National Healthcare Group
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ECOS Launch Frequently Asked Questions (FAQ)

VERSION #16, DATED 09 DECEMBER 2024

INTRODUCTION

- The Ethics and Compliance Online System (ECOS) is the new ethics review infrastructure that is co-developed by NHG and SingHealth. The ECOS system replaces the previous NHG ROAM system.

- This ECOS Launch FAQ document will be periodically updated with latest information as they become available.

- We recommend that you check back to the **ECOS End-User Support Portal FAQs** *(Both NHG-Intranet & Internet accessible)* to obtain the latest version of the FAQ document.

- For other information on ECOS Support, you may refer to ECOS End-User Support Portal for NHG Research Community or scan the QR codes below:

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1. DSRB SUBMISSION DEADLINES

Qn 1.1: Where can I submit new study applications and study amendments to DSRB?

- You need to submit **all new study applications and amendments** on ECOS (launched on 10 May 2024). Please refer to the NHG OHRPP Website for DSRB submission timelines.

- Migration of all eligible studies (as per below) from ROAM to ECOS have been completed:
  - Wave 1 migration (studies that achieved DSRB review outcome before 1 April 2024)
  - Wave 2 migration (studies that achieved DSRB review outcome before 8 June 2024)
  - Final migration (studies that achieved DSRB review outcome before 10 July 2024)

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Qn 1.2: Where can I submit study renewals to DSRB?

- You need to submit **Study Status Report (SSR)** on ECOS to renew your study approval or update DSRB on the study status (e.g., suspended, completed).

- To support the transition from ROAM to ECOS, DSRB had granted a one-time approval extension of 6 months for ongoing studies with expiry dates between **1 February to 31 July 2024** (both dates inclusive). The extension letter had been issued by DSRB for each impacted study.

  If your study had received the approval extension, you need to submit a study status report on ECOS to renew your study approval or update on the study status.

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Qn 1.3: Where can I submit supplementary forms to DSRB?

- You need to submit the following supplementary forms on ECOS:
  i. Study Deviation/ Non-Compliance Report (DNC)
  ii. UPIRTSO Report (UPT)
  iii. Serious Adverse Event Report (SAE)
  iv. Other Study Notification (OSN)

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Qn 1.4: Will I still have access to ROAM?

- ROAM is no longer accessible.

[1st published: FAQ #2, 20 Dec 23, Updated: FAQ #6, 28 Feb 24, FAQ #7 15 Mar 24, FAQ #9, 30 Apr 24, FAQ #10, 10 May 24, FAQ #11, 31 May 24, FAQ #12, 1 July 24, FAQ #12.1, 4 July, FAQ #13, 6 Aug 24, FAQ #15, 1 Oct 24]

Qn 1.5: Am I required to submit my CY2024 Financial Conflict of Interest (FCOI) Declaration?

- The validity period of CY2023 FCOI Declarations was extended **till 30 June 2024**.

- The **new FCOI declaration cycle** has started since the launch of ECOS (10 May 2024). The validity period will be from 01 July 2024 to 31 Dec 2025. You will need to submit declarations for this new declaration cycle on ECOS.

[1st published: FAQ #3, 08 Jan 24, Updated: FAQ #7, 15 Mar 24, FAQ #10, 10 May 24, FAQ #12, 1 July 24, FAQ #13, 6 Aug 24]

Qn 1.6: Where should I submit new Standing Database (SDB) Applications?

- The SDB Module was launched on 30 September 2024. **NHG and NUHS** researchers who wish to store data for future research can now submit new SDB applications on ECOS.
- ECOS SDB Module User Guides are available here on the ECOS Launch Support Webpage.
- For queries pertaining to NHG Standing Database, please email **RDOCSecretariat@nhg.com.sg**.

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Qn 1.7: Was my SDB migrated to ECOS?

- Only **Approved SDBs** from the Standing Database (SDB) Online System were migrated to ECOS on 02 December 2024.
- SDBs in ROAM (including NUHS SDB & TB) were **not** migrated to ECOS. Custodians would need to **re-submit** an application in ECOS should they wish to retain their SDBs.

[1st published: 9 Dec 24]

2. DATA MIGRATION FROM ROAM TO ECOS

Qn 2.1: Were all my approved DSRB studies migrated to ECOS?

