MEMORANDUM

Date: March 18, 2020
To: VCH and PHC Research Community
From: Dr. W. Robert McMaster, Executive Director, Vancouver Coastal Health Research Institute and
Dr. Darryl Knight, President, Providence Health Care Research Institute
Subject: Advisory on clinical trials and clinical research operations at Vancouver Coastal Health (VCH) and Providence Health Care (PHC)

During this time we must follow VCH and PHC directives relating to the COVID-19 pandemic, and be aware that these directives will change to accommodate the rapidly evolving situation. Efforts to reduce, minimize or eliminate risks related to research participants and the public are critical at this point, and we must minimize any burden that clinical trials and clinical research activity can create for our health care system.

Key principles:

1. Safety of our research participants, their families and staff.
2. Limit excessive use of resources within VCH and PHC, given the increased risks involved with decreased number of staff and increasing demands on our health care system.
3. Minimize the potential spread of COVID-19.
4. Limit adverse impact on the integrity of ongoing trials.
5. Guidance is subject to change as the situation evolves. We will review and advise on any changes on a regular basis.

Clinical trials and clinical research operations at VCH/PHC sites

With consideration for continuity of care and participant and staff safety, VCH and PHC are suspending the initiation of new clinical trials/clinical research projects and halting recruitment for new and ongoing clinical trials/clinical research studies until **Monday April 6, 2020**.

Enrollment into clinical trials and clinical research studies that are part of essential clinical care, projects related to the COVID-19 pandemic, or those that have significant cost or time-related implications will be assessed on a case by case basis. Please contact the appropriate operational site contact(s) noted below to discuss further.

We recognize that some ongoing clinical trials and clinical research studies require important safety monitoring and/or on-site visits that are critical to the participant's clinical care, and therefore encourage investigators to use good judgment and consider the level at which this is appropriate for each ongoing protocol and patient participant.

The following are to be instituted in regards to ongoing clinical trials and clinical research studies:

1. At the direction of VCH and PHC, all visitors to VCH and PHC sites are being restricted to immediate family members only. Study sponsor on-site monitoring visits should be re-scheduled or conducted remotely where possible.

2. Study sponsor scheduled monitoring visits may be permitted outside of the VCH and PHC clinical settings. Monitors with a history of U.S. or international travel within 14 days are not permitted into the facility. Remote monitoring and virtual appointments must be conducted where possible (e.g. meeting with the PI or other staff).

3. Clinical trials and clinical research staff should contact clinical trials and clinical research participants beforehand to actively screen for symptoms of or exposure to COVID-19 infection prior to their appointments in the clinic or facility.

4. Good communication with study sponsors, when applicable, should be maintained to inform them of any protocol deviations or interruption of accrual activities. Attempts should be made to contact and screen monitors attending a facility outside of the VCH or PHC clinical setting prior to the visit.

5. Please be mindful of any FDA or Health Canada directives that may be affecting the conduct of specific clinical trials when applicable.

Research ethics considerations

In relation to practical aspects where protocol deviations may be necessary due to COVID-19, while the Tri-Council Policy Statement (TCPS2) typically requires review and approval of modifications prior to implementation, “changes that are necessary to eliminate an immediate risk(s) to the participants may be implemented as needed, but must be reported to the REB at the earliest opportunity.” (Article 6.15). In relation to FDA regulated trials, 21 CFR 56.108(a)(4) similarly allows for modification without prior approval “where necessary to eliminate apparent immediate hazards to the human subjects”, and again, these changes must be reported to the REB at the earliest opportunity.

We ask that any Post Approval Activities (PAAs) or e-mails sent to the REB that relate to issues or queries relating to COVID-19 are named accordingly so that they can be more easily tracked. For example, the PAA nickname should include “COVID-19”, or e-mail subject line should include “COVID-19”. In all cases, accurate and detailed documentation of the circumstances surrounding any alterations or amendments is extremely important.

If you are submitting a new research project directly related to COVID-19, please contact the REB to discuss and inform your regional medical director.

We recognize the impact this will have on our research staff and their work. However, our decision is consistent with many of our peer organizations, as well as with the current escalation of school and other business closures. We will continue to assess the situation on a real time basis and prepare for scenarios that allow restoration of research activity as soon as possible.

For **OPERATIONAL** questions and concerns relating to clinical trials and clinical research activities, please contact:

For VCH:

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For **REB** related questions or concerns, please contact:

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For more information and situation updates related to COVID-19, visit:

- VCHRI
- PHC
- UBC Faculty of Medicine
- U.S. Food and Drug Administration