



IRB

Guidebook:

Migrated studies (CIRB)

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Migrated On-going Approved Studies (“Migrated Studies”)

Migrated Studies refer to studies which were approved by CIRB on iSHaRe prior to launch of ECOS and the studies status is “Approved” as of 28 Mar 2024. All Migrated Studies retain the CIRB Reference Number. The CIRB Reference Number would be the ECOS Reference Number. The slash (/) in the CIRB Reference Number will be replaced by dash (-). Please quote the ECOS Reference Number in your communication with IRB.

1.1 Studies approved by CIRB

- My Study List

To locate the Migrated Studies: Click on “My Study List” and click “🔍” to view the study summary.

ECOS Ref	IRB	Study Status	Study Title	PI/Site-PI Name	Action
2024-3069	SingHealth CIRB-Board A	Approved	Study Title	PI/Site-PI Name	🔍
2024-3046	SingHealth CIRB-Board B	Approved	Study Title	PI/Site-PI Name	🔍
2024-3171	SingHealth CIRB-Board A	Approved	Study Title	PI/Site-PI Name	🔍
2024-3203	SingHealth CIRB-Board A	Approved	Study Title	PI/Site-PI Name	🔍
2024-3202	SingHealth CIRB-Board A	Approved	Study Title	PI/Site-PI Name	🔍

- **Study Summary**

The latest approved or acknowledged Application Form or Amendment Form from iSHaRe will be migrated as “Smart Form”. You can view the migrated form in the Study Summary Page, under “All Forms”.

2024-2187 Approved

Valid Till Date: 21-Feb-2025 Initial Review Category: Full Board

PI/Site-PI Name: The PI/Site-PI Name of Your Study (e.g., Dr Marilyn Lam (Singapore General Hospital))

Study Title: Your Study Title

All Forms All Forms Attachments Study Letter Migrated Study Documents

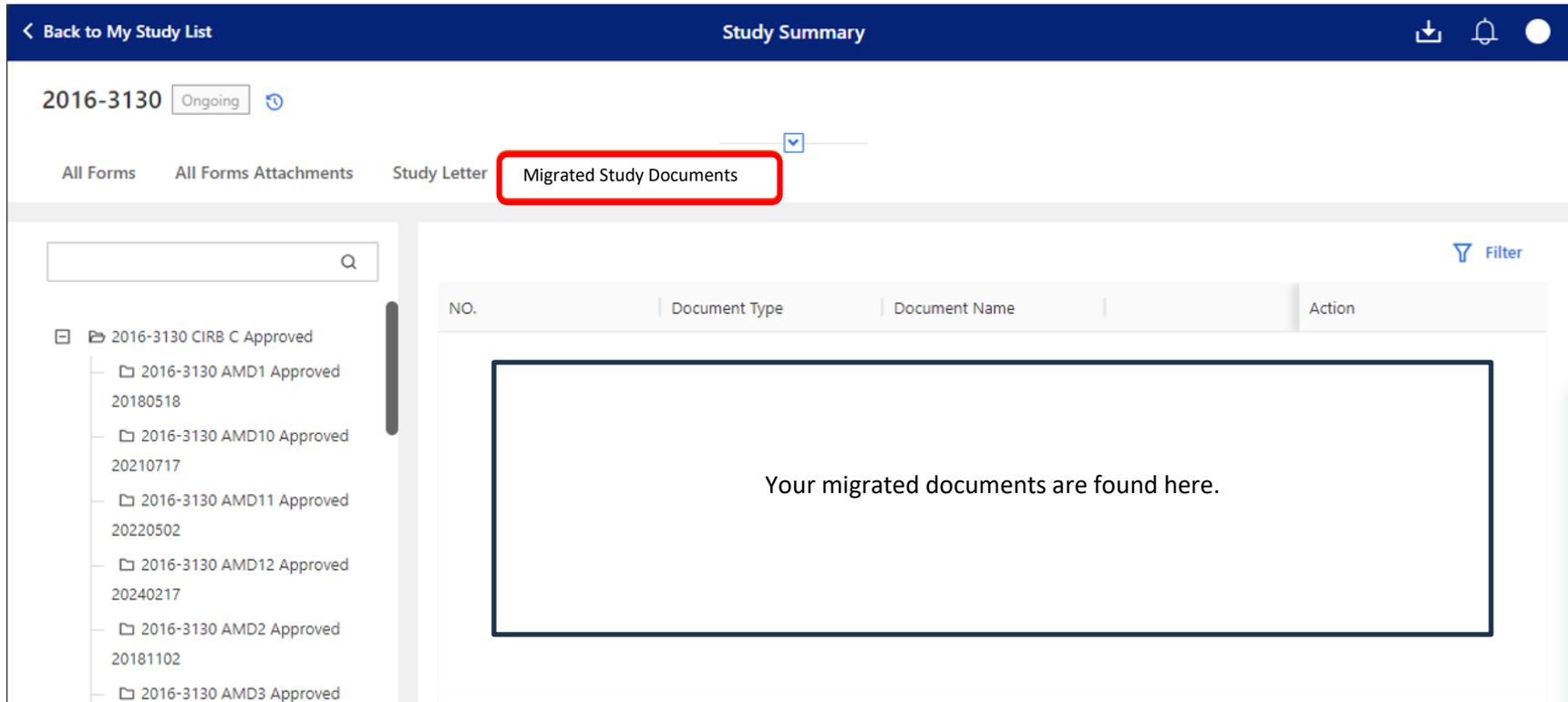
Form Type	Form Ref	Form Status	Form Outcome	Review Category	Outcome Date
Application	2024-2187-APP1	Review Completed	Approved	Full Board	14-Mar-2024

