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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 March 2021 |

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

**Full Board Continuing Review Form and Progress Report**

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 if you are requesting Continuing Review of this study at a Full Board meeting. **Full Board review is required for FDA regulated or US federally funded studies that have begun enrolling participants and that have had active participants since the last renewal (or since initial approval, if this is the first renewal)**; all other studies can complete the [Delegated Continuing Review Form](http://stmichaelshospitalresearch.ca/staff-services/research-ethics/research-ethics-board/forms/). If you have any questions, consult with your REB Coordinator. If you are unsure whether a study is FDA regulated, check with the study sponsor.

The continuing review application must be reviewed at a Full Board (FB) meeting that takes place within the 30 days before the REB approval expires. Consult the [REB meeting schedule](http://stmichaelshospitalresearch.ca/staff-services/research-ethics/research-ethics-board/reb-meeting-dates-and-deadlines/) and submit prior to the appropriate meeting deadline.

Form Completion Date:dd-Mon-yyyy

Section 1: Study Information

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| --- | --- |
| REB number: xx-xxx | Unity Health PI name: PI name |
| Study title: Study title |
| Unity Health site(s): [ ]  SMH [ ]  SJHC [ ]  PHC |
| Original approval date: dd-Mon-yyyy | Annual review date: dd-Mon-yyyy |
| FDA regulated: [ ]  Yes [ ]  No | Receives US federal funds: [ ]  Yes [ ]  No |

Section 2: Study Summary

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| Study design:Brief (1-2 sentences) description in lay language |
| Primary objective:Brief (1-2 sentences) description in lay language |

Section 3: Current Study Status and Progress at Unity Health

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| Enrollment status: Choose a status  | Study status: Choose a status |
| Summary of study progress since last renewal:Brief (1-2 sentences) summary of study progress since the last renewal and any issues that have been encountered |
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| Interval Enrollment Summary |
| Number of participants consented since last renewal\* | Enter number |
| Number of participants who have withdrawn or been withdrawn since last renewal | Enter number |
| Number of currently active participants | Enter number |

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\*If this is the first renewal, provide the requested information since initial approval for this and all other questions that refer to last renewal

Section 4: Documents Currently in Use

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| Attach the version of the consent form that is currently in use (or that was most recently used)[ ]  Attached  |
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|  |  |
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| Document Type | Version date currently in use (or most recently used) |
| Protocol | dd-Mon-yyyy |
| Consent Form | dd-Mon-yyyy |
| Investigator’s Brochure(s), Product Monograph(s), Device Manual(s) | Product Name – IB or PM version date (dd-Mon-yyyy) |

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Section 5: Unity Health Enrollment Summary

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| Cumulative Enrollment Summary |
| Enrollment (consented) target at Unity Health | Enter number |
| Number consented to date | Enter number |
| Number of participants who have withdrawn or who have been withdrawn *prior* to receiving/undergoing the research-related intervention | Enter number |
| Number of participants currently receiving research-related interventions | Enter number |
| Number of participants who have withdrawn or who have been withdrawn *after* receiving/undergoing the research-related intervention | Enter number |
| Number of participants currently in post-intervention follow-up | Enter number |
| Number of participants who have completed the study (including all follow-up and contact) | Enter number |

Section 6: Unity Health Withdrawal Summary

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| Have any Unity Health participants withdrawn or been withdrawn from this study?[ ]  No – Go to Section 7 [ ]  Yes – Duplicate next row as needed for each withdrawal reason |
| Reason for withdrawal:e.g. Screen Failure | Cumulative withdrawals:e.g. 4 participants | Withdrawals since last renewal:e.g. 2 participants |

Section 7: Amendment Summary

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| Since the last renewal, have there been any protocol amendments?[ ]  No – Go to Section 8 [ ]  Yes – Duplicate next row as needed for all amendments since the last renewal |
| Protocol version date:dd-Mon-yyyy | Date submitted to REB:dd-Mon-yyyy | List major changes:High-level summary of the amendment. e.g.: modified inclusion criteria, removed secondary objective, added safety visit |

