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CIRB Updates: Submissions and Notifications during COVID-19 situation

7th April 2020

The following are important clarification on CIRB's requirements during COVID-19 situation: i) changes to the research protocol that require CIRB's review and approval prior to implementation, ii) the reporting of Protocol Deviation/Non-compliance and Local Serious Adverse Event [28-Apr-2020] and other frequently asked questions.

(A) Changes to Research Protocols

All changes to research protocols need to be reviewed and approved by CIRB with some exceptions. If Principal Investigator is uncertain whether a change requires CIRB's approval prior to implementation, please contact CIRB immediately.

1. Changes to eliminate an immediate hazard to research participants

If there is a need for immediate action to eliminate immediate hazard to research participant, the Principal Investigator may make the change first before obtaining CIRB's approval. The PI is responsible for making the assessment that there is a need for immediate action to protect the safety and welfare of the research participants, [28-Apr-2020] e.g. direct investigational product delivery to patients, follow-up through phone call or survey. As the COVID-19 situation is uncertain, Principal Investigator should make plan to submit amendments to include the additional research activities which are required during the COVID-19 situation, refer to Point 3 below.

Nonetheless, Protocol Deviation Report Form should be submitted to CIRB at the earliest possible but no more than 14 calendar days. The nature of the event should be described in detail.

2. Incorporation of mandatory screening for COVID-19 of research participants

This does not require amendments to the protocol nor CIRB's approval. Researchers are to follow the Institutions' guidance. All study teams should implement procedures to screen research participants for potential infectious risk prior to scheduled study visits.

3. Replacing in-person visits with remote visits (e.g. phone/video call, internet-based video technology)

All changes to research procedures (including process of obtaining informed consent) require CIRB's review and approval prior to implementation, except those that are necessary to eliminate an immediate apparent hazard to participants.

When submitting an amendment, Principal Investigator should add the option to perform research remotely during COVID-19 situation and include that once in-person visit is allowed again, the study will return to previously approved procedures. This will eliminate the need to submit another amendment when normal study activities resume.

Please include the following in amendment, where applicable:

- Potential impact on subject safety and protections
- Potential privacy and confidentiality concerns
- Plan for how existing subjects will be notified
- Telephone script
- Explain how recordings are to be made remotely
- Any other information to support the remote visits

(B) Reporting of Protocol Deviation/Non-compliance (PD/NC) and Local Serious Adverse Event (LSAE)

To protect the safety and welfare of research participants, there is no change to the reporting of PD/NC and LSAE to CIRB during COVID-19 situation.

(C) Notification of Study Suspension of any part of the study (e.g. new recruitment, in-person visits) to CIRB

Non-therapeutic study: If the research is a non-therapeutic study where the temporary suspension would not impact the safety or welfare of research participants and the suspension is in accordance to the Institutions guidance and advisory, notification to the CIRB is not required. However, this should be documented in the study file and this information should be included in [28-APR-2020]question 3(h) of the Study Renewal Report at the time of requesting for renewal of CIRB approval. This is an exception to the reporting procedure of suspension during COVID-19 situation.

Therapeutic study: If the study is therapeutic, Principal Investigator need to notify CIRB of the suspension and include information on contingency planning related to interruption or changes in investigational product and/or safety monitoring. [28-Apr-2020] The notification should be submitted using the "Other Reportable Event Form" in iSHaRe and submit "CIRB Amendment Form" by updating the applicable questions in Section F (e.g. question F10) if necessary. Therapeutic study refers to study involving investigational products. Principal Investigator should take note of the "Guidance on the Conduct of Clinical Trials in relation to the COVID-19 situation" by H.S.A.

(D) CIRB Review Timeline during COVID-19 Situation [28-Apr-2020]

There is no change to the CIRB Review Timeline. Please refer to CIRB website for the Full Board Meetings schedule. For enquiries on whether there will be additional Full Board Meetings, CIRB will assess the need based on the submitted applications. The additional Full Board Meetings will only be arranged on a need basis.

For COVID-19 related studies, in particular on investigation of new treatments for COVID-19, CIRB will assess if an application/amendment needs to be prioritized. We encourage researchers to submit the applications/amendments with complete and sufficient detailed information and documents on iSHaRe once you are ready. CIRB may contact the research team to discuss timelines if there is a need. We advise researchers not to enquire on the review timeline as CIRB will only be able to assess when the study details are available. This will help CIRB to focus on the more urgent enquiries and request for support by researchers during this period. We seek your understanding in this. If any COVID-19 related application/amendments require CIRB's immediate attention, you may email the board secretariat (see question B3(i) of the CIRB Application/Amendment Form to check the submission board) by providing the CIRB Reference Number of the application or amendment submitted and inform CIRB the reasons that the submissions need to be prioritized.

For amendments submitted to manage the COVID-19 situation, CIRB will also prioritise the review as much as we can.

(E) Does CIRB review non-COVID19 related studies during COVID-19 situation? [28-Apr-2020]

There is no change to the type of studies that CIRB will review during this period. However, CIRB may prioritise the review of COVID-19 related studies/amendments. Hence, the review of non-COVID-19 studies may take longer. Your understanding will be much appreciated.

(F) Can I continue with my study if SDOT has approved the continuation during COVID-19 situation? [28-Apr-2020]

Yes, you can continue with your study if you have received SDOT's approval. If changes to the research protocol are needed, please refer to Section A.

If SDOT has rejected your application for the continuation during the COVID-19, the research activities should be suspended. Please refer to Section C on the notification to CIRB.

The CIRB staff are working remotely and continue to operate as usual. If you have any questions, please contact CIRB at irb@singhealth.com.sg.For study-specific enquiries, please contact the board secretariats through the following emails:

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A	Chia Joo Yi	chia.joo.yi@singhealth.com.sg
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