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| --- |
| OFFICE USE**REB/CTO Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |



Unity Health Toronto Institutional Approval Form and Ethics Submission Checklist

**This form must be completed for all clinical research studies at Unity Health Toronto**

This form must be submitted for all [CTO](http://stmichaelshospitalresearch.ca/staff-services/research-ethics/cto/) and [Unity Health REB](http://stmichaelshospitalresearch.ca/staff-services/research-ethics/research-ethics-board/templates-guidelines/) applications. It replaces the CREC and Clinical Research Restart Approval (CR3C) forms, the REB Submission Checklist, and the individual site Study Impact Forms.

You must obtain appropriate approval from the Unity Health Toronto site representative of each impacted department prior to submitting this form. If you have questions about completing this form prior to submitting with your application, please email Elizabeth.Huggins@unityhealth.to **Incomplete applications will not be accepted and will be returned to you for resubmission**.

**Submission Instructions:**

* **Unity Health REB Applications**: Email the form to researchethics@smh.ca with your REB application (TAHSN form) and submission documents
* **CTO Centre Applications (Please submit this form when completing Centre Initial Applications NOT the Provincial Initial Application)**: Email to Elizabeth.Huggins@unityhealth.to

Section 1: Administrative Information

1. Type of Review

|  |
| --- |
| **SUBMISSIONS TO THE UNITY HEALTH REB**[ ]  Delegated Review (minimal risk\*)[ ]  Full Board Review (greater than minimal risk\*)***\* Minimal risk****:**probability and magnitude of possible harms is no greater than those encountered by participants in aspects of everyday life that relate to the research. (TCPS2 2014).* |
| **CTO SUBMISSIONS**  [ ]  Clinical Trials Ontario Centre Initial Application (CTO CIA) - Unity Health REB is the Board of Record [ ]  Clinical Trials Ontario Centre Initial Application (CTO CIA) - Unity Health REB is **NOT** the Board of Record *Must also complete the CTO addendum at the end of this form* |

1. Study Title:

|  |
| --- |
| Click or tap here to enter text. |

1. Contact Information:

|  |
| --- |
| **Principal Investigator (PI) Name:** Click or tap here to enter text.**PI Email Address:** Click or tap here to enter text.**PI Division:** Click or tap here to enter text.**Secondary Contact Name:** Click or tap here to enter text.**Secondary Contact Email Address:** Click or tap here to enter text. |

1. Unity Health sites involved in this research study and name of Unity Health PI at each site:

|  |  |
| --- | --- |
| **Unity Health Toronto Site** | **Name of Unity Health Site Investigator** |
| [ ]  St. Michael’s Hospital | Click or tap here to enter text. |
| [ ]  St. Joseph’s Health Centre  | Click or tap here to enter text. |
| [ ]  Providence Healthcare | Click or tap here to enter text. |

Section 2: Clinical Research Emergency Preparedness Assessment

These questions will indicate whether and how your study can be adjusted in emergency situations that necessitate a reduction in research activities – on site, in the community, and overall. The information provided will be used by Research Leadership to guide the safe and equitable ramp down of clinical research activities during emergencies.

1. Study Enrollment

*For each question, please specify applicable participant type (patient, patient family, community, staff, resident, etc.), if applicable.*

|  |
| --- |
| **Total study enrollment goal at Unity Health:** Click or tap here to enter text. |
| **Number of participants enrolled per month (approx.):** Click or tap here to enter text. |
| **Expected duration of participation (i.e. How long participants will be followed for):** Click or tap here to enter text. |

1. Does this study require external personnel, students, volunteers or visitors to come on site at Unity Health?

[ ]  No – Go to Question 7

[ ]  Yes – Complete table below

|  |  |  |  |
| --- | --- | --- | --- |
| **Name or Role** | **Organization** | **State/Province, Country** | **Reason for being on site** |
| 1.  |  |  |  |

1. Clinical Alignment of Research

|  |
| --- |
| **In an emergency situation that impacts usual practices at Unity Health, can all study activities be aligned with clinical visits?**[ ]  Yes – all activities are already aligned with a clinical visit[ ]  Yes – all activities can be aligned with a clinical visit[ ]  No – there are activities that cannot be aligned with a clinical visit[ ]  No – the participant population does not have clinical visits (e.g. community research, healthy volunteers, etc.)[ ]  N/A – this study does not involve visits of any kind (e.g. chart reviews, online surveys, etc.) |