- The final migration of eligible studies from ROAM to ECOS was completed in **end July** 2024.
- **Approved and Ongoing** studies were migrated to ECOS.
- **For Ongoing Studies***, the following Study Status in ROAM were included in the migration:
  a. NOT YET INITIATED
  b. ONGOING
  c. ENROLMENT CLOSED, SUBJECTS ON FOLLOW UP ONLY
  d. LAST PATIENT LAST VISIT OVER, DATA ANALYSIS ONGOING
  e. SUSPENDED

  **Ongoing studies are studies that have a valid DSRB approval.*
- Studies that were **Completed**, **Withdrawn**, **Terminated** or **Review Not Required** were **NOT** migrated to ECOS.

[1st published: FAQ #1, 27 Nov 23, Updated: FAQ #2, 20 Dec 23, FAQ #4, 19 Jan 24, FAQ #6, 28 Feb 24, FAQ #9, 30 Apr 24, FAQ #10, 10 May 24, FAQ #11, 31 May 24, FAQ #12, 1 July 24, FAQ #13, 6 Aug 24, FAQ #15, 1 Oct 24]

Qn 2.2: Were Expired Studies migrated to ECOS?

- Only studies that **expired** from 1 November 2023 onwards were migrated to ECOS.

[1st published: FAQ #1, 27 Nov 23, Updated: FAQ #2, 20 Dec 23, FAQ #6, 28 Feb 24, FAQ #13, 6 Aug 24, FAQ #15, 1 Oct 24]

Qn 2.3: Was my ROAM User Account migrated over to the ECOS system?

- **ONLY** specific ROAM Users had their ROAM Account Profile migrated over to the ECOS system.
- The ROAM User must have met the following criteria for their Account Profile to be designated for migration to ECOS:
  - The User is listed as the **Principal Investigator (PI)**, **Site Principal Investigator (Site-PI)** or **Co-Investigator (Co-I)** in an **Active Study** [A] which has been designated for migration to ECOS.

    OR
  - The User is designated as a **ROAM System Key Appointment Holder** *(such as Dept Rep, Inst Rep, DSRB Domain Chair & Member etc)*.
    AND
  - In addition to meeting the above Appointment requirements, the User must have a **valid and completed** [B] ROAM Account Profile.
  - Users who did not qualify for their ROAM Account Profiles to be migrated to ECOS will need to create a new ECOS User Account.

[A] *What is an Active Study?*
- *A DSRB-Approved Study, which is Ongoing (expired from 1 November 2023 onwards).*

[B] *What is a valid and completed ROAM Account Profile?*
- *User has provided a **valid Email Address*** which is consistent with their Employment information.*

- *User has provided a **valid Primary Appointment** consistent with their Appointment/Job Title/Research role in their ROAM Account Profile.*
- *User has updated and validated their **Minimum Training Certifications** as required by the DSRB.*

* **FOR PHI-STAFF:** *The provided Email Address must be a **valid Public Healthcare Institution (PHI) Email Address** (eg: name**@nhg.com.sg** , name**@nuhs.com.sg** etc) in their ROAM Account Profile.*

FOR NON-PHI STAFF: *The provided Email Address must be a **valid corporate Email Address** from their Organization in their ROAM Account Profile.*

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Qn 2.4: What happened to the ROAM account profiles of Collaborators and Study Administrators?

- The ROAM Account Profile of Collaborators and Study Administrators were **NOT** migrated to ECOS **even if they were involved in active studies**.

- In ECOS, **only** the **PI, Site PI** and **Co-I** (**of NHG and NHG Partner Institutions**) are required to be listed in the IRB application form.

- External Co-Is (from Non-NHG / non-NHG Partner Institution), Collaborators and Study Administrators on ROAM who require access to the study information (IRB documents and submissions etc.) will need to register for an ECOS User Account. They may be added to the study in the ECOS Clinical Research Management System (CRMS) module if they require access to ECOS.

- On the CRMS module, 3 roles can be assigned:
  - Study Sponsor
  - Study Administrator – Not directly involved in research but only provides administrative support to study
  - Study Team Member – Directly involved in research

- Addition / removal of the Study Sponsor, Study Administrator and Study Team Member on ECOS will not require IRB review and approval. Changes will be managed at the site level. Please refer to the **CRMS User Guide** for more information.

[1st published: FAQ #6, 28 Feb 24, Updated: FAQ #7, 15 Mar 24, FAQ #10, 10 May 24, FAQ #11, 31 May 24, FAQ #13, 6 Aug 24, FAQ #14, 16 Aug 24, FAQ #15, 1 Oct 24]

Qn 2.5: I am an investigator (PI/ Site PI / Co-I) and all the studies I am involved in are completed. Was my ROAM Account Profile migrated to ECOS?

