Effective Date: Wednesday March 25, 2020

COVID-19: FAQs

Guidance for clinical research in the context of COVID-19:

All non-essential clinical research activity should be reduced (see guidance below).

Refer back often- this page will be updated as required

Sunnybrook research ethics oversight activities are continuing primarily remotely, with modified procedures as per SOP 501.

Changes in approved research may not be initiated without REB approval except where to eliminate an immediate hazard/risk to participants. COVID-19 presents an immediate hazard/risk. Refer to FAQs below for guidance:

Do NOT submit paper applications to the Research Ethics Office

- All **new essential initial submissions** MUST be submitted through **SunRISE**
- Studies submitted through **SunRISE** should continue through **SunRISE**
- Ongoing studies previously submitted via paper (including renewals, amendments, notifications, ongoing communications, internal SAEs, change in Principal Investigator forms), should be **submitted by email** to:
    - Monica Hung: monica.hung@sunnybrook.ca
    - Catherine Parry: catherine.parry@sunnybrook.ca
- Include in the subject line: **REB#, PI Name, Type of submission**

How should I reduce non-essential clinical research activity?

Continuity of participant care, participant safety and consideration for demand on hospital and operational resources are paramount.

When making decisions to reduce activity consider the following:

1. defer submission of new studies (e.g. to CCTS, REB, Legal, Study Impact review etc.)
2. pause initiation/activation of new studies
3. pause recruitment to active studies
4. limit in-person visits for ongoing studies to treatment, safety, critical endpoint visits
5. where possible and practical, consider alternate visit method (e.g. mail outs, telephone, digital platform while mindful of privacy and confidentiality concerns)
6. consult study sponsors regarding any protocol changes
7. communicate plans to pharmacy/labs/impacted areas

8. contact enrolled participants and advise them of any potential changes that affect their study participation
9. notify the REB of record of deviations, amendments and closures (as per the REB of record SOPs/direction)
10. **REMEMBER** - ALL external sponsor site and monitoring visits MUST BE SUSPENDED until further notice.

Which essential clinical research is allowed to continue and will it be prioritized?

Essential clinical research includes the following and will be prioritized:

1. COVID-19 directly related/funded research
2. Clinical research studies that are part **of essential clinical care** (e.g where the investigational product/intervention is the treatment).
3. Clinical assessments/study visits to ensure patient safety.

What if I am unsure as to whether a clinical research study is considered essential?

Principal Investigators should seek clarification from their applicable Program Research Director/Platform Director, and if necessary discuss with Dr. Kullervo Hynynen, Vice President Research and Innovation.

If my study is deemed non-essential, are there any exceptions?

Exceptions can be requested and need the approval of the PI's platform director and the VP Research and Innovation.

Should I be submitting the Clinical Research Pandemic Planner?

1. It is important to keep your Clinical Research Pandemic Planners up to date. Planners should be modified regularly as the situation changes.
2. Notify keitha.mcmurray@sunnybrook.ca when a study is placed on hold to accrual
3. Notify the REB of record for reportable events, amendments, closures.

Should on-site sponsor monitoring and other on-site visits continue?

No. External sponsor visits, including site initiation visits, monitoring visits, close-out visits etc. MUST be postponed until further notice. External monitors are not permitted to come to Sunnybrook until further notice. Sponsors are encouraged to work with our teams to perform remote monitoring and data management review where feasible.

Should research personnel be screening patients?

Research personnel involved with scheduling patient/participant visits MUST follow hospital screening procedures and cancel/postpone visits where necessary. Refer to Sunnynet for instructions and updates:

- All updates: http://sunnynet.ca/Default.aspx?cid=129909&lang=1(opens in a new window)
- For screening resources and posters: http://sunnynet.ca/Default.aspx?cid=129919&lang=1(opens in a new window)

For studies that include home visits, should the home visits still continue?

No, home visits should not continue. See below for further information on required protocol modifications.

Studies that are placed on hold to accrual for operational/workload reasons:

1. Should be reported institutionally to keitha.mcmurray@sunnybrook.ca
2. Do not require notification to the REB of record
3. Site teams should update their pandemic planner as decisions are made
4. At time of next scheduled continuing review/renewal, make note of this action in the submission to the REB

Protocol modifications that involve changing in person visits/assessments to remote phone or telemedicine assessments:

1. May be implemented prior to notifying the REB of record
2. Notify the REB of record in a timely manner and as soon as there is sufficient information to provide to the REB
3. See our REB templates for guidance

Protocol modifications that are temporary in nature due to demand on resources, and do not affect participant safety and data integrity (e.g. not performing certain tests; changing visit timelines):

1. Obtain written approval/directive from the sponsor for modified plan
2. If no sponsor is involved, contact the REB of record for direction
3. Notify the REB of record of the modified plan. This can be in the form of standard submission processes, or could be a memo, letter or email as long as it provides sufficient information for the REB to make an ethical determination.
4. We also have tools/templates that can be used to submit to the REB
5. It is the sponsor's responsibility to determine whether an amendment or notification to Health Canada is required

Protocol deviations and changes that affect patient safety and/or data integrity:

1. Deviations made in order to eliminate an immediate hazard may be done prior to REB approval, however, the REB of record must be notified as soon as possible (within 5 days)

2. All other changes to the conduct of the study must receive written approval/direction from the sponsor AND should be submitted as an amendment to the REB of record for approval PRIOR to implementation
3. Re-consent is not required unless the change fundamentally alters what the participants previously consented to. If participants need to know about the change, then this should be done in the least burdensome route and should be supported by documentation of the process (e.g. verbal, email, discussion documented, photo of signature etc.).
4. Consideration must be given to the potential harms versus benefits of continuing both ongoing and new study activities

FDA Guidance:

The guidance is intended to provide general considerations to assist in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity during the COVID-19 pandemic

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic(opens in a new window)

Is it safe to handle human biological specimens in the context of COVID-19?

Biological specimen handling MUST always comply with biosafety standards. Sunnybrook is taking an inventory of current practices, specimen types and processing locations to ensure safe practices are in place.

- Questions should be directed to SRI's Biosafety Officer kkathir@sri.utoronto.ca .

All other questions can be directed to: Keitha McMurray, Executive Director Research Integrity and Clinical Research Services keitha.mcmurray@sunnybrook.ca