       |       |       |

1. **Prospective Data/Biologic Specimens** (e.g. Clinical Trials, Qualitative Studies, Registries, Prospective Chart Reviews, etc.)

[ ] N/A, this study was not collecting any prospective data or biologic specimens

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| **Complete each line** |
|       | Target number of enrolled participants approved by the REB (per original submission or amendment) |
|       | Number of charts reviewed/specimens accessed to determine eligibility |
|       | Number of participants approached by Unity Health study site personnel |
|       | Number of participants consented by Unity Health study site personnel(should equal sum of a to d below) |
| **a.** |       | Number of participants who were consented but did not start intervention/data collection |
| **b.** |       | Number of participants who withdrew their consent or were withdrawn (e.g. screen failures, early termination) **prior** to receiving/undergoing intervention |
| **c.** |       | Number of participants who withdrew their consent or were withdrawn (e.g. lost to follow-up, early termination) **post** start of study intervention |
| **d.** |       | Number of participants who have completed the study (including completed follow-up) and no further contact for study purposes is planned |
| Number of participants consented **at each Unity Health site** by Unity Health personnel | **PHC** | **SJHC** | **SMH** |
|       |       |       |

1. Safety Reporting

|  |  |
| --- | --- |
| Have all reportable serious adverse events been reported to the REB? | [ ] Yes [ ] No\* [ ] None |
| \*If no, submit immediately. |

1. Publication/Dissemination of Results

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| --- |
| Have any articles been published or presentations been given using the results of the study? |
| [ ] Yes. Please submit a copy of the abstract(s) or provide a list of references:       |
| [ ] No. Explain:       |
| [ ] N/A. Explain:       |

1. Study Data Storage

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| Study data will be stored in a secure/confidential manner in accordance with applicable guidelines and regulations.[ ] YesStudy data will be retained for (select one):[ ] 15 years (for drug, biologic, and natural health product regulated clinical trials)[ ] minimum 7 years (for medical device regulated clinical trials)[ ] minimum 7 years (for non-regulated clinical trials)[ ] minimum 5 years (for non-clinical trials) |

DECLARATION BY UNITY HEALTH LEAD APPLICANT

I confirm that there is no further participant involvement and all data collection, clarification, and transfer is complete (including access to the participants’ medical records).

I confirm that I will post summary results to the respective registry in accordance with the requirements.

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, the Unity Health Toronto by-laws, the Catholic Health Alliance of Canada Health Ethics Guide, and other relevant laws, regulations or guidelines (e.g., Health Canada Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations, the Medical Devices Regulations, and ICH/GCP Consolidated Guideline E6).

This study should be officially closed by the REB.

|  |  |  |  |  |
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| **Printed Name of Unity Health Lead Applicant**  |  | **Signature\***\*Original ink or authenticated electronic/digital signature (copy/pasted images of scanned signatures are not acceptable) |  | **Date** |