Note:

1. As the ECOS Application Form is different from the iSHaRe Application Form, there are new data fields which are displayed as blank and data fields in iSHaRe which are not migrated. When the first Amendment Form of migrated studies is created, the PI/study team members are expected to complete all mandatory fields.
2. The latest approved or acknowledged Application Form or Amendment Form are migrated “Smart Form” so that subsequent amendments can be submitted in ECOS. Do not use the migrated “Smart Form” as reference. Do refer to the Migrated Study Documents for the PDF of the iSHaRe Application Form or Amendment Form.
3. The CIRB decision letter for the latest approved or acknowledged Application Form or Amendment Form will not be available under “All Forms”. Decision letter can be downloaded from the Migrated Study Document if required.

- **Migrated Study Documents**

All other Forms reviewed by CIRB previously are migrated to ECOS as PDF. The documents can be found under “Migrated Study Documents”.



Note:

1. Study Renewal Report Form, Study Re-activation Report Form and Study Closure Report Form are reflected as SSR, SRR and SCR respectively in ECOS.
2. Local SAE Report Form is reflected as SAE in ECOS.
3. Protocol Deviation/Non-compliance Report Form is reflected as DNC in ECOS.
4. Other Reportable Event Report Form is reflected as OSN in ECOS.
5. Submissions reviewed offline would be migrated at a later stage.

1.2 How to make submission for Migrated Studies

- Creation of Other Forms

The screenshot shows the ECOS Submission List interface. The 'New Other Forms' button is highlighted with a green box. A modal window titled 'New Study Form' is open, showing a search field for 'ECOS Ref or Study Title' and a dropdown menu for 'Form Type'. Two blue callout boxes with white text provide instructions: '1. Search for study with ECOS Ref or Study Title' and '2. Select Form Type to be created'. The dropdown menu lists several form types: Amendment Form (Amendment), Study Deviation/ Non-Compliance Report Form (DNC), Other Study Notifications Report Form (OSN), Serious Adverse Event Report Form (SAE), and Study Status Report Form (SSR).

ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title	PI/Site-PI Name	Action
2023-0131	CIRB-Board D	2023-0131-AMD1	Amendment	• Draft	LLY -1	Prof SERI_PI1(Singapore Eye Research (SERI)),A/Prof SGH_Site-PI1(Singapore Hospital (SGH))	👁
2024-0219	CIRB-Board A	2024-0219-APP1	Application	• Pending Endorsement	CG/JY/KT - Testing (26-Jan-2024)	Dr SERI_PI(Singapore National Eye Cer	👁

1. Under the IRB module, Submission List, click on the “ **+ New Other Forms** ” button.
2. Search for the study with the ECOS Reference Number or Study Title.
3. Select the Form Type to be created.
4. Click on “ **Confirm** ”button.

