National Healthcare Group

Adding years of healthy life

ECOS Launch Frequently Asked Questions (FAQ)

VERSION #13, DATED 6 AUGUST 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 will replace the current 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 Launch Support for NHG website (ECOS FAQs)** (https://for.sg/ecos-faq) *(Both NHG-Intranet & Internet accessible)* to obtain the latest version of the FAQ document.

TABLE OF CONTENTS

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 Research 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)

[1st published: FAQ #1, 27 Nov 23, Refreshed: FAