SingHealth
Defining Tomorrow's Medicine

CIRB Updates

1 February 2024

The CIRB Updates cover the following:

1. iSHaRe shut down for data migration from 28 Mar 2024, 5pm
2. Submissions of Protocol Deviation/Non-compliance Report (DNC), Serious Adverse Events (SAE) and Other Reportable Event (ORE)
3. Submissions of Study Closure Report Form
4. Management of Study Team Members for on-going IRB approved studies and new IRB application in Ethics and Compliance Online System (ECOS)
5. Preparation for ECOS launch
    a. User Accounts Migration
    b. Minimum Training Certificates
6. Upcoming Training

We strongly recommend investigators and researchers to read through the updates. If you are working with industry partners, Clinical Research Organizations (CRO), pharmaceutical companies and others, please keep them informed of the changes and updates.

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1. iSHaRe shut down for data migration from 28 Mar 2024 (Thursday), 5pm

In view of the Good Friday long weekend, iSHaRe will be shut down from 28 Mar 2024 (Thursday), 5pm onwards for data migration to ECOS.

a) Submissions Pending Review – CIRB is working towards completing the review of submissions with status "Pending CIRB Review" before iSHaRe shutdown. In this regard, we would appreciate it if Principal Investigators (PIs) respond to CIRB's queries at the earliest possible. In the event where submissions (all form types) are still pending in iSHaRe after 28 Mar 2024, CIRB secretariats will communicate with the respective PIs via email to complete the reviews. For such studies reviewed off iSHaRe, they will only be made available in ECOS through a separate data migration after the reviews are completed, even if ECOS is already up and running. We hope to avoid this scenario as much as possible as any further submissions relating to these studies can only be made online after they are migrated to ECOS.

b) Studies Migration – Only on-going studies will be migrated to ECOS, i.e. Study Status is "Approved" in iSHaRe as of 28 Mar 2024. PIs and study team are reminded

to download and save a copy of your study related documents before iSHaRe shuts down. For CVs, CITI Biomed and GCP certificates, only those that are attached in the application forms or latest amendment forms will be migrated.

2. **Submissions of Protocol Deviation/Non-Compliance Report (DNC), Serious Adverse Events (SAE) and Other Reportable Event (ORE)**

   From 16 Mar 2024 until ECOS is launched, please submit DNC, SAE and ORE directly to the IRB secretariat via email. Their contacts can be found here. For submissions of DNC and SAE, please download and complete the relevant forms from the CIRB website. The forms will be available in the first week of Mar. For ORE, please email the IRB secretariat directly and attach the related documents.

   Note the following when submitting DNC, SAE and ORE:

   - Indicate the CIRB Reference Number and the type of submission in the email subject, e.g. 2022/3200 SAE or 2022/3200 DNC or 2022/3200 ORE.
   - If the submitter is not the PI, please include the PI in the email to facilitate the communication between CIRB and the PI.
   - Please also include your Institution Research Administrator(s) in the submission for their oversight of the research.

3. **Submissions of Study Closure Report Form**

   From 16 Mar 2024 until ECOS is launched, please notify the relevant IRB secretariat of the study closure via email. You will still need to submit the study closure report via ECOS when it is up. Do include the CIRB Reference Number and Study Closure Report in the email subject, e.g. 2022/3200 Study Closure Report and include your Institution Research Administrator(s).

4. **Management of Study Team Members for on-going IRB approved studies and new IRB application in ECOS**

   The IRB application form in ECOS is jointly developed by SingHealth CIRB and NHG DSRB. It is vastly different from the iSHaRe Application Form.

   - The current section B2 (Study Team Members) of iSHaRe IRB application form is for the listing of the following study roles: PI, Site-PI, Co-Investigator (Co-I) and Study Team Member. The Protocol Administrators are listed under the current section A2.