- **Amendment Form**

Due to differences between the iSHaRe Application Form and ECOS Application Form, there would be new questions when you create an amendment form. For the first time submitting an amendment form in ECOS, please ensure that all mandatory questions are answered.

Please note the following:

- Data from some sections of the iSHaRe Application Form will not be mapped over to the ECOS Amendment Application Form.
- Data from some sections of the iSHaRe Application Form may be mapped over to a single section in the ECOS Amendment Application Form.
- Some sections in ECOS Amendment Application Form have been mapped by default to a certain option to facilitate data mapping.

Do check the first ECOS Amendment Form thoroughly and update accordingly. Do ensure that you check this against the latest IRB Approved Application/ Amendment Form.

Submission Detail

ECOS Ref: -

Form Detail

Amendment Form

Study Amendment Cover Note

0 characters entered

1. Describe the proposed change(s) to the research and include a rationale for each proposed change.

2. Will the enrolled research participants be informed of these changes?

3. Will the enrolled research participants be re-consented?

4. Do the proposed amendments:

5. If any of the above is true, please elaborate.

0 characters entered

Cancel Save

Study Amendment Cov...

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

Section D: Study Type a...

Section G: Research M...

Section H: Research D...

Section J: Recruitment ...

Section L: Research Pa...

Section T: Research Da...

Section W: Biological M...

Section X: Data & Safet...

Points to note when you create your first amendment form (for migrated studies) on ECOS:

- **Section B**
 - Section B1 information cannot be updated during amendment submission.
 - Approved study sites cannot be removed. If these sites no longer involved in the research, please submit a Study Status Report Form to update the site status to either “Completed” or “Terminated”.
 - If your existing studies involved study site without Site-PI in iSHaRe, the study PI has been set by default as that study site’s site-PI. Please review if you need to update the Site-PI for that study site.
 - Study investigator(s) listed in Section B2 would need to complete their minimum training and obtain the required training label before the amendment form can be submitted. (i.e., clinical trial involving drug/ biologics would need the clinical trial label).

- **Section C**
 - Please review and update the Grant information and Sponsor’s contact details/CRO’s contact details/IRB billing information via the CRMS module. You will not be able to update this information in the amendment form. Change in Sponsor should be updated via the amendment form.

- **Section D**
 - Please review if the options mapped in Section D3 and D5 are accurate. There may be missing information as the options for these questions were expanded.
 - ❖ If your study involved Medical Device and it was not selected in Section D3, please select “Medical Device” in Section D3 and complete Section I accordingly.
 - ❖ If your study involved Software or Mobile Application and it was not selected in Section D3, please select “Software or Mobile Application” in Section D3 and complete Section V accordingly.
Note: Screenshots of Software or Mobile Application relating to collection of data should be attached in Section E3 or G7. Attachments relating to the Software or Mobile Application should be attached in Section V (For example, mobile app user guide).
 - ❖ If your study involved combination of wavier of documentation of consent and obtaining consent, “waiver of documentation of consent” may not be selected in Section D5. Please select the “waiver of documentation of consent” and “consent will be obtained” in Section D5 and complete Section O (wavier of documentation of consent) and Section J (informed consent).

- ❖ If your study is a Clinical Trial regulated by HSA, the option “Interventions/ Invasive Procedures” should be selected at Section D3. Do not uncheck this option.
- ❖ More than 1 option can be selected for Section D3 and D5.
- The default selection for migrated study in Section D4 is “Yes”. Please review if the option selected in Section D4 is accurate. If the study does not involve recruitment, please update it to “No”.

- **Section E/G**

- The text box in iSHaRe Application Form Section F allows for formatting and insertion of tables. The text box in ECOS only allows insertion of text (without formatting and does not support data in tabular format). Please review the response migrated for these sections. You may need to update the response.
- Section E7/G16 – Potential Risk: The default selection is “Social risk”. Please review if the classification of risk is accurate and update accordingly. More than one option can be selected.
- Section G7 – Response from iSHaRe Section F8, F10 and F11 was migrated to Section G7. You may need to update the response accordingly if there were repetition.
- Section G7/G9 – Visit schedule attachment(s) was migrated to Section G7. Please review if this attachment should be moved to Section G9.
- Section G7/G10 – Management of incidental findings were indicated in iSHaRe Section F8 (now migrated to G7). Please update Section G10 (Management of incidental findings) accordingly. Note: G10 only appears if consent will be obtained.
- Section G13 - Please indicate the age group of the research participants if it was not already included.
- Section G14 - If pregnant women will be excluded from the study, please indicate, if it was not already included.

- **Section J**

- Section J4 - Response from iSHaRe Section H2 and H3 was mapped to Section J4. Please review the response and update if required.
- Section J5 – The default selection is face-to-face consent. Please update if your study has been approved by the IRB for obtaining informed consent remotely.
- Section J6 - Response from iSHaRe Section P1, P2 and P3 was mapped to Section J6. Please review the response and update if required.

- **Section S**

- For studies requested for waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3, the default selection is “Epidemiology research or population wide studies at national or regional level with potential direct benefit to the public at large”. Please review if this is the correct option. Otherwise, please select the correct options accordingly.

- **Section W**

- Please review and update Section W1 accordingly. For example, if your study involves collection of blood samples (some stored locally, some transferred overseas) and archival tumor samples. The migrated form will display them as 1 entry in prospective collection and 1 entry as existing human biological materials. Please update this section as such: The blood samples to be split into 2 different entries under the prospective collection while the archival tumor samples will be under the existing human biological materials.

- **Section X**

- Section X2 - Response from iShare Section T2, T3, T4 and T5 was mapped to Section X2. Please review the response and update if required.

For more information, please refer to the IRB Guidebook: Application Form and IRB Guidebook: Other Forms (Section A: Amendment Form).

- **Study Status Report Form**

Study Renewal Report Form, Study Re-activation Report Form and Study Closure Report Form have been combined into one single form – Study Status Report Form. Please refer to the IRB Guidebook: Other Forms (Section B: Study Status Report Form) for more information.

< Back to Submission List
Submission Detail

ECOS Ref:

[Form Detail](#)

Study Status Report Form

X Cancel
Save

NOTE:

- For renewal of IRB approval, please submit the Study Status Report Form 90 days before study expiry.
- For reactivation of expired study, please submit a Study Deviation /Non-Compliance Report Form if the study team had continued to carry out research activities during the lapse period before IRB approval is renewed.
- For study closure, please submit the Study Status Report Form within 30 days after study completion.

*1. I am requesting for:

2. Status and Recruitment Information
 Note: If your study involves only the use of human biological samples/records, please state the number collected for each study site.

Current Study Status Report Form

Study Site	Proposed Enrolment Target	Total No. of Screen Failures	Total No. of Research Participants Enrolled	Total No. of Research Participants Who Have Completed Study	Total No. of Research Participants Withdrawn from Study	Site Status	Action
* 8ac0802d8f1532e8018f2417dd6919b0	* 12	* <input style="width: 30px;" type="text"/>	* <input style="width: 30px;" type="text"/>	* <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/>	Save Cancel

3. Research Participants Enrolment by Gender: Please give us a break down of the total enrolled research participants as follows:

* 3. (a) Number of Male Adult:

* 3. (b) Number of Female Adult:

Study Status Report Form

Declaration of Principal ...

- **Study Deviation/ Non-compliance (DNC) Report Form**

DNC Report Form is for submission of Study Deviation/ Non-compliance. Please refer to the IRB Guidebook: Other Forms (Section C: Study Deviation/ Non-compliance (DNC) Form) for more information.

ECOS Ref: 📄



[Form Detail](#)

Study Deviation/Non-Compliance Report Form

✕ Cancel 📄 Save

Guidance

This report form should be submitted once Principal Investigator is aware of the non-compliance/ study deviation according to the reviewing IRB's requirement. All sections must be completed. Principal Investigators are obliged to suspend their research immediately pending their report to the IRB if deviations are substantial or are likely to result in greater harm or greater likelihood of harm to the research participants.