- No, your ROAM Account Profile would not have been migrated. Only the ROAM Account Profile of PI, Site-PI or Co-I in an **active study** were migrated.

[1st published: FAQ #6, 28 Feb 24, Updated: FAQ #11, 31 May 24, FAQ #13, 6 Aug 24]

Qn 2.6: When is the last day I can access information on NHG Monitoring Website (for PISAF & Monitoring) / Standing Database Online System (for SDB)?

- You will have access to existing information on the NHG Monitoring Website / Standing Database Online System till **28 February 2025, 23:59**. Please ensure you download all required information **by 28 February 2025**.

[1st published: FAQ #16, 9 Dec 24]

3. MINIMUM TRAINING AND FINANCIAL CONFLICT OF INTEREST (FCOI)

Qn 3.1: Are there any changes to the DSRB minimum training requirements with the transition to ECOS?

DSRB Minimum Training Requirements:

- There are no changes to the current **Collaborative Institutional Training Initiative (CITI) and Financial Conflict of Interest (FCOI) CITI** minimum training requirements.

- For Clinical Trials regulated by HSA (Effective **01 April 2024**):

Who	Current DSRB Requirements	Revised CT Min DSRB Requirements *(Effective 1April 2024)*
Investigators (conducting clinical trial)	Mandatory for **PI & Site PIs** to complete GCP prior to IRB submission	**Mandatory** for PI, Site-PIs and **Co-Is** to complete GCP prior to IRB submission.
Other **Study Team Members (STM)** (conducting clinical trial)	GCP training is not mandatory per DSRB requirements.	**Mandatory** for **Study Team Members (STM)** conducting *significant trial related tasks to complete GCP before study involvement.

*For STM: * Significant trial related tasks include informed consent taking, eligibility assessment, IP management, key efficacy and safety assessment etc. You may refer to HSA website for more details.*

The DSRB will recognise generic GCP courses (such as CITI GCP) and trainings as meeting the acceptable minimum training standard. The DSRB does not mandate a specific validity period for these GCP training certificates. However, individuals should ensure that their trainings remain relevant.

A valid GCP training certificate is required to be uploaded and validated on ECOS, prior to the submission of new Clinical Trials and amendments.

Other Minimum Training Requirements:

- Your Research Institution may also require you to complete a Human Biomedical Research Act (HBRA) minimum training.

[1st published: FAQ #6, 28 Feb 24, Updated: FAQ #7, 15 Mar 24]

Qn 3.2: What were the Minimum Training Certifications that had been migrated from ROAM to ECOS?

- For **ROAM Users** whose profiles have been migrated to ECOS (refer to Qn 2.3), the following minimum training certificates would be available on ECOS if they were uploaded in the ROAM Account Profile **before 1 March 2024**:

  i. Collaborative Institutional Training Initiative (CITI) Training Completion Report
  ii. Financial Conflict of Interest (FCOI) CITI Training Completion Report
  iii. Good Clinical Practice (GCP) Training Certificate

- If your training records were not preloaded into ECOS, you will need to upload the training certificates on ECOS.

- For **SingHealth ROAM Users**, please note that your ROAM training certificates were NOT migrated to ECOS. You will need to submit your minimum training certificates on ECOS per SingHealth 's requirements. The

SingHealth Institutions' Minimum Training Secretariats will verify the minimum training certificates on ECOS (refer to qn 3.5).

- If your training certificates were not loaded onto ECOS, you will not be allowed to submit new applications and study amendments (refer to Qn 3.6).

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Qn 3.3: Why is there a Temporary Training Certificate in my migrated User Profile on ECOS?

- Temporary certificates were issued for some of the training records that had been verified by the minimum training team prior to user profile migration to ECOS, to facilitate the issuance of the Minimum Training ECOS labels (refer to Qn 3.5).

- The temporary certs will be valid till **30 April 2026**. You are advised to replace the cert by clicking the **edit** button. Your **ECOS labels will be retained** if you replace the temporary cert with a valid training certificate.

[1st published: FAQ #12, 1 July 2024, Updated: FAQ #12.1, 4 July]

Qn 3.4: My Research Institution requires that I complete HBRA minimum training. Where do I upload my HBRA minimum training certificate?

- Please upload your HBRA minimum training certificate on ECOS.

- For **NHG Staff**, you can refer to this guide on how to download your HBR ERC e-Certificate.

Please check with your specific Research Institution (RI) regarding the HBRA minimum training requirements, as these requirements may vary among different RIs.

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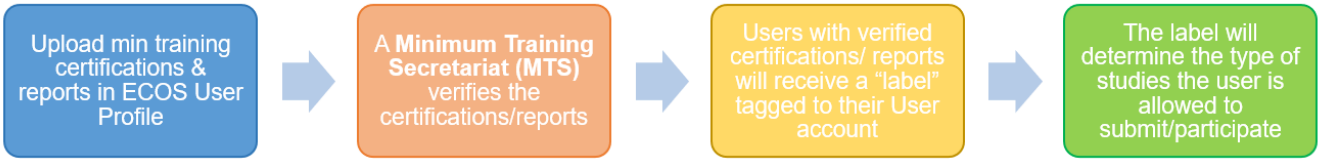
Qn 3.5: What happens when I upload my training certificates on ECOS?

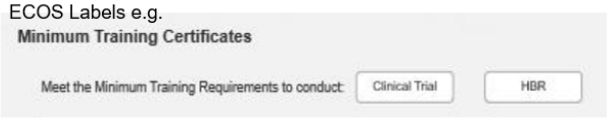
- Your training certifications will go through a validation process as per below.

ECOS Validation Process



Note: Migrated ROAM profiles (with verified FCOI, CITI, GCP records) will receive the applicable ECOS labels upon ECOS launch.

ECOS Labels e.g.



- All applicable trainings must be completed before an ECOS label can be issued. Please refer to the table below for the minimum training requirements.

For Staff of NHG and Partner Institutions

Label	Type of Study	Minimum Training Requirements
Non-HBR	Non-Human Biomedical Research	CITI Biomed CITI FCOI
HBR	Human Biomedical Research	CITI Biomed CITI FCOI HBR Minimum Training*
Clinical Trials	Clinical Trials regulated by HSA	GCP CITI FCOI
SBE	Social, Behavioural, Educational Research *(applicable to submissions to NHG DSRB Domain F)*	CITI SBE CITI FCOI

*Name of HBRA Training Certification might differ for different cluster/institution

Note: Please refer to your cluster's/institution's minimum training policy/requirements

IMPORTANT
If you encounter any issues, please contact your **respective Institution Research Office** who will direct your queries to the designated Minimum Training Secretariats of your Institution for assistance.

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Qn 3.6: Are there any changes to the Financial Conflict of Interest (FCOI) Declaration process with the transition to ECOS?

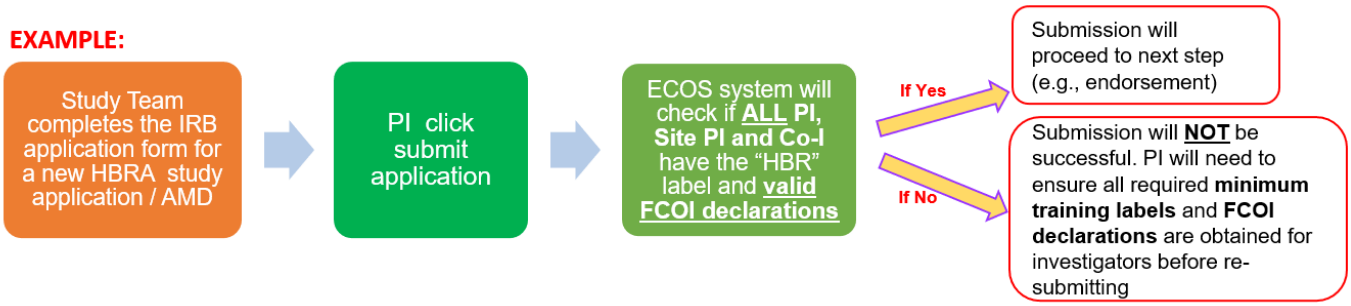
- The FCOI declaration will continue to be an annual exercise. However, to help with the transition to ECOS:
  - A one-time extension of the validity period of CY2023 FCOI Declarations had been given (up **till 30 June 2024).**
  - CY2022 and CY2023 annual FCOI declarations of PI, Site PI or Co-I (**in active studies only**) have been preloaded into ECOS.
- The **new FCOI declaration cycle** has started since the launch of ECOS (10 May 2024). The validity period will be from 01 July 2024 to 31 Dec 2025. You will need to submit declarations for this new declaration cycle on ECOS.