- For the application form in ECOS, listing of only PI, Site-PI and Co-Investigator are required. PI, Site-PI and Co-I must receive IRB's approval before they can conduct the research.
- With immediate effect, it is the responsibility of the PI/Site-PI to ensure that the Study Team Members who are directly involved in research have the relevant training and are qualified to participate in the research. They shall be delegated and documented in a Delegation Log.
- For on-going IRB approved studies that will be migrated to ECOS, the Study Team Member and Protocol Administrator roles will not be migrated. Study Team Members and Protocol Administrators who require access to the IRB documents and submissions should be added in the Clinical Research Management System (CRMS) module. More information on CRMS will be shared later.

SHS-RSH-CIRB-231 Responsibilities of Principal Investigators [Intranet Access]

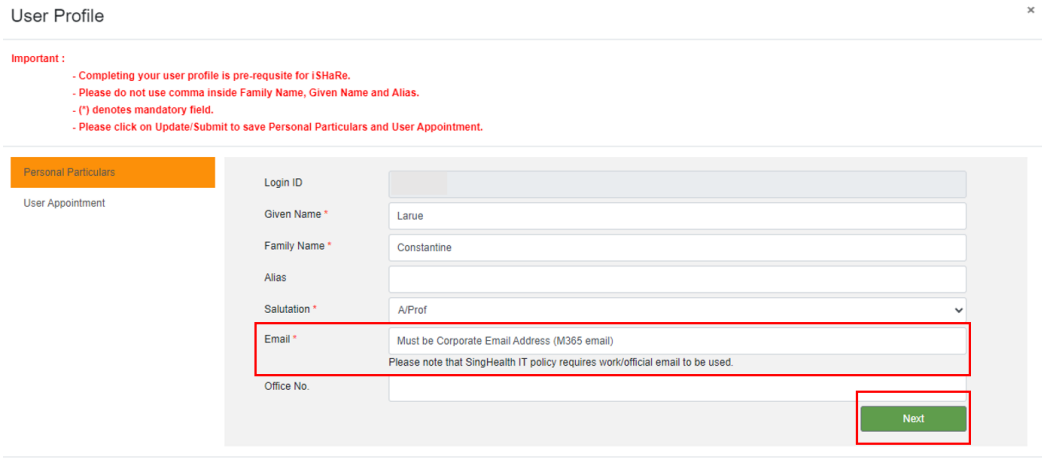
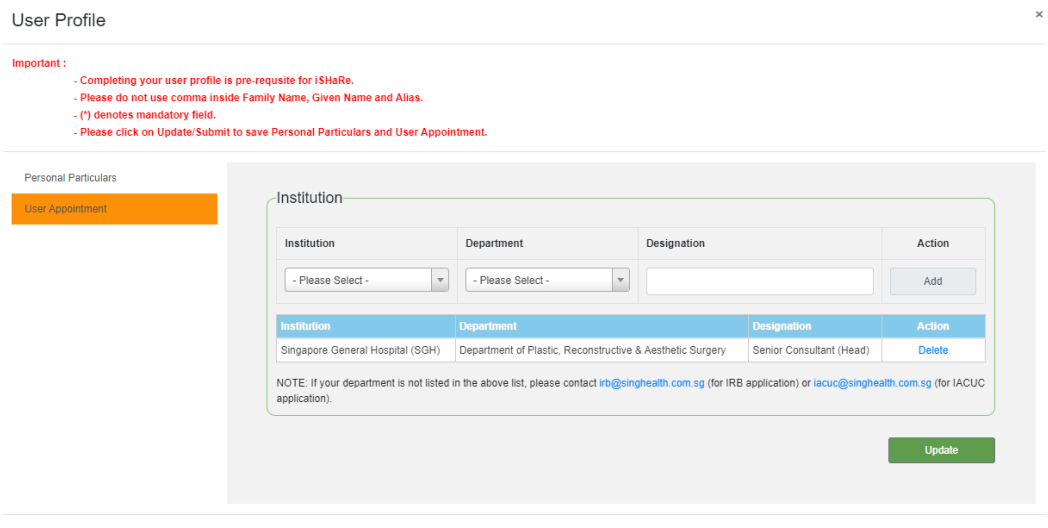
SHS-RSH-CIRB-234 Conflict of Interest – Investigators and Study Team Members [Intranet Access]