Definitions

Study Deviation: is an unplanned excursion from the study that is not implemented or intended as a systematic change.

- A study deviation could be a limited prospective exception to the protocol (e.g. agreement between sponsor and investigator to enroll a single research participant who does not meet all inclusion/exclusion criteria). Like study amendments, deviations initiated by the investigator must be reviewed and approved by the IRB and the sponsor prior to implementation, unless the change is necessary to eliminate an immediate hazard to the research participants.
- Study deviation is also used to refer to any other, unplanned, instance(s) of study non-compliance. For example, situations in which the investigator failed to perform tests required by the protocol or failures on the part of the research participant(s) to complete scheduled visits as required by the protocol.

Non-Compliance: is a failure by an investigator or any study team member to abide by the policies and procedures of the IRB or applicable regulations governing the protection of human subject research. Some examples of non-compliance include but are not limited to:

- Failure to obtain prior approval for research
- Failure to obtain informed consent when required
- Failure to use the latest IRB approved version of the protocol or consent form
- Failure to report an adverse event report according to IRB timeline and procedure
- Performance of research at an unapproved study site
- Performing an unapproved research procedure
- Failure to adhere to the approved protocol
- Failure to submit study amendments for review and approval
- Performance of a drug trial without a valid HSA Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC)
- Any other failure to adhere to regulations, policies and procedures related to research

[Guidance](#)

[DNC Form](#)

[Declaration](#)

- **Serious Adverse Event (SAE) Report Form**

SAE Report Form is for submission of local and overseas SAE. Please refer to the IRB Guidebook: Other Forms (Section D: Serious Adverse Event (SAE) Form) for more information.

ECOS Ref: 📄



[Form Detail](#)

Serious Adverse Event (SAE) Report Form

✕ Cancel 📄 Save

Note:

1. This form is for submission of related SAE only.
2. For DSRB reviewed studies, if the related SAE is unexpected, please submit using the UPIRISO Report Form.
3. Do not use terms such as "Refer to attached document" or similar.

Section A: Determination of SAE

***A1. Please determine if the event is related:**

- Related: Related means there is a reasonable possibility that the incident, experience or outcome may have been caused by the procedures involved in the research. Also includes reasonable possibility that the event occurred as a result of participation in the research.

***A2. Please classify the SAE into at least one of the following categories:**

- Resulted in or contributed to death
- Was life-threatening
- Required inpatient hospitalisation or prolongation of existing hospitalisation
- Resulted in or contributed to persistent or significant disability or incapacity
- Resulted in or contributed to a congenital anomaly or birth defect
- Resulted in transmission of communicable disease
- Resulted in any misidentification or mix-up of any type of tissue, gametes or embryo
- Required intervention to prevent permanent impairment or damage (devices)
- Medical event that may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above
- Others

***A3. Please determine the expectedness of the event:**

- Expected: These are risks or events reported and listed in the study protocol, informed consent form or other study documents.
- Unexpected: These are any unexpected untoward event or medical occurrence in a participant that is not consistent with the known, predicted possible effects of the research protocol. An unexpected adverse event can therefore be any unanticipated, unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the study that was not listed in the protocol, informed consent document or Investigator's Brochure (IB). This includes adverse drug

Section A: Determinatio...

Section B: Basic Inform...

Section C: Investigation...

Section D: Event Summ...

Section E: Comments b...

Section F: Investigator's...

- **Other Study Notification (OSN) Report Form**

OSN Report Form is for submission of other study notifications. Please refer to the IRB Guidebook: Other Forms (Section E: Other Study Notification (OSN) Report Form) for more information.

ECOS Ref: 



[Form Detail](#)

Other Study Notification Report Form

[X Cancel](#) [Save](#)

NOTE: Miscellaneous study documents that DO NOT require IRB approval may be submitted for acknowledgment using this Other Study Notifications Form.

***1. Notification type**

Please select

- DSMB Report
- Annual/Interim /Periodic Safety Report
- Interim Data Analysis
- Letter from Study Sponsors
- Other Notification

OSN Form

Declaration