1. Ability to Convert to Remote Research

|  |
| --- |
| **In an emergency situation that impacts usual practices at Unity Health, can all study activities be converted to remote activities?**[ ]  Yes – all activities are already remote[ ]  Yes – all activities can be converted remote[ ]  No – there are activities that cannot be converted to remote |

1. Ability to Completely Pause Research Activities

|  |
| --- |
| **In an emergency situation that impacts usual practices at Unity Health, can all study activities be paused?**[ ]  Yes**Ramp Down plan:** Click or tap here to enter text. |
| *Any ‘No’ selection must be justified below*[ ]  No, because the study is evaluating the current emergency[ ]  No, because the study provides participants with a treatment option where no other option exists[ ]  No, because the study involves safety follow-ups that would put the participant at risk if not completed[ ]  No, due to other factors**Describe/Justify your selection:**Click or tap here to enter text. |

Section 3: Submitted Documents

1. List all documents being submitted with this application:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Document** | **Version Number** | **Version Date**(dd-mmm-yyyy)*Must be in the document footer* |
| [ ]  | TAHSN Human Subjects Research Ethics Application |
| [ ]  | Study Protocol *(mandatory)* |  |  |
| [ ]  | Consent Form(s) *(if applicable)\***\*for US federally funded studies, a summary page must be included (in compliance with the revised Common Rule)* |  |  |
| [ ]  | Case Report Forms/ Data Collection Sheet *(if applicable)* |  |  |
| [ ]  | Master Linking Log *(if applicable)* |  |  |
| [ ]  | Health Canada Authorization (NOL / ITA / NOA etc.)*(if applicable – must post-date protocol)* |  |  |
| [ ]  | Investigator’s Brochure / Product Monograph / Device Manual *(if applicable)* |  |  |
| [ ]  | Add an item. |  |  |

*Note: to add more items to the list, right click a row and select add row. A row above can then be copied and pasted into the newly created row.*

Section 4: Study Staff and Research Personnel

1. L**ist all individuals involved in conducting research activities at a Unity Health Site**

This list should include **all individuals** (e.g. Investigators, coordinators, and study personnel including students, trainees, fellows, etc.) **involved in conducting research activities at a Unity Health Site** (i.e. any involvement at a Unity Health site, on behalf of Unity Health Toronto, with Unity Health participants/charts/identifiable data, etc.).

**Individuals who are not currently staff or registered visitors/students at the Unity Health site(s) where they wish to perform study activities are required to contact each Unity Health site’s research registration office prior to initiating study activities.** For more information, please visit: <http://stmichaelshospitalresearch.ca/staff-services/research-ethics/research-ethics-board/integrated-reb-info/>

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Personnel Name**(Including qualifications, i.e. MD, PhD, BSc, etc.) | **At which Unity Health sites will they conduct research activities?** | **Study Role**(i.e. Assistant, Coordinator, study RN) | **Study Tasks**\*use numbers from the task list below | **Research Training Completed** |
| *e.g. John Smith, BSc****Email:*** *smithl@domain.com****Primary Site:*** *PHC* | [ ]  *PHC*[x]  *SJHC*[x]  *SMH* | *RC* | *1,2,4,5* | [x]  *TCPS2* [x]  *GCP* [x]  *Div5* |
| **Name:**      **Email:**      **Primary Site:**       | [ ]  PHC[ ]  SJHC[ ]  SMH |  |       | [ ]  TCPS2[ ]  GCP[ ]  Div5 |
| **Name:**      **Email:**      **Primary Site:**       | [ ]  PHC[ ]  SJHC[ ]  SMH |  |       | [ ]  TCPS2[ ]  GCP[ ]  Div5 |
| **Name:**      **Email:**      **Primary Site:**       | [ ]  PHC[ ]  SJHC[ ]  SMH |  |       | [ ]  TCPS2[ ]  GCP[ ]  Div5 |
| **Name:**      **Email:**      **Primary Site:**       | [ ]  PHC[ ]  SJHC[ ]  SMH |  |       | [ ]  TCPS2[ ]  GCP[ ]  Div5 |
| **Name:**      **Email:**      **Primary Site:**       | [ ]  PHC[ ]  SJHC[ ]  SMH |  |       | [ ]  TCPS2[ ]  GCP[ ]  Div5 |
| **Name:**      **Email:**      **Primary Site:**       | [ ]  PHC[ ]  SJHC[ ]  SMH |  |       | [ ]  TCPS2[ ]  GCP[ ]  Div5 |
| **Name:**      **Email:**      **Primary Site:**       | [ ]  PHC[ ]  SJHC[ ]  SMH |  |       | [ ]  TCPS2[ ]  GCP[ ]  Div5 |

