MEMO

Date: April 20, 2020

To: Research Community at Unity Health Toronto

From: Dr. Ori Rotstein

Vice-President Research & Innovation

Re: **COVID-19 Research Evaluation Committee and Approval Process**

Many of our researchers at Unity Health Toronto are actively engaged in setting up research projects related to COVID-19. These projects include local, city-wide, national, and international initiatives. Given the large number of projects that are being proposed, we need to ensure that we do not overburden our patient/participant population and that we adequately consider the potential impact on our institutional resources and facilities. Hence, we are instituting a special review and approval process specifically for COVID-19 related research.

Chaired by the VPRI, the **COVID-19 Research Evaluation Committee** has been recently established to complement the existing REB approval and contract process by enabling research coordination, information sharing, and prioritization of resources and support for investigators. The Committee **will review, prioritize and approve all COVID-19 related research projects prior to submitting to the REB or CTO as applicable and to Research Contracts.**

This new approval process for COVID-19 research will determine the feasibility of projects as well as determine **a)** the ability to recruit participants[1], **b)** access to research facilities, **c)** impact on clinical departments (including diagnostic imaging, labs, clinical inpatient units etc), and **d)** the ability to obtain personal protective equipment (PPE) or other materials as needed[2]. The process is designed to also ensure that investigators consult with impacted research and clinical departments that will be involved in their projects prior to launching research studies, and that the normal activity of Unity Health Toronto staff is not disrupted during a time of unprecedented demand, while maintaining the highest ethical standards for research at our respective sites. The Committee may also identify opportunities for collaboration among investigators pursuing similar research objectives.

[1] CREC must approve all research projects that require access to human participants (including COVID-19 positive patients and front line health care workers who are at risk of developing COVID-19), data and specimens.

[2] Please note that access to relevant materials (e.g. PPE, swabs, reagents etc.) may be constrained at this time

FAQ: COVID-19 Research Evaluation Committee and Approval Process

1. How do I submit my COVID-19 research project for CREC approval?

The Principal Investigator must complete and submit the new Research Study Impact Approval Form with COVID-19 Addenda to Elizabeth.Huggins@unityhealth.to prior to REB submission. CREC will evaluate your application form and will endeavour to notify the PI and the REB of the decision within **3 business days.** If your project is approved by the CREC, you can then submit to the REB for review. No COVID-19 study will be permitted to begin without **both** CREC and REB approval. Approval from CREC does not guarantee that your project will be approved by the REB. See question #5 to download the correct form.

2. Who is on the COVID-19 Research Evaluation Committee (CREC)?

The Vice-President of Research & Innovation will chair the CREC. Other members are representatives of Li Ka Shing Knowledge Institute, Keenan Research Centre, Office of Research Administration, and Research Ethics Board, plus *ad hoc* members with other expertise (e.g., pandemic research and clinical trials) as required.

3. Why is REB and ORA/contact approval alone no longer sufficient for COVID-19 research studies?

Due to the growing number of COVID-19 related research studies, the VPRI needs to determine the feasibility of implementing every COVID-19 project at each site. Specifically, the Committee will ensure that the resources needed to complete the study are available.

CREC will review 1) implementation and feasibility of the study, 2) possibility of integration/collaboration with other studies, 3) availability and impact of associated clinical resources (labs, medical imaging, pharmacy etc.) to support the study, 4) supply of materials required for the study (e.g., PPE), 5) space required to conduct the study and 6) adequate research funding to conduct the study. If appropriate, for specific study activities, CREC will make recommendations for collaboration with other studies to minimize impact (e.g. opportunity to align blood draws, consent etc. to conserve PPE).

Once the COVID-19 project is approved by CREC, you must submit your application to REB or CTO for review and approval as you normally would.

4. If an amendment to an approved study is being considered, do I need to resubmit to the CREC?

If the amendment has material changes (see examples below), you need to fill out the **Amendment Form** (see question #5 to download the correct form) and submit it to **Elizabeth.Huggins@unityhealth.to**.

Here are some examples when you need to submit an Amendment Form:

- Adding or changing the participant population
- Adding additional procedures: blood draws, biospecimens, CT scan, etc.
- Requiring additional institutional or clinical resources

5. Where do I find the correct form?

Type of Submission	**REB Submission Pathway (CTO or UHT REB)**	**Forms**
New Submission - COVID	CTO	SMH COVID Study Impact Form *(clinical ethics sign off is required if UHT is NOT the REB of Record)*
	UHT REB	SMH COVID Study Impact Form *(clinical ethics sign off is not required)*
Amendment - COVID	CTO	**1.** CTO ***Centre*** Amendment Form/Documentation if UHT is NOT REB of Record); **OR** CTO ***Provincial*** Amendment Form/Documentation if UHT is REB of Record 2. Brief summary of the changes proposed 3. Description of any substantive changes to the resources required (e.g., clinical impact, funding, PPE, interventions). 4. Approvals from impacted clinical departments/resources (can be email confirmation)
	UHT REB	1. UHT REB Amendment Form/Documentation 2. Brief Summary of the changes proposed 3. Description of any substantive changes to the resources required (e.g., clinical impact, funding, PPE, interventions). 4. Approvals from impacted clinical departments/resources (can be email confirmation)

CTO=Clinical Trials Ontario

For **All Non-COVID-19** related CTO and UHT REB submissions should continue to follow the standard process found at: St. Michael's

St. Joseph's

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Providence

Coming soon. Please contact Elizabeth Huggins if you are planning a COVID-19 study to take place at Providence.

6. Who can I contact if I have questions related to the CREC approval process?

Please direct your questions to Elizabeth Huggins at Elizabeth.Huggins@unityhealth.to