

e-CIRB Quick Reference Guide: Study Renewal Report Form

1. General Information

- a) The study renewal report form will be available on iSHaRe e-CIRB from 3 July 2015. For studies submitted and approved through e-CIRB, study renewal must be submitted using the online study renewal report form.
- b) It is the responsibility of the Principal Investigator (PI) to keep track of expiring studies.
- c) Submission of the study renewal report form is allowed only 90 days prior to the valid till date of the study.
- d) The study renewal report form is to be submitted at least 2 months before the expiry of ethics approval for the study.
- e) At any one time, only one study renewal report form can be created.
- f) Only the PI is able to submit the study renewal report form.
- g) Study renewal reminder email and system notifications will be sent out via iSHaRe to remind of impending study expiry. These email and system notifications will only be sent to the person who is listed as the PI, Site PI and Protocol Administrator (PA) on the CIRB Application Form. The following email and system notifications are sent out automatically by iSHaRe:
 - Study Expiry Reminder – 90 days prior to expiry of ethics approval
 - Study Expiry 2nd Reminder – 60 days prior to expiry of ethics approval
 - Study Expiry Notification – 14 days prior to expiry of ethics approval
 As long as the study renewal report form is not submitted to CIRB, the email and system notifications will continue to be sent.
- h) For study closure, please contact CIRB at irb@singhealth.com.sg.

1.1. Differences between the hardcopy Study Status Report Form and online Study Study Renewal Report Form

| Study Status Report Form (Hardcopy) | Study Renewal Report Form (Online) |
|---|---|
| Use for renewal of approval, study termination and study completion that have been approved in paper format. | Use for renewal of approval that have been approved in e-CIRB. |
| Study renewal reminders are sent by CIRB administrative assistant or Secretariat. | Study renewal reminders are sent out via email and system notifications generated by iSHaRe e-CIRB. |
| Study status to be reported. | Status for each site, where applicable, to be reported. |
| Both Section i – For studies involving participants recruitment and Section ii – For studies involving the use of human biological samples/records <u>ONLY</u> are available on the form. | Section i – For studies involving participants recruitment and Section ii – For studies involving the use of human biological samples/records <u>ONLY</u> is available depending on the selections in Section D1 of the application form. |

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| | <ul style="list-style-type: none"> - If “Clinical Trials” or “Questionnaire/ Survey/ Interviews” is selected, Section i will be displayed. - If “Medical Records Review” is selected, Section ii will be displayed - If “Clinical Research” is selected, both Section i and ii will be displayed. |
| <p>Changes to conflict of interest require the completion and submission of Annex B – Conflict of Interest Declaration Form for each individual having the conflict.</p> | <p>Changes to the conflict of interest require completion and submission of an amendment to Section C of the application form.</p> |

2. Getting Started

2.1. Check validity of the ethics approval

Steps:

1. Validity of the study’s ethics approval is as indicated by the “Valid Till Date”. It can be found in a) the “My Studies” listing and b) the “Study Workspace”.

My Studies

- At the dashboard, click “My Studies”.

Study Workspace

- Click “My Studies”, locate the reference number of the study and click on any of the blue hyperlinks.

Note: The “Valid Till Date” will also be displayed in the study information header in the study renewal report form, if it is created.

2.2. Create and submit a study renewal report form

Steps:

1. Initiation of a study renewal report form is available via a) the shortcuts on the dashboard or b) the “Study Workspace”.

Shortcuts on the dashboard

- Under shortcuts, click “CIRB”. Studies available for renewal of ethics approval will be displayed. Select the study you wish to renew ethics approval.

Study Workspace

- Click “My Studies”, locate the reference number of the study you wish to renew ethics approval. Click on any of the blue hyperlinks. At the study workspace, click on the “Study Renewal Report” link.

2. All data fields are to be filled where appropriate except for the institution and proposed recruitment target/ target which are auto-populated from the last approved application form or amendment form.
Note: Remember to save periodically by clicking on the save icon () when filling up, navigating out or exiting the study renewal report form.
3. To finalise the study renewal report form, click on the finalise icon ().
4. Upon finalisation, user will be prompted if mandatory questions are not filled. This is indicated by a pop-up box and an indicator () beside the relevant question.
5. While Study Team Members (STMs) and PAs are allowed to assist in the filling up of the study renewal report form, only the PI is allowed to submit the form to CIRB. After finalisation, this will appear as a pending task (i.e. Pending PI Declaration) in the PI's "My Task" for the PI's review, declaration and submission
6. If the PI is the one creating the study renewal report form, he/she may proceed to declare after finalisation by clicking on PI Declaration icon () and submit the form to CIRB.

2.3. Returned study renewal report form from the Secretariats

Once the study renewal report form has been submitted to CIRB, the Secretariats will review the form for accuracy and completeness. If the Secretariats require amendments to the submitted form, they will return it to the PI and inform the study team via email. This will appear as a pending task (i.e. Pending PI Reply) in the PI's "My Task". The PI can amend the form or delegate the role to his/her STMs or PAs. Similarly, while the STMs or PAs are allowed to assist in the making the changes, only the PI is allowed to submit the form to CIRB. After finalisation, this will appear as a pending task (i.e. Pending PI Submit) in the PI's "My Task" for the PI's review and submission. This can be done by clicking on submit to CIRB icon ().

3. Contact Us

If you have any queries, please contact irb@singhealth.com.sg.