\*Study Tasks:
1 - Chart review 2 - Data collection

3 - Participant recruitment 4 - Obtain informed consent

5 - Study protocol assessments/procedures 6 - Protocol development only

7 - Data entry 8 - Data analysis

9 - Manuscript preparation (aggregate data only)

Section 5: Impact and Authorization

1. Does your study require:

|  |  |  |
| --- | --- | --- |
|  | YES | NO |
| Clinical services (e.g. Pharmacy, Decision Support, Cath Lab, etc.)? (see 13a for all services) | [ ]   | [ ]  |
| **Department/Division staff time (e.g. nursing), in-patient beds, clinic space, medication or medical tests from a department other than the PIs department? (see 13b for all Dept./Divisions)** | [ ]  | [ ]  |

If you answered No to all of the above – Go to Section 6

1. Impacted Area Authorization

To obtain and demonstrate this authorization:

* 1. ***Seek approval via e-mail*** from all relevant contacts listed in the table below. Each e-mail to the contact must (1) describe the impact of your study on the specific service(s)/resource(s)/clinical and community space(s), (2) include a completed copy of this form and (3) request explicit approval to start your study.
	2. Authorizing signatories are required to review your request and provide e-mail approval or non-approval.
	3. Attach all impact description(s) and e-mail approval(s) to your application. ***Please be sure that each description and approval is clearly labeled.***
	4. Check off all impacted services

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Service** | **Contact(s) for Approval**  | **Description of Work**  |
| [ ]  | Biobank | Dr. Sunit Das Sunit.Das@unityhealth.toValeria Di Giovanni Valeria.DiGiovanni@unityhealth.to |  |
| [ ]  | Biosafety | Neha Chauhan Neha.Chauhan@unityhealth.to |  |
| [ ]  | Decision Support(including Clinical Informatics) (pulling specific patient data from the clinical systems) | Laura Rodrigues decisions@unityhealth.toJenny Lieu Jenny.Lieu@unityhealth.to (copied only for SJHC) |  |
| [ ]  | Medical Imaging, CT, MRI, Ultrasound | ☐ SMH – Yangmei Li Yangmei.Li@unityhealth.to ☐ SJHC – Lisa Hicks Lisa.Hicks@unityhealth.to  |  |
| [ ]  | Research MRI only (SMH) | Anthony Sheen Anthony.Sheen@unityhealth.to |  |
| [ ]  | Health Records | Natalie Kouyoumdjian Natalie.Kouyoumdjian@unityhealth.to  |  |
| [ ]  | Pharmacy | ☐ SMH – Laura Parsons Laura.Parsons@unityhealth.to☐ SJHC – Jiten Jani Jiten.Jani@unityhealth.to  |  |
| [ ]  | Laboratory MedicineSample(s) taken for:☐ Research ☐Clinical ☐ Both | ☐ SMH & SJHC – Matthew Doggart Matthew.Doggart@unityhealth.to |  |
| [ ]  | Heart & Vascular Program/Medical Diagnostics☐Cath lab☐ ECG & Echocardiography | ☐ SMH – Desa Hobbs Desa.Hobbs@unityhealth.to☐ SJHC – Carolyn Nolan Carolyn.Nolan@unityhealth.to  |  |
| [ ]  | Infection Prevention and Control (IPAC) | ☐ SMH – Dr. Matthew Muller Matthew.Muller@unityhealth.to☐ SJHC – Dr. Mark Downing Mark.Downing@unityhealth.to Network Clinical Program Director – Paula Podolski |  |
| [ ]  | \*Health Professions/Interprofessional Practice\*Nursing and support from other health disciplines | ☐ SMH – Jane Topolovec-Vranic Jane.Topolovec-Vranic@unityhealth.to☐ SJHC – Sarah Dimmock Sarah.Dimmock@unityhealth.to ☐ Providence – Lorna Bain Lorna.Bain@unityhealth.to  |  |
| [ ]  | Pulmonary Function Lab | ☐ SMH – Eva Leek Eva.Leek@unityhealth.to |  |
| [ ]  | Research Facilities (access to core facilities such as -80 freezers, histology core, vivarium, etc.) | Stephen Barker Stephen.Barker@unityhealth.to |  |

