THE UNIVERSITY OF BRITISH COLUMBIA

UBC Clinical Research Ethics Office
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UBC CREB Bulletin #1

Dear Clinical Research Staff and Investigators

In addition to information you have been receiving from VCH and PHC regardnig the COVID19 pandemic, Advisory on clinical trials and clinical research operations at Vancouver, we would like to briefly inform you of the following:

- The REB will **continue to review** new protocols and work with PIs to bring them to a state of readiness

- No studies involving **in-person interaction** with participants will receive a Certificate of Approval and recruitment may **not** begin until further notice (exceptions may be made in special situations, such as research involving COVID-19 infection)

- New studies that do not involve any in-person interaction with participants may be **approved** on a case-by-case basis, depending in part on hospital and VCH / PHC considerations, as well as risk to researchers,

- Ongoing studies that involve in-person interaction with research participants should **not** be **recruiting** new participants into the study unless the PI determines that the potential benefit to participants outweighs the risk to the individual and family members, and the risk to research staff is minimized. In such cases, the researcher will need to weigh the possible risk of exposure to COVID-19 virus against the possible benefit to the participant. If there is any doubt regarding a given study, please contact the REB and we will offer the PI advice regarding who best to consult to make this decision.

- Ongoing studies that involve research-related in person interaction should reschedule all non-urgent in-person study visits and procedures.

- Ongoing studies include some clinical trials that require important safety monitoring and/or patient visits that are critical to the participant's clinical care; researchers must use good judgement and consider the level at which this is appropriate for each protocol and patient participant. If the researcher believes that it is in the best interest of the participant to attend the clinic for research-related procedures, this should be

discussed with the participant/family so that they can make an informed decision regarding the visit. As noted in the recent post form the RESEARCH FAQS RELATING TO COVID-19

Where in-person participant contact cannot be modified, delayed or eliminated, because they are critical to the participant's care, we recommend that study-related personnel call each study participant prior to their visit. Specifically, please ask the participant the following:

- *Have they recently travelled outside of Canada?*
- *Do they have the following symptoms: cough, sneezing, fever, sore throat or difficulty breathing?*
- *Have they been in close contact with a sick person, especially if they had a fever, cough or difficulty breathing?*

If they respond with a yes to any of these questions, please consider rescheduling their study visit. Following this pre-screening, some participants may require additional screening at the site to ensure that they are symptom-free and provide appropriate advice for isolation or testing if necessary.

- While immediate modifications to study procedures typically require research ethics board review and approval prior to implementation, an exception can be made where the change is **necessary to eliminate an immediate risk to participants** [TCPS2 Article 6.15]. Therefore, such changes may be implemented immediately but are to be reported to the REB at the earliest opportunity (ideally within 5 business days). For clinical trials regulated by the US Department of Health and Human Services (DHHS) and where REBs are subject to the Code of Federal Regulations, the exception to prior REB approval before implementation of an amendment to study procedures/protocol is "where necessary to eliminate apparent immediate hazards to the human subjects" [21 CFR 56.108(a)(4)].

- With regards to clinical trial protocol deviations, Article 3 of the UBC Guidance notes states that it is the responsibility of the Principal Investigator to notify the applicable UBC REB of all protocol deviations that:
    1. Expose subjects to potential increased risk
    2. Compromise the integrity of the entire study
    3. Are repetitive in nature
    4. Alter subject eligibility or
    5. Affect the privacy of the subject

  More here: https://ethics.research.ubc.ca/clinical-research-ethics/creb-guidance-notes/post-approval-guidance-notes#deviations

- We ask that any Post Approval Activities (PAAs) or e-mails sent to 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.

Please be aware that, as the current situation is very fluid, these interim policies may well change, and we will update you as necessary in future bulletins. Should you have any questions about these policies or other issues, please do not hesitate to contact Pia Ganz, CREB manager at Pia.Ganz@ors.ubc.ca

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