

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

**Staff Change Form**

This form is to be used for changes in study personnel or investigator positions including replacement of the Unity Health Lead Applicant, **at any Unity Health site:** Providence Healthcare (PHC), St. Joseph’s Health Centre (SJHC), and St. Michael’s Hospital (SMH).

**Do not include this page with your submission.**

**Definitions:**

**Unity Health Lead Applicant:** Individual responsible for the ethical and scientific conduct of the study across all Unity Health sites.

* For studies submitted **prior to REB integration (June 2018)** this is the individual listed as the “Principal Investigator” in the Submission Checklist and TAHSN.
* For studies submitted **after January 2019,**(to the Unity Health REB), this is the individual listed as the “Unity Health Lead Applicant” in the Submission Checklist.

**Site Investigator:** Individual who oversees the ethical and scientific conduct of the study at a Unity Health site. The Site Investigator must be an employee of or have an active appointment at the site where they will be the Site Investigator. There must be one Site Investigator for each site. The Unity Health Lead Applicant can serve as the Site Investigator at any site at which they have an appointment.

**Primary Site:** This is the main Unity Health site (PHC, SJHC, SMH) that the individual is affiliated with. The individual must be an employee of or have an active appointment at their listed primary site.

**Tips for completing the Unity Health REB Staff Change Form:**

* Individuals not currently staff or registered visitors/students at the Unity Health site(s) where they wish to perform study conduct, are required to contact each Unity Health site’s registration office prior to initiating study activities.

Registration Office Contacts:

* + *Providence Healthcare:* Please contact your Research Ethics Coordinator.
  + *St. Michael’s Hospital & St. Joseph’s Health Centre:* Cordelia Cooper ([Cordelia.Cooper@unityhealth.to](mailto:Cordelia.Cooper@unityhealth.to))
* If a Site Investigator is being removed from the study, please ensure a new Site Investigator is indicated in section **2a** (Addition/Removal of Co-Investigators) under “Site Investigator?” (see example in the form)
  + If the new Site Investigator was not previously part of the study team, please add the new Site Investigator to the study team in section **2a**.
* If an individual is not being added or removed from the study but something about their role in the study has changed (e.g. contact person, position, site investigator, etc.), please use the **Update (U)** option and complete the entire row with the individual’s current study role information.
* Research training in Good Clinical Practice (GCP) and the Tri-Council Policy Statement 2 (TCPS2) is **required** for anyone who conducts or is involved in conducting human research activities at any Unity Health site.
  + For retrospective studies without participant contact, only TCPS2 training is required.
  + For Health Canada regulated clinical drug trials, Health Canada Division 5 training is also required

Please visit the [Research Training](http://stmichaelshospitalresearch.ca/staff-services/research-ethics/research-ethics-board/research-training/) website for more information on the training requirements.

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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)**

**Staff Change 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”

**Date:**       **REB #:**

**Study Title:**

**Current Unity Health Lead Applicant:**

**1a. Nature of Change & Rationale** (Check all that apply)

|  |  |
| --- | --- |
|  | Addition, Removal or Update to **Co-Investigator(s)** (including Site Investigators) **→ Complete Section 2a** |
|  | Addition, Removal or Update of **Study Personnel** (e.g. Research Coordinator, Research Assistant) **→ Complete Section 2b** |
|  | Change in Unity Health Lead Applicant → Complete Section 2c  Note: If the outgoing Unity Health Lead Applicant is to remain on the study as a co-investigator going forward, please detail their addition as co-investigator under Section 2a. Otherwise, they will be removed from the study personnel. |

**1b. Specify the reason(s) for the change(s) in study personnel or investigator(s):**

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| --- |
|  |

**Task List**

Please use the Study Tasks list below to complete the Study Tasks column in Sections **2a**, **2b and 2c**. In the Study Tasks column, indicate the study tasks each individual will be involved in, using the numbers below.

1 - Chart review 6 - Protocol development only

2 - Data collection 7 - Data entry

3 - Participant recruitment 8 - Data analysis

4 - Obtain informed consent 9 - Manuscript preparation (aggregate data)

5 - Study protocol assessments/procedures only

**2a. Addition/Removal of Co-Investigator(S)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Co-Investigator Agreement:** I/We agree to participate in this study as described in this application and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects and any other relevant laws, regulations or guidelines. I/We also agree that if I/We receive any personally identifiable information (including but not limited to personal health information and biological samples), I/We will only use or disclose the information as set out in the Protocol, the conditions of the REB, the research participant's consent (unless consent is waived), and the conditions and restrictions imposed by the relevant information guardian who supplies the information. I/We will notify the Unity Health Lead Applicant immediately if there is any deviation from the Protocol or other adverse event. | | | | | | | |
| **Add (A), Remove (R) or Update (U)** | **Co-Investigator Name**  (Including qualifications i.e. MD, PhD, BSc, etc.) | **Signature**  If a signature cannot be obtained, provide an explanation and/or documentation | **Study Tasks**  \*use numbers from the task list on page 1 | **Access to PHI?**  If yes, indicate why this is necessary | **Site Investigator?**  \*if removing Site Investigator, indicate the new Site Investigator | **At which Unity Health sites will they conduct research activities?** | **Research Training Completed** |
| *R* | *e.g. John Smith, MD*  ***Email:*** *johnsmith@domain.com*  ***Primary Site:*** *SJHC* |  | *1,2,4,5* | *Y, mining charts* | *Y,* ***new Site Investigator:*** *Dr. Jane Smith* | *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 |

