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CIRB Updates

15 September 2023

The CIRB Updates cover the following:

1. Revised CIRB Review Fee for Industry Sponsored Studies
2. Management of IRB Study Documents in iSHaRe
3. IRB Renewal and Extension of Validity Period
4. Minimum Training Requirements

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1. Revised CIRB Review Fees for Industry Sponsored Studies

The review fees for new research applications will be revised as follows from 1st Apr 2024:

Initial Application review involving Single Cluster institution(s) - S$3,000
Initial Application review involving Cross Cluster institution(s) - S$4,000

The fees for the following remain unchanged:

Amendment - S$200
Addition of the first cross-cluster site - S$1,000
Study renewal - S$1,000

The fees are subject to prevailing GST.

2. Preparation for Migration from iSHaRe to ECOS

A new IT system "Ethics and Compliance Online System" (ECOS) will be launched in the first quarter of FY2024, and it will replace the iSHaRe IRB module. In addition, ECOS also has i) quality module for audit and monitoring, ii) compliance module for PI self-assessment submission and reporting to Research Institution Secretariat for submission to MOH and iii) Clinical Research Management System (CRMS). More information on ECOS and the detailed implementation timeline will be shared closer to the launch.

a) Study Documents Management

Regulations and guidelines require study team to keep a copy of all submitted documents and a copy of IRB decision letter in their study file as record. Principal Investigators and study team are reminded to download and save a copy of your study related documents from iSHaRe, as soon as possible, before the iSHaRe IRB module is decommissioned following the launch of ECOS. Please note that only on-going studies (i.e. study status is Approved) will be migrated to ECOS. Studies of other study status will not be migrated and will become inaccessible once migration to ECOS is completed.

b) Study Closure

For studies that are completed or terminated, please submit a study closure report in iSHaRe at the earliest possible moment to close the studies. These include studies approved under the exemption categories.

c) Submission of New Application

We would like to encourage all new IRB applications to be submitted (i.e. reached CIRB when IR(s) completed the endorsement) by 1st Feb 2024. This is to allow the CIRB to complete the review of the submissions before the shutdown of iSHaRe IRB module. After 1st Feb 2024, any new applications are to be submitted in ECOS when is available and a longer review turnaround time is anticipated to complete the review. We seek your support and thank you in advance for the early submissions to enable a smooth transition.

d) Submission of Other Forms

To ensure sufficient time is allocated for data migration from iSHaRe to ECOS, all submissions shall observe the following cut-off dates and submission process while waiting for the ECOS to be implemented:

No	Form Types	Submission Process
i)	Amendment	All required amendments to be submitted via iSHaRe by 1st Feb 2024. Thereafter, please submit the amendment in ECOS when the system is launched.
ii)	Local SAE Report Form	For the submission of Local SAE Report Form: - Submission via iSHaRe must reach CIRB by 15th Mar 2024. - From 16th Mar 2024 until further notice, please submit the Local SAE Reporting Form to the relevant IRB secretariat via email. The template will be made available on the CIRB website by 15th Mar 2024.
iii)	Protocol Deviation/Non-Compliance Report Form	For the submission of Local Protocol Deviation/ Non-Compliance Report Form: - Submission via iSHaRe must reach CIRB by 15th Mar 2024. - From 16th Mar 2024 until further notice, please submit the Protocol Deviation/ Non-Compliance Report Form to the relevant IRB secretariat via email. The template will be made available on the CIRB website by 15th Mar 2024.

iv)	Other Reportable Event Report Form	For the submission of Other Reportable Event Report Form: - Submission via iSHaRe must reach CIRB by 15th Mar 2024. - From 16th Mar 2024 until further notice, please submit the Other Reportable Event Report or any notification to the relevant IRB secretariat via email. However, you may be asked to hold on to the submission to be submitted through ECOS instead.
v)	Study Closure Report Form	For the submission of Study Closure Report Form: - Submission via iSHaRe must reach CIRB by 15th Mar 2024. - Form 16th Mar 2024 until further notice, please notify the relevant IRB secretariat of the closure of the study via email. You will need to submit the study closure report in ECOS when it is launched.
vi)	Study Renewal Report Form and Study Reactivation Report Form	For Study Renewal Report Form, no submission is expected during the transition period. Please refer to paragraph 3 below. The CIRB will not accept any study reactivation request after 1st Feb 2024.

3. IRB Renewal and Extension of Validity Period

For studies with Valid Till Date before 15th Feb 2024 that require renewal, please submit the Study Renewal Report Form as soon as you receive the 1st reminder. Otherwise, please submit a Study Closure Report Form if the study has been completed or terminated.

In preparation for migration of study information from iSHaRe to ECOS, studies with Valid Till Date between 15th Feb 2024 and 31st Jul 2024 will be automatically extended by 6 months in Nov 2023. This is to avoid lapses during the data migration and submission freeze period. CIRB will issue an update once the Valid Till Date is extended by 6 months.

Should there be any necessary study update to CIRB before the next renewal, please email the relevant IRB secretariat.

4. Minimum Training Requirements

From 1st Apr 2024, all investigators and researchers (i.e. PI, Site-PI, Co-I and study team members) who are directly involved in the conduct of research must meet the following training requirements:

Types of Research	Training Requirements
Human Biomedical Research and all other human subjects research	- CITI Program - Biomedical Research Investigators and Key Personnel Module) and - SingHealth eHBRA training or equivalent
Clinical Trials regulated under Health Products Act or Medicine Act	- CITI Program (Biomedical Research Investigators and Key Personnel Module) and - ICH GCP Course, the following completion/ attendance certificates are acceptable: o SingHealth Academy o National Healthcare Group o National University Health System o CITI Program - GCP (Good Clinical Practice) o Mass General Brigham RICE is also reviewing other available GCP courses, the list will be updated from time to time. Please refer to RICE website.

Investigators and researchers are required to submit their training certificates in the ECOS Minimum Training Module, prior to being able to submit new IRB applications via ECOS. Details on submission of the certificates will be shared later. In the meantime, all investigators and researchers are encouraged to complete the above courses, if not already done so.

Please refer to the Policy and Procedure: SHS-RSH-CIRB-233 Minimum Training and Minimum Requirements for Study Team Members (intranet access is required).

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