[1st published: FAQ #6, 28 Feb 24, Updated: FAQ #9, 30 Apr 24, FAQ #10, 10 May 24, FAQ #11, 31 May 24, FAQ #12, 1 July 24]

Qn 3.7: What happens if PI/Site PI/ Co-I do not have the required minimum training requirements or valid FCOI declaration on ECOS?

- In ECOS, **only** the **PI, Site PI and Co-I** (of NHG and NHG Partner Institutions) are required to be listed in the IRB application form.
- If the PI, Site PI or Co-I **do not** have the required **minimum training requirements** or **valid FCOI declaration**, ECOS will **not** allow submissions of new study applications and amendments of the corresponding study type (e.g., HBR, Clinical Trial study) selected in the IRB Application Form.

EXAMPLE:



- We strongly urge **PI, Site PI and Co-I** to **promptly check and submit** all minimum training requirements and FCOI declarations on ECOS.
- Incomplete ECOS training records and FCOI declarations of **other** study team members listed in ECOS CRMS module (e.g., study coordinators, collaborators, external Co-Investigators (Non-NHG / Non-NHG Partner Institutions) will **not** hinder the submission of new applications and amendments on ECOS. However, PI/ Site PI must ensure that they complete the necessary trainings and declarations in a timely manner.

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4. NEW ECOS SYSTEM

Qn 4.1: Who can access and login to the ECOS system?

- ECOS (internet based) can be accessed by both Public Healthcare Institution (PHI) and non-PHIs (e.g. Sponsors, CROs, academic institutions). Please refer to training resources on ECOS Launch Website for more details on how to login to ECOS.

[1st published: FAQ #6, 28 Feb 24, Updated: FAQ #9, 30 Apr 24]

Qn 4.2: When will ECOS be launched?

- The ECOS system will include the following modules:

Module (Phase 1)	Function
1. Institutional Review Board (IRB) & Minimum Training	▪ For submission of IRB applications ▪ Includes minimum training validation
2. Clinical Research Management System (CRMS)	For tracking of study & site milestones and recruitment
3. Financial Conflict of Interest (FCOI)	For submission of annual FCOI declarations
Modules (Phase 2)	**Function**
4. Compliance	▪ For completion of PI-self assessment forms (PISAF) ▪ For review of reportable events (safety events and non-compliances) to MOH for HBRA regulated studies
5. Audit & Monitoring	For auditing and monitoring activities
6. Standing Database (SDB)	For submission of standing databases applications (NHG & NUHS sites only)

- ECOS modules will be launched in phases:
  - Modules in Phase 1 (launched on 10 May 2024) are **IRB, Minimum Training, CRMS** and **FCOI** modules.
  - Modules in Phase 2 are scheduled for a staggered launch starting from end July 2024.
    - ❖ The Compliance (DNC/SAE) Module was launched on 01 August 2024.
    - ❖ The Compliance (PISAF) Module was launched on 30 September 2024.
    - ❖ The Standing Database (SDB) Module was launched on 30 September 2024.
    - ❖ The Monitoring Module was launched on 9 December 2024.

    More details on the Audit module will be provided later.

Dates are correct at the time of publication and may be subjected to further changes.

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Qn 4.3: With the launch of ECOS, will there be changes in the IRB review structure for NHG DSRB?

- Although NHG DSRB will be using a common IRB review platform (ECOS) as SingHealth CIRB, both IRBs will continue to function as independent review boards. Please refer to the respective IRB's policies and requirements.

- If there are cross cluster studies, the IRB review will be done in accordance with the current mutual recognition / cooperative agreements. For more information, please refer to the NHG OHRPP website DSRB FAQs (nhg.com.sg).

[1st published: FAQ #7, 15 Mar 24, Updated: FAQ #15, 1 Oct 24]

Qn 4.4: Who will need to complete the Principal Investigator Self-Assessment Form (PISAF) & Study Closure Checklist (SCC) on ECOS Compliance (PISAF) Module?

- PI(s) who need to complete the Principal Investigator Self-Assessment Form (PISAF) and Study Closure Checklist (SCC) will be contacted by the NHG Research & Quality Management (RQM).

- Refer to ECOS Compliance (PISAF) Module User Guides for more information on how to navigate.