* 1. **Check off all impacted Departments/Divisions (do not include the PIs department - this sign off is obtained on TASHN or CTO application)**

*Department of Medicine*

|  |  |  |  |
| --- | --- | --- | --- |
| **Uses Division Space/Staff/****Resources** | **Department of Medicine (DoM)** | **Contact(s) for approval:** | **Description of impact**  |
| [ ]  |  | **SMH Physician-in-Chief:** S. Straus**SMH Clinical Program Director**: Orla Smith**SJHC Physician-in-Chief:** G. Berlyne**SJHC Clinical Program Director:** Sonya Pak |  |
| [ ]  | Cardiology, DoM | **SMH Division Head:** K. Connelly**SJHC** **Division Head:** P. Mitoff |  |
| [ ]  | Clinical Immunology/Allergy, DoM | **SMH Division Head:** P. Vadas |  |
| [ ]  | Endocrinology, DoM | **SMH Division Head:** A. Advani**SJHC** **Division Head:** S. Khan |  |
| [ ]  | Gastroenterology, DoM | **SMH Division Head:** G. May**SJHC Division Head:** I. Bookman |  |
| [ ]  | Geriatrics, DoM | **SMH Division Head:** M. Zorzitto**SJHC Division Head:** F. Menzies |  |
| [ ]  | Haematology/Oncology, DoM | **SMH Division Head:** M. Sholzberg**SJHC Division Head:** D. Lo |  |
| [ ]  | Infectious Diseases, DoM | **SMH Division Head:** L. Taggart**SJHC Division Head:** M. Downing |  |
| [ ]  | General Internal Medicine, DoM | **SMH Division Head:** V. Dounaevskaia**SJHC Division Head:** P. Jaksa |  |
| [ ]  | Nephrology, DoM | **SMH Division Head**: J. Zaltzman**SJHC Division Head:** A. Berbece**Clinical Program Director:** Jonathan Fetros |  |
| [ ]  | Neurology, DoM | **SMH Division Head:** G. Midroni |  |
| [ ]  | Occupational Medicine, DoM | **SMH Division Head:** L. Holness**Clinical Program Director:** Joyce Fenuta |  |
| [ ]  | Oncology | **Clinical Program Director:** Joyce Fenuta |  |
| [ ]  | Respirology, DoM | **SMH Division Head:** E. Tullis**SJHC Division Head:** M. Heffer |  |
| [ ]  | Rheumatology, DoM | **SMH Division Head:** D. Mahendira**SJHC Division Head:** J. Stein |  |

*Department of Surgery*

|  |  |  |  |
| --- | --- | --- | --- |
| **Uses Division Space/ Staff/ Resources** | **Department of Surgery**  | **Contact(s) for approval:** | **Description of impact** |
| [ ]  |  | **SMH Surgeon-in-Chief:** N. Ahmed**SMH Clinical Program Director:** Tasha Osborne**SJHC Surgeon-in-Chief:** M. Aarts**SJHC Clinical Program Director:** Laurie Thomas |  |
| [ ]  | Cardiovascular Surgery | **SMH Division Head**: D. Latter |  |
| [ ]  | General Surgery | **SMH Division Head** J. Simpson**SJHC Division Head:** P. Sullivan |  |
| [ ]  | Neurosurgery | **Division Head:** J. Spears |  |
| [ ]  | Orthopaedic Surgery | **SMH Division Head:** T. Daniels**SJHC Division Head:** G. Vincent |  |
| [ ]  | Plastic Surgery | **SMH Division Head:** B. Murphy**SJHC Division Head:** C. Fielding |  |
| [ ]  | Urology | **SMH Division Head:** K. Pace**SJHC Division Head:** A. Chawla |  |
| [ ]  | Vascular Surgery | **Division Head:** M. Al-Omran |  |