Section 8: Reportable Serious Adverse Events (SAEs) and Unanticipated Problems (UPs) Summary

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| Since the last renewal, have there been any reportable local or external SAEs or UPs?[ ]  No – Go to Section 9 [ ]  Yes – Duplicate next row as needed for all reportable SAEs/UPs since last renewal |
| Date of event:dd-Mon-yyyy | Date submitted to REB:dd-Mon-yyyy | Description:Brief (1-2 sentence) summary of the event or problem |
| Assessment:Briefly (2-3 sentences) describe whether the nature, frequency and severity of the events or problems are in line with what is expected based on the protocol, consent and IB |

Section 9: DSMB Report Summary

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| Since the last renewal, have any DSMB reports been issued?[ ]  N/A – No DSMB – Go to Section 10 [ ]  No – Go to Section 10[ ]  Yes – Duplicate next row as needed for all DSMB reports since the last renewal |
| DSMB report date:dd-Mon-yyyy | Date submitted to REB:dd-Mon-yyyy | DSMB recommendation:Brief (1-2 sentence) summary of the DSMB recommendation(s) |

Section 10: Auditing and Monitoring Summary

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| Since the last renewal, has this study been monitored or audited?[ ]  No – Go to Section 11 [ ]  Yes – Duplicate next rows as needed for each organization or agency that has audited or monitored the study since the last renewal |
| Monitoring Visits by:Organization or Agency that monitored the study | Visit Date(s):dd-Mon-yyyy | Outcomes and actions:Brief (1-2 sentence) description of the outcome and actions taken to address any findings |
| Audit by:Organization or Agency that conducted the audit | Date of event:dd-Mon-yyyy | Outcomes and actions:Brief (1-2 sentence) description of the outcome and actions taken to address any findings |

Section 11: New Safety Information Summary

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| Since the last renewal, has there been any new information in the literature, interim findings, or preliminary results that would change the rationale, procedures, study design, and/or risk/benefit profile for this study?[ ]  No – Go to Section 12 [ ]  Yes – Duplicate next row as needed for all information since the last renewal |
| Date of information:dd-Mon-yyyy  | Description:Brief (1-2 sentence) summary of the new information |

Section 12: Complaints Summary

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| Since the last renewal, have there been any substantive complaints about this study from participants or others?[ ]  No – Go to Section 13 [ ]  Yes – Duplicate next row as needed for all complaints since the last renewal |
| Complaint Date:dd-Mon-yyyy | Complaint summary:Brief (1-2 sentence) summary of the complaint |

Section 13: Study Personnel Information

List all individuals currently involved in conducting research activities at a Unity Health site or on behalf of Unity Health and indicate whether they have completed the mandatory training below:

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| --- | --- | --- |
| Personnel Name | Study Role(e.g. Unity Health Lead Applicant, Site Investigator, Research Assistant, etc.) | Is required training (TCPS2, GCP, Div5) up to date? |
|  |  | Yes | No – Rationale for incomplete training |
| *e.g. John Smith* | *Coordinator* |[ ]  [x]  *On parental leave* |
| Enter name | Enter role | [ ]  | [ ]  Rationale |
| Enter name | Enter role | [ ]  | [ ]  Rationale |
| Enter name | Enter role | [ ]  | [ ]  Rationale |
| Enter name | Enter role | [ ]  | [ ]  Rationale |
| Enter name | Enter role | [ ]  | [ ]  Rationale |

Section 14: Continuation Rationale

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| Rationale why this study approval should be renewed:Brief (1-2 sentence) rationale for requesting renewal of this study |

DECLARATION BY UNITY HEALTH LEAD APPLICANT

I warrant that this study will continue to be 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, 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, Medical Devices Regulations, and ICH/GCP Consolidated Guideline E6].

In addition, I affirm that all individuals listed above have completed the mandatory training and education (as applicable) in accordance with Unity Health Toronto’s requirements.

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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** |