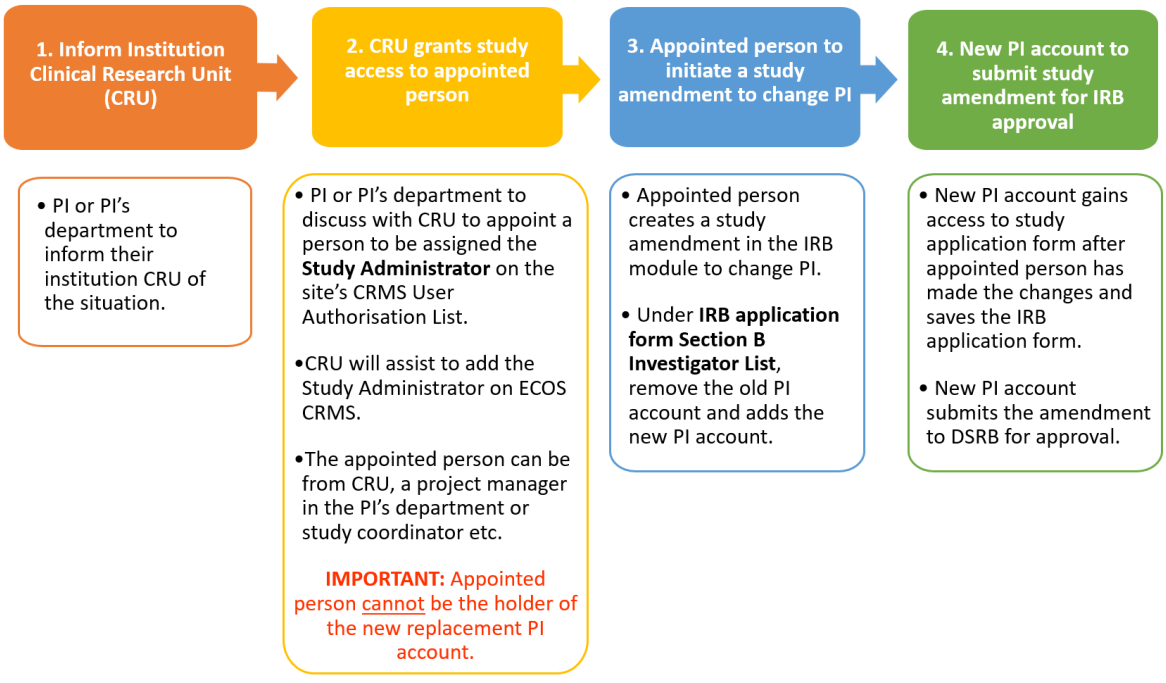
[1st published: FAQ #15, 1 Oct 24]

Qn 4.5: How to change the study PI(s) on ECOS if they are the sole study team member and have either left the institution OR cannot access the study due to a change in their ECOS login profile?

- Follow the steps below if the PI is the only person in the study team and the following situations occurs:

  (a) PI has left the institution prior to initiating a study amendment submission on ECOS to change PI.

  (b) PI has changed his / her ECOS login profile (e.g., change email domain from @mohh.com.sg to @ttsh.com.sg) and is unable to use the old account profile to access his / her studies.



[1st published: FAQ #16, 27 Nov 24]

5. ECOS USER TRAINING & RESOURCES

Qn 5.1: Will there be training or User Guides to familiarise users with the ECOS platform / modules?

- Yes, there are training materials to familiarise users with ECOS and its functions:
  - ✓ **Slides** for the ECOS Onboarding Training Webinars (conducted in April 2024) is available on Training (nhg.com.sg)
    - ➢ For NHG staff only, the Webinar **recording** is available on NHG eLEARN Marketplace (https://elearn.sg/).
    - ➢ For NUHS staff, you may approach your Research Office for more info to access the Webinar recording.
  - ✓ **ECOS Module-specific User Guides** are available on ECOS Launch Support Webpage > User Guides Tab
- Do regularly check the ECOS Launch Support Website for the latest information.

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Qn 5.2: Will there be changes to the DSRB submission forms and reporting requirements with the launch of ECOS?

- There are no changes to the DSRB reporting requirements (Non-compliance, study status report, expected SAE, UPRITSO, other notifications).
- DSRB and CIRB have aligned the main IRB application form and some of the supplementary forms (e.g., non-compliance, study status reports). The updated IRB application form and supplementary forms are now available on ECOS.
- You can refer to the IRB Guidebook: Application Form on the ECOS Launch Support Webpage > User Guides Tab to understand how to complete the ECOS IRB application form.

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