From: Wouters, Brad, **Sent:** March 19, 2020 10:17 AM
To: research-community-news@uhnresearch.ca**, Subject:** Clinical Research Update – REB

COVID-19 Update as of March 19, 10:15am

Purpose of today's message:

- Update for **clinical researchers** on the UHN Research Ethics Board (REB)
- Guidance for **clinical researchers** on COVID-19 related REB submissions

Other trusted resources:

- **COVID-19 Intranet page:** Visit for the most up-to-date information.
- **COVID-19 Research Intranet page**: Visit for information specifically related to research.
- **Additional questions?** Contact reb@uhnresearch.ca

Dear colleagues,

The UHN REB recognizes the significant impact the current emergency situation is having on clinical research at UHN, and the changes to the daily conduct and procedures in clinical research. We understand that many are concerned about the safety of their research participants and the risks to study integrity. In order to assist researchers with maintaining ethics approval during this emergency, the UHN REB has created the following guidance, which includes modifications to normal procedures.

Additionally, in order to give priority to essential clinical research and COVID-19 related research, the following procedures are being implemented to ensure that resources are available to continue ongoing ethics oversight of research involving humans.

If you have any questions about this guidance or require assistance with your specific situation, please contact the REB at reb@uhnresearch.ca

1) New Study Submissions:

The REB will prioritize new COVID-19 research, new essential clinical research studies, and study amendments due to COVID-19 measures. Other new studies and amendments should expect a longer than usual review time. **Please identify new COVID-19 studies by including "COVID-19" in the study nickname or study abstract field in the CAPCR system for appropriate triaging.**

2) Study Amendments due to COVID-19:

PIs are asked to review their current studies, and consider what changes, if any, are required due to the restrictions caused by COVID-19 restrictions.

If the change is only a pause in recruitment or other study activities AND there are no potential safety implications and no changes to the study, PIs are NOT required to notify the REB immediately but are requested to disclose this on their next renewal.

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Changes in approved research may not be initiated without UHN REB review and approval except where necessary to eliminate an apparent immediate risk to research participants. Changes to the study necessary to eliminate apparent immediate hazards/risks to participants may include:

- Changing from in-person visits to virtual;
- Change or elimination in study visits/procedures that do not impact the integrity of the study or participant safety – e.g., change to dispensing of study medications;
- Incorporation of screening questions to identify potential COVID-19 exposure. The incorporation of this screening procedure does not require UHN REB approval given that they are being utilized across UHN.

If a sponsor or investigator needs to make a change to a study in order to eliminate apparent immediate risks to participants, these changes can be made and then reported to the UHN REB as an amendment in a timely manner.

PIs should consider a "master/all in one" amendment that addresses the revisions via one submission per study. This will alleviate the REB burden by avoiding the submission of multiple amendments for each study. **Please identify the amendment as "COVID-19" in the description field in the CAPCR system for appropriate triaging.**

3) All submissions (studies, amendments) currently under review by the REB:

The REB will prioritize COVID-19 studies and amendments. In addition, studies that are deemed essential clinical research will continue to be reviewed. Other studies and amendments should expect a longer than usual review time.

4) All Studies:

Please continue to submit study renewals or closures as required for your study. This applies even if you have paused activities due to COVID-19.

5) Note that ALL submissions, including but not limited to, below MUST be submitted through CAPCR.

- Initial
- Amendments
- Renewal
- Protocol Deviations
- Adverse Events
- Requests for modified procedures

The REB cannot approve any requests outside of CAPCR (via email or by phone).