SingHealth
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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 and ii) the reporting of Protocol Deviation/Non-compliance and Local Serious Adverse Event.

(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.

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 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. 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.

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.