SingHealth
*Defining Tomorrow's Medicine*

# CIRB Updates

## 1. Study Closure for Exemption Study

Exemption Study refers to study where the application was made via CIRB Exemption Application Form and approved by the CIRB.

Currently, there is no mandatory requirement to submit Study Closure Report Form for the Exemption Study. Moving forward, it is mandatory to submit the Study Closure Report Form to update CIRB of the study status upon study completion, withdrawal or termination.

For Exemption Study approved via hardcopy, CIRB deemed all the Exemption Studies have been completed or closed. Any on-going Exemption Study where the exemption falls under categories 1-6 will be required to re-apply as a new CIRB exemption application on iSHaRe.

For Exemption Study approved on iSHaRe, Principal Investigator should submit the Study Closure Report Form upon study completion, withdrawal or termination.

## 2. Assessment of the Suitability of the Research Site by Department Representative/HOD and Institution Representative

The Department Representative and Institution Representative are reminded to assess the suitability of the research site for the proposed research. If research activities will also be carried out at non-SingHealth sites (e.g. nursing home), the assessment of site's suitability should be done as well. The Department Representative should indicate the suitability in the following question found in the checklist and the checklist should be reviewed by the Institution Representative during endorsement.

| Checklist | Department Representative Endorsement Checklist |
|---|---|
| Question 5 | Is the Principal Investigator's environment suited to conduct the study? Is there an adequate patient pool and are there adequate resources? Yes or No.<br><br>*Department Representative may also include any comments in the Comments box available on the Checklist.* |

## 3. Revamped Participant Information Sheet and Consent Form Template

CIRB has revamped the Participant Information Sheet and Consent Form Template. Version 12 of the template should be used for all new applications.

For existing approved studies, there is no need to revise the approved consent documents. If your application is already pending check by your research office or pending Department Representative or Institution Representative's endorsements, CIRB will review the consent document based on the previous template. All new applications submitted from 1 July 2020 onwards should use the revised template except for studies where study sponsor's template will be used.

Guidelines have been developed to assist you in designing the consent document. Please read the guidelines before working on any consent document for a new application. The revamped template and guidelines are available on CIRB website.

**4. iSHaRe Enhancement – Form Changes**

Changes to the CIRB Application/Amendment Form and Study Closure Report Form will be rolled out during the system maintenance on 22 May 2020. The updated sections are:

CIRB Application/Amendment Form

4.1 Selection of Application Form – Question 2 has been added to replace the manual upload of Type of Study Determination Form and Restricted Human Biomedical Research Form, if applicable.

4.2 Section P – Question P3(iv) has been added. Study team should indicate whether consent will be obtained in the presence of witness.

4.3 Section Q –There are options available for waiver of consent. Study team should select the waiver option(s) that is applicable for the application and provide the necessary justification and supporting documents.

4.4 Section S – If the study involves collection and/or use of biological samples, there should be a plan on how to manage and store the samples – such as involving tissue bank. The plan should be part of the study design and should not be decided only at the end of study. Study team is reminded to comply with Human Tissue Framework under Human Biomedical Research Act (HBRA), if applicable.

Study Closure Report Form

4.5 Question (l) has been added. Information on how left over samples will be managed should be provided during the submission of Study Closure Report Form.

More details can be found in the "iSHaRe Enhancement – Form Changes" slides on CIRB website.

**Action required for all approved and on-going studies:**

For approved and on-going studies, Question 2 (abovementioned 4.1) will appear when a new amendment is created after 22 May 2020. For studies where the Type of Study Determination Form have been submitted previously, study team should complete Question 2 in accordance to the submitted Form and there should not be any changes from the Form that was submitted.

For studies where the Form have not been submitted, Principal Investigator should make the determination and complete Question 2. Please do not rush to submit an amendment just to complete Question 2. We recommend that Question 2 to be completed when there are other amendments to be made to the study.

If there are no changes to the study, all on-going studies that will continue beyond 31 Oct 2020 will be required to submit an amendment to complete Question 2 by 31 Oct 2020.

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## 5. Reporting Requirement and Timeline for Serious Adverse Events (SAE)

The reporting requirements and timeline for SAE document have been updated. The updated document is available on CIRB website. The reporting timeline has been updated to align with the Human Biomedical Research Act's requirements. Kindly read the "Important Note" and "Definitions". A Non-Local SAE Reporting Form (new) is also available for download on CIRB website. This form may be used for reporting of Non-Local SAE if there is no other format available (e.g. CIOMS).

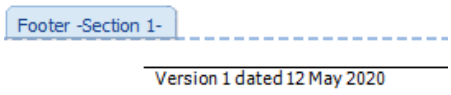
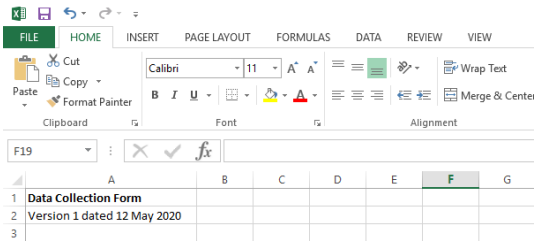
The updated requirement and timeline is to be implemented with immediate effect. SAEs that occur from 19 May 2020 should follow the updated requirements and timeline.

## 6. Study Expiry Reminder Notifications

Currently, Study Expiry Reminder Notifications are sent 90 days, 60 days and 14 days before the study expire. Despite these reminders, there are still studies that failed to renew before the expiry date. CIRB will be changing the notification frequency to 90 days, 60 days and 30 days before study expiry. The change will be made during iSHaRe system maintenance in June 2020.

## 7. Removal of Version Number and Version Date from the Attachment Upload Component on iSHaRe

To minimise the administrative update required by the study team to tally the information, CIRB will be removing the Version Number and Version Date from the attachment upload component on iSHaRe. However, ALL the study documents must have appropriate and adequate version control. The Version Number and/or Version Date should be indicated. Please refer to the examples.

| Example in MS Word at document footer | Example in MS Excel at top row |
|---|---|
|  |  |





Both the Version Number and Version Date columns in the Study Workspace will also be removed. The changes will be applied during the system maintenance in June 2020.

Please be reminded that obsolete document should be removed when a revised document is submitted. A revised document is to replace the previous version. To facilitate review, a clean and tracked change of the revised document should be submitted.

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