*Other Departments*

| **Uses Dept. Space/Staff/Resources** | **Other Departments** | **Description of impact** |
| --- | --- | --- |
| [ ]  | Anaesthesia  | **SMH Department Head**: A. Baker**SJHC Department Head:** R. Cirone |  |
| [ ]  | Critical Care | **SMH Department Head**: J. Friedrich**SMH Clinical Program Director:** Tasha Osborne**SJHC Department Head:** J. Meyer**SJHC Clinical Program Director:** Laurie Thomas |  |
| [ ]  | Dentistry | **SMH Department Head:** K. Lee**SJHC Department Head:** G. Tershakowec |  |
| [ ]  | Emergency\*This includes any department/service whose patient enters the hospital through the emergency department (e.g. trauma) | **SMH Department Head\*\*:** C. Snider**SMH Clinical Program Director:** Orla Smith**SJHC Department Head:** J. ChengSJHC Clinical Program Director: Sonya Pak\*\*A separate Emergency Department impact assessment is required at SMH |  |
| [ ]  | Family Medicine | **SMH Department Head:** K. Weyman**SJHC Department Head:** D. Williams**Clinical Program Director:** Linda Jackson |  |
| [ ]  | Laboratory Medicine  | **SMH & SJHC Department Head:** C. Streutker |  |
| [ ]  | Medical/Diagnostic Imaging | **SMH Department Head:** T. Dowdell **SJHC Department Head:** T. Williams |  |
| [ ]  | Obstetrics and Gynaecology | **SMH Department Head**: F. Meffe**SJHC Department Head:** S. Judah (interim) |  |
| [ ]  | Ophthalmology | **SMH Department Head**: D. Wong**SJHC Department Head:** L. Derzko-Dzulynsky |  |
| [ ]  | Otolaryngology | **SMH Department Head**: J. Anderson**SJHC Department Head:** A. Gantous |  |
| [ ]  | Paediatrics | **SMH Department Head:** M. Sgro**SJHC Department Head:** H. Yang |  |
| [ ]  | Psychiatry | **SMH Department Head**: K. Chin**SJHC Department Head:** J. Lofchy**Clinical Program Director:** Janet Wilson |  |
| [ ]  | Research Director, Providence\*approval required for all Providence applications | **Providence:** Dr. Shane Journeay |  |

Section 6: Principal Investigator Attestation and Signature

[ ]  I have reviewed the form and confirm that this study **does not** involve hospital resources, and/or patient care areas, and/or staff and that NO authorizations are required for the conduct of this study

**OR**

[ ]  I have reviewed the form and determined that this study involves hospital resources, and/or patient care areas, and/or staff. I attest that to the best of my knowledge I have indicated the areas where authorizations are necessary and have obtained the appropriate signatures.

**AND**

[ ]  I understand it is my responsibility to ensure contracts with all third parties (e.g. sponsor, external lab, app vendor, online service provider contracted members of the research team) are in place before the study begins. Any questions can be directed to researchcontracts@smh.ca

[ ]  I affirm that all individuals listed above have completed the mandatory training and education (as applicable) in accordance with Unity Health’s institutional requirements.

|  |  |  |
| --- | --- | --- |
| Name: Principal Investigator | Signature | Date(dd/mmm/yyyy) |

Clinical Trials Ontario (CTO) Addendum

**This section must be completed for all CTO Centre Initial Applications (CIA) at Unity Health Toronto where Unity Health REB is NOT the Board of Record (BoR)**

CTO SUBMISSION TYPE

|  |  |
| --- | --- |
| [ ]  | **Clinical Trials Ontario Centre Initial Application** (CTO CIA) only if Unity Health Toronto is **NOT** the BoR**Please indicate:****Lead Site:** Click or tap here to enter text. **Board of Record:** Click or tap here to enter text. |
|  |

Health Canada Regulated

|  |  |
| --- | --- |
| [ ]  | Not applicable/Non-regulated |
| [ ]  | Yes | Please specify: [ ]  Drug ☐ Natural Health Product [ ]  Device |

**FUNDING**

Do you have funding for this research project? [ ]  Yes [ ]  No

If yes, please specify if these funding sources are **secured** (include available $ amount) or **anticipated**.

Click or tap here to enter text.

STUDY SUMMARY

Provide a short lay description of your study (1/4 page max)

|  |
| --- |
| Click or tap here to enter text. |

**APPROVALS:**

|  |  |  |
| --- | --- | --- |
| [ ]  Clinical Ethics | Contact: Michael SzegoPlease send protocol and ICF toMichael.Szego@unityhealth.to  | Signature: an email approval is also accepted |
| [ ]  Privacy | Contact: Elizabeth HugginsElizabeth.huggins@unityhealth.to  | Note: A privacy assessment must be completed and reviewed by the Information Access & Privacy Department. Privacy will also determine if an IT security review is also required. |