**REB guidance for research during the COVID-19 pandemic**

**A reminder:**

* All **essential** research activities as defined below can continue.
* No new studies can be initiated unless they are approved COVID-19 related research. BRI operations will provide notification of when all other new studies may commence.
* All **non-essential** research activities that involve in-person contact with clients, families, staff, trainees and volunteers should have been put on hold. All non-essential research activities that require you to be physically on-site at Holland Bloorview or in the community should be on hold.
* Amendments to continue conducting non-essential research activities that do not involve participants (e.g. data analysis) that can be conducted off-site are being accepted by the REB.
  + The amendment should include:
    - Data access mechanism i.e. Citrix, HB VPN
* Amendments to continue conducting non-essential research that involves direct contact with clients, families, staff, trainees and volunteers that can be done virtually (phone, zoom, etc.) are being accepted for review by the REB.
  + This amendment should describe:
    - the justification for continuing your research during this pandemic,
    - your plan to convert an in-person research activity to one that is conducted virtually,
    - the impact of this change on participant risk.

**Essential research activities** during the COVID-19 pandemic arethose activities which cannot be deferred or paused during this emergency as doing so would place participants at risk of harm. For example:

* + Regulated drug studies where a research participant needs to continue to receive active drug as part of the study/trial.
  + Clinical assessments to ensure patient safety
  + \* All COVID-19 directly related/funded research is considered essential

For currently enrolled participants, when determining which visits are essential, which may be deferred and which can be completed remotely, consider the following:

* + The underlying health of the participants (e.g. whether they are immune compromised etc.)
  + The type of clinical trial – investigational drug or devices vs observational surveys.
  + The type of visit – essential visits include treatment, drug reconciliation, safety testing.

**Considerations for conducting essential research activities:**

* Be sure to contact enrolled participants and advise them of any potential changes that affect their study participation.
* Where possible and practical, consider alternate visit methods, such as mailing out / emailing questionnaires, or conducting a visit by telephone or via Zoom. As always, be mindful of privacy and confidentiality concerns when using digital platforms.
* Suspend new recruitment for any studies that cannot adhere to physical distancing (e.g. studies involving active interventions, in-hospital visits, etc.) and defer initiation of any new studies unless approved COVID-19 related research.
* Consult the study sponsor regarding any protocol changes and submit amendments to the REB for review and approval.
* Ensure communication to Pharmacy/Labs and other support services in case of visit schedule changes.
* Evaluate study supplies and/equipment
* Contact sponsors to ensure adequate supply of investigational products and, study kits.
* Communicate with pharmacy if there are any changes to shipping or supply requirements
* Ensure you have a back-up and delegation for signing authority and decision-making.

**Non-essential but permissible research activities** during the COVID-19 pandemic are those activities that can be conducted virtually provided they comply with the current requirement of physical distancing. For example:

* + Conducting interviews by phone or Zoom instead of in person. Other permissible activities include data analyses, literature reviews, manuscript writing.

For currently enrolled participants, when determining which non-essential research activities can continue, consider the following:

* the nature of the protocol,
* the type of participants engaged in the research,
* any additional risk that may arise by delaying visits or switching them from in person-to virtual communication (e.g. privacy concerns).
* \*A reminder that no storage of research data on personal computers is permitted due to the increased risk of release of personal health information (PHI) and/or a data breach.
* No unsecured public Wi-Fi may be used when conducting research activities of any kind.

**Temporary Changes to REB Approved Human Subjects Research Activities during the COVID-19 Publicly Declared Emergency**

* While TCPS2 typically requires review and approval of modifications prior to implementation, an exception can be made where the change is necessary to eliminate an immediate risk to participant(s) (Article 6.15). Such changes may be implemented but must be reported to the REB at the earliest opportunity (within 5 business days as a guide).
* Similarly, studies that must comply with the US federal regulations require that the REB review any revision to the protocol before they are implemented except in cases, “where necessary to eliminate apparent immediate hazards to the human subjects.” 21 CFR 56.108(a)(4).
* If you are carrying out any temporary changes to approved study procedures as a result of the publicly declared emergency please submit for approval a Study Amendment form prior to making the change, or a Protocol Deviation form found on our webpage at [HB REB Website](https://www.hollandbloorview.ca/research-education/bloorview-research-institute/research-ethics-board).
* Regulated Studies:
  + Notification to the sponsor of the study where applicable is required. This is the responsibility of the investigator.
  + Health Canada Regulated studies may ship investigational products directly to the participants home provided that participants can take the drug on their own and without medical supervision or in a clinical setting. Please refer to the link below for further information: [Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/management-clinical-trials-during-covid-19-pandemic.html)

**Research Ethics Office and REB Operations during the COVID-19 Publicly Declared Emergency**

* The Research Ethics Office will continue to review submissions, however, no **new** study approvals will be issued with the exception of COVID-19 related submissions
* REB review will be prioritized for: COVID-19 related submissions, including amendments, consent form changes, staff changes, amendments to virtual contact, etc.
* If you are planning to submit a **new** protocol related to COVID-19 please email Marie Steele ([msteele@Hollandbloorview.ca](mailto:msteele@Hollandbloorview.ca)) to ensure that the submission is appropriately triaged. For all other REB correspondence and non-COVID-19 research submissions please submit electronically to either Marie Steele ( [msteele@Hollandbloorview.ca](mailto:msteele@Hollandbloorview.ca)) or Alisa Dermawan ([adermawan@hollandbloorview.ca](mailto:adermawan@hollandbloorview.ca)). This includes new applications, renewals, amendments, staff changes, SAEs, protocol deviations.
* Further information and guidance can be found on our webpage at: [HB REB Website](https://www.hollandbloorview.ca/research-education/bloorview-research-institute/research-ethics-board).