SingHealth
Defining Tomorrow's Medicine

CIRB Updates

Note: All the documents and templates mentioned in this updates can be downloaded from RICE website, click here.

1. Reporting Timeline for Protocol Deviation and Non-compliance

With immediate effect, protocol deviation and non-compliance should be reported to CIRB immediately. All questions in the Protocol Deviation/Non-compliance Report Form should be completed, particularly the corrective action and preventive action. This will allow Office of Research Integrity, Compliance and Ethics (RICE) sufficient time to notify MOH within 7 calendar days under the Human Biomedical Research Regulations Section 8(3) should the event needs to be reported.

2. Removal of requirement to submit translated documents

Translated documents (e.g. consent documents, questionnaire, survey forms) do not need to be submitted for review prior to use, unless specifically required by CIRB. Study team should track the use of the translated documents and the various versions in the investigator/study file using a tracking log. Certification of translation should also be filed in the investigator file.

3. Revised Participant Information Sheet and Consent Form Template

Administrative changes have been included in the Participant Information Sheet and Consent Form template version 12.1. Please refer to the summary of changes and always prepare the consent document using the latest template for a new study. Guidance on the requirements for informed consent document is also available on the CIRB website.

For the existing approved informed consent form that meets the HBRA section 12 or ICH-GCP elements of informed consent, there is no need to update the informed consent to align with the revised template.

4. Additional/Extra Human Tissue Collection

Collection of additional or extra human tissue not for the proposed research should be excluded from new application submitted to CIRB. Such collection should be conducted under a Tissue Bank and using the Tissue Bank's consent document.

CIRB will only review the human tissue required for the proposed research. For new application that are submitted on or after 1 Nov 2020 which include such collection, CIRB will return the application form for it to be removed.

For on-going studies that approved before 1 Nov 2020 which includes such collection, study team should identify a Tissue Bank for such collection. It will be a contravention under the Human Tissue Framework if such collection is not conducted under a Tissue Bank. The study team may contact

singhealthtissuebank@singhealth.com.sg for any enquiry and refer to RICE Newsletter no. 11 for details.

If you have any questions, please contact CIRB at irb@singhealth.com.sg