**2b. Addition/Removal of Study Personnel**

Detail the study personnel addition(s) and/or removal(s) in the table below:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Add (A), Remove (R) or Update (U) | Personnel Name  (Including qualifications, i.e. MD, PhD, BSc, etc.) | Study Role  (i.e. Assistant  Coordinator, study RN) | **Study Tasks**  \*use numbers from the task list on page 1 | **Access to PHI?**  If yes, indicate why this is necessary | **New REB Contact Person?**  (Y/N) | **At which Unity Health sites will they conduct research activities?** | **Research Training Completed** |
| *A* | *e.g. John Smith, BSc*  *Email: smithl@domain.com*  *Primary Site: PHC* | *RC* | *1,2,4,5* | *Y, mining charts* | *Y* | *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 |

**2c. Incoming Unity Health Lead Applicant**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name:** | | | | | | | | |
| **Dept/Div:** | | | | **Primary Site:** | | | | |
| **Telephone:** | | | | | **Email:** | | | |
| **Study Tasks**  \*use numbers from the task list on page 1 | **Access to PHI?**  If yes, indicate why this is necessary | | **At which Unity Health sites will they conduct research activities?** | | | **At which Unity Health sites will they also act as Site Investigator?** | **Research Training Completed** | |
|  |  | | PHC SJHC  SMH | | | PHC SJHC  SMH None | TCPS2 GCP  Div5 | |
|  | | | | | | | | |
| I assume full responsibility for the scientific and ethical conduct of the study as described in this application and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects, Personal Health Information Protection Act (2004) and any other relevant laws, regulations or guidelines. I also agree that if I receive any personally identifiable information (including but not limited to personal health information and biological samples), I will only use or disclose the information as set out in the Protocol, the conditions of the REB, the research participant's consent (unless consent is waived), and the conditions and restrictions imposed by the relevant information guardian who supplies the information. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified or will undergo appropriate training to fulfill their role in this project. | | | | | | | | |
|  | | | | | | | | |
|  | |  | | | | | |  |
| **Name of Incoming Unity Health Lead Applicant** | | **Signature**\*  \*Original ink or authenticated electronic signature | | | | | | **Date** |
|  | | | | | | | | |
| I authorize the change in Unity Health Lead Applicant and will transfer all study documents and responsibility to the incoming Unity Health Lead Applicant. | | | | | | | | |
|  | | | | | | | | |
|  | |  | | | | | |  |
| **Name of Outgoing Unity Health Lead Applicant** | | **Signature**\*  \*Original ink or authenticated electronic signature | | | | | | **Date** |
|  | | | | | | | | |

* + 1. **Conflict of Interest Declaration**

Not applicable - None of the added study personnel or their immediate family members have a Conflict of Interest to disclose

Conflicts of Interest do not imply wrongdoing. It is the responsibility of the Unity Health Lead Applicant to determine if **any of the conflicts** listed below apply to **any persons** listed above in the research study or any member of their immediate family. Disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project. Conflict of interest may also arise with regard to the disclosure of personal health information. **NOTE:** This disclosure does not replace institutional guidelines and requirements for declaration and management of Conflicts of Interest.

|  |  |
| --- | --- |
| **Explain how the identified Conflict(s) will be managed**: | |
| **Identify the nature of the Conflict(s):** | |
|  | Function as an advisor, employee, officer, director or consultant for the study sponsor |
|  | Have direct or indirect interest in the drug, device or technology employed in this research study (including inventorship, patents or stocks) |
|  | Receive an honorarium or other personal benefits from the sponsor (apart from fees for service) |
|  | Using services of a family member or a company in which you or a family member has a direct interest. |
|  | Receive direct or indirect financial benefit from the disclosure of personal health information |
|  | Competing interest (situations in which the researcher may be influenced to draw conclusions against the interest of the sponsor or another interested party to the study because the researcher or a family member has an opposing interest related to the research, including a legal suit against a company or sponsor or a financial interest in a competing company or product) |
|  | Other; describe: |

* + 1. **Changes to Study Documents**

Do the requested change(s) require modification to the following?

NOTE: For any changes other than staff changes, please complete and submit an ‘Amendment Request Form’.

|  |  |
| --- | --- |
| **Protocol** | **Yes, and the revised documents are attached** |
| **No. Justification why no change is required:** |
| **Participant Materials** (Information Letters, Consent Forms, Study Ads, Questionnaires, etc.) | **Yes, and the revised documents are attached** |
| **No. Justification why no change is required:** |
| **Other** | **Specify:** |

List the included revised documents below.

A clean copy and a tracked copy of all revised documents must be submitted.

|  |  |  |
| --- | --- | --- |
| Document Title | Version # | Version Date  (dd-mmm-yyyy) |
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* + 1. **EXISTING CONTRACTS**

This change in staff may require a revision to existing contracts/agreements related to this study.

Not applicable, this study does not have any existing contracts

**OR Research Contracts has been contacted and:**

|  |  |
| --- | --- |
|  | A submission has been made to the Office of Research Administration |
|  | The change does not affect current contracts/agreements in place |
|  | A contract/agreement is not required for this change |

DECLARATION BY UNITY HEALTH LEAD APPLICANT

I warrant that this study was conducted/will continue to be conducted in accordance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), 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 requirements.

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