memorandum

To: NSHA and IWK Research & Innovation Communities

From: Dr. Gail Tomblin Murphy, VP Research, Innovation & Discovery and Chief Nurse Executive, NSHA
Dr. Jordan Warford, Senior Director Research, NSHA
Ms. Doris Grant, Senior Director Innovation, NSHA
Dr. Chris MacKnight, Executive Chair, NSHA Research Ethics Board

Dr. Jeannie Shoveller, VP Research & Innovation, IWK
Ms. Kathleen Leadon, Director, Research Operations, IWK
Dr. Adam Huber, Co-Chair, IWK Research Ethics Board
Ms. Eleanor Fitzpatrick, Co-Chair, IWK Research Ethics Board

Date: March 20, 2020

Re: **Non-Urgent Clinical Visits Suspended in NSHA and IWK Sites: Important Implications for Onsite Research**

The suspension of routine clinical visits by NSHA & IWK in response to COVID-19 has a direct impact on all research study visits including clinical trials. The high risk of community transmission of COVID-19 alongside the forthcoming strain on essential health care services has led to the necessity of **suspending non-urgent clinical visits and pausing recruitment through on-site visits effective immediately.** This will effectively stand down a large portion of active clinical research across our organizations.

This decision was not made without serious consideration to the impact on patient outcomes and is supported by evidence collected by the NSHA Research & Innovation Research Methods Unit. National guidelines do not provide clear direction on how randomized clinical trials will proceed under a public health emergency. We face supply-chain interruptions, high patient flow, infrastructure restraints, staffing shortages, and heavy demand on core services required for sustainable research operations. By providing this framework, we aim to deliver clarity, supports and consistency across programs and between our two health authorities that will ensure patient safety during this unprecedented time.

All the directives provided here have important caveats for life altering/saving research to continue and will be fully supported by NSHA and IWK. Patients receiving life altering/saving research medications will continue to receive their life altering/saving research intervention, but some of the protocol driven procedures (for example, central blood work, diagnostic imaging) may not be completed. Standard of care will not change.

Patient monitoring for interrupted studies will continue by telephone, email, or as directed by Sponsor. We remind teams contacting patients via telephone or email to uphold NSHA / IWK privacy policies pertaining to personal health information and use of NSHA / IWK -issued devices (as applicable).

The IWK and NSHA IM/IT teams are actively working on provision of other communication solutions such as virtual and telehealth visits. We will keep you updated on developments.

We recognize that delineating a "life-altering" study from "non-essential" is challenging. To address this problem, we will be creating a form through the ROMEO platform in the coming days to appropriately

capture the needs of our research community. The NSHA REB and IWK REB will review and consult with their respective Bioethics expertise, where appropriate on a case-by-case basis. Detailed instructions will be provided and supports put in place to ensure timely decisions.

- If NSHA investigators are uncertain whether or not their trial is life-altering/saving, contact: ResearchEthics@nshealth.ca
- If IWK investigators are uncertain whether or not their trial is life-altering/saving, contact: research@iwk.nshealth.ca

NSHA Researchers: For your research study to continue, it must be cleared by the NSHA REB and will be placed on an approved list that will be provided to NSHA Finance, Pharmacy, Laboratory Services, and Diagnostic Imaging. Unauthorized submissions to these services will not be processed and flagged for follow-up. Requests are to be submitted to NSHA REB via ROMEO for any changes from study protocol. While an online system is being put into place at NSHA, it is the expectation of NSHA Research & Innovation Senior Leadership that all research study visits cease immediately.

IWK Researchers: For your research study to continue, it must be cleared by the IWK REB and will be placed on an approved list that will be provided to IWK Finance, Pharmacy, Laboratory Services, and Diagnostic Imaging. Unauthorized submissions to these services will not be processed and flagged for follow-up. IWK Researchers wanting to submit a request for clearance of "life altering/saving" research can submit a request via the "Protocol Amendment" screen on ROMEO, please select "Yes" to the "COVID-19 LIFE-ALTERING STUDY" option. Until investigators receive approval from the IWK REB, it is the expectation of IWK Executive Leadership that all research study visits cease immediately.