5. Preparation for ECOS launch

a) User Accounts Migration

- The account of users with on-going IRB approved studies and with study roles of PI, Site-PI and Co-I, their accounts will be migrated to ECOS. This is to ensure the continuity of access to their studies. The other iSHaRe users will not be migrated to avoid outdated information imported to ECOS. For Research Office Checkers (ROC), Department Representatives (DR) and Institution Representatives (IR), your accounts will be migrated if you have an iSHaRe account.
- If you are from Public Healthcare Institutions (PHIs), your ECOS login will be your corporate email address (M365 email). This differs from the iSHaRe login which uses Domain and ADID. To ensure a smooth transition, please ensure your iSHaRe profile page is updated with your corporate email address by **29 Feb 2024**. This is only applicable to those whose accounts will be migrated. Please follow the steps to check your email address:

1	Login to iSHaRe via intranet or HVPN. https://ishare.singhealth.com.sg/
2	Click on your name on the top right of the screen.

	
3	Check if the email address is your corporate email address. Otherwise, please update and click Next. 
4	You may also want to update your appointment if there have been any changes and click Update. 

- If you are not from PHIs, your current iSHaRe login email address will be the ECOS login ID. This is only applicable to those whose accounts that will be migrated.

- For accounts that will not be migrated and for new users, the registration of ECOS account is straight forward. Please follow the guide which will be provided during the ECOS launch.

b) Minimum Training Certificates

This is applicable to:

- SingHealth staff and
- Non-PHIs users where they were/will be added as Site-PI or Co-I to a new application or amendment.

Moving forward, the following will not be required for every new IRB application.

- CV
- CITI - Biomedical Research Investigators and Key Personnel completion report
- Good Clinical Practice (GCP) completion certificate

Taking into account of users' feedback on the inconveniences and challenges encountered, ECOS will have a new "Minimum Training" module.

CV	Upload of CV is no longer required. Users will need to complete the necessary information under User Profile upon login to ECOS.
CITI Biomed	For all studies: A copy of the CITI - Biomedical Research Investigators and Key Personnel completion report must be uploaded under the User Profile Page > Minimum Training Certificates section. For the CITI Biomed training, you can access the CITI Program here https://www.citiprogram.org/
HBR Essential	For HBR studies: A copy of the HBR Essential completion certificate must be uploaded under the User Profile Page > Minimum Training Certificates section. For the HBR Essential training, please register here https://elearning.singhealthacademy.edu.sg/
GCP	For Clinical Trials (regulated by HSA) A copy of the GCP certificate must be uploaded under the User Profile Page > Minimum Training Certificates section.

	If you do not have the GCP certificate, you can complete the GCP in the CITI Program https://www.citiprogram.org/ or GCP by other providers.

Your Institution's Minimum Training Secretariat will complete the check of the completion report and certificates submitted. We encourage all investigators to get ready your certificates for upload as soon as ECOS is launched. This is to minimise any delay in your submission of new application or amendment. PI, Site-PI and Co-I must meet the minimum training requirements before the forms can be submitted.

SHS-RSH-CIRB-233 Minimum Training and Requirements for Investigators and Study Team Members [Intranet Access]

Training Requirements:
https://www.singhealthdukenus.com.sg/research/rice/Pages/Training-Requirements.aspx

6. Upcoming Training

ECOS, the new web-based platform will serve as a one stop solution to support the research lifecycle from Study Initiation to Completion. The IRB application form had been revised to request for more comprehensive information during the submission, and there are changes to the minimum training requirement for researchers conducting research.

In preparation for the launch of ECOS, the training will prepare the attendees for the following:

- Minimum training requirement for researchers
- Revision to the application form
- Preparation of the form in advance for submission

Please refer to the enclosed flyer or Events for more information and registration.

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