NSHA and IWK Wet Lab Researchers: For NSHA and IWK wet lab investigators who are not approved for the conduct of COVID-19 specific protocols, you are required to use the Dalhousie issued Laboratory Ramp Down Checklist to document the suspension of your lab's activities and submit to respective research offices.

Guidelines for triaging clinical trials:

1. Placebo controlled, active comparator-controlled drug or natural health product: If these types of trials are 'add-on' therapy to current standard of care (SOC) and not life-altering/saving, when a study participant runs out of study medication they will not be re-supplied until the NSHA or IWK restriction of clinic visits is lifted. Protocol related telephone visits, or as instructed by Sponsor, can continue.

2. Open label drug or natural health product studies that are life-altering/saving will continue clinically, but the research component does not need to be included. Local safety labs that are SOC would monitor patient's response. Some of these studies are out-patient based, therefore the study medication would need to be dispensed. The study participant could be seen in the department clinic as part of urgent care. **No study participants will be seen in the Centre for Clinical Research for open label study medication resupply.**

3. Phase I and II studies will be conducted for research that are COVID-19 related or continued for studies that are life-saving/altering (suspending the trial will pose risks to the patient or there is no SOC for the ailment).

4. Emergency Department and ICU research will be suspended unless the research is related to COVID-19.

5. Device trials will only continue based on urgent SOC clinical visits that might otherwise pose risks to the patient. Routine monitoring on-study site visits will cease.

6. All non-Health Canada regulated interventional studies will suspend any institutional visits.

7. No screening or recruitment visits through on-site visits are permitted until further notice.

8. All observational studies will be suspended to ensure adequate resources for NSHA REB or IWK REB oversight and compliance enforcement.

REB Directive:

- The NSHA REB will continue with protocol reviews and processing through an emergency REB subcommittee and meetings will take place remotely via videoconferencing. NSHA REB will be operational on Mondays from 4:00-6:00pm or on an as-need basis ONLY to support **COVID-19 research and life-altering/saving protocols** and will work diligently, along with the researcher, to have a rapid approval.

- IWK REB will continue as per SOP 5.503 with prioritization given to **COVID-19 research and life-altering/saving protocols**. **Reminder:** IWK Researchers submitting **non**-life-altering/saving protocol amendment requests due to COVID-19 should do so via the "Protocol Amendment" screen on ROMEO, please select "Yes" to the "COVID-19 TEMPORARY PROTOCOL AMENDMENT". **Note:** Select "Yes", only if the requested amendment is to accommodate change in work environment due to the COVID-19 pandemic and we will prioritize your request.

Contact the NSHA REB office (ResearchEthics@nshealth.ca) or the IWK REB office (research@iwk.nshealth.ca) if you have questions as you are preparing an application for COVID-19 research.

Protocol deviations are expected at this time. Protocol violations relating to study suspension are **not** required by the REB at this time due to emergency priorities and will be requested at a later date for future reporting purposes.

Please communicate this information to Sponsors with a reminder there are no monitoring, site initiation, close-out, or sponsor audit visits allowed on-site until further notice. Additionally, the U.S. Food and Drug Administration (FDA) issued a guidance for industry, investigators, and institutional review boards conducting clinical trials during the coronavirus (COVID-19) pandemic.

Principal Investigators are directed to notify clinical research participants of their study status, monitoring plan, and care strategy within 48 hours.

We are committed to ensuring your teams are supported as we navigate this complex challenge together. Decisions will be reviewed on a bi-weekly basis and communication provided to the NSHA and IWK Research & Innovation communities.

There remain many unanswered questions relating to human resources, financial impact, and downstream operational sustainability. We are working closely with our Emergency Operations Centre and Executive Leadership Teams to respond to your questions in the coming days.

Thank you for the work you do and the passion you invest to improve the lives of others through research and innovation. We acknowledge this communication is disheartening in light of the important work you do. Please reach out to us should you require further supports or clarification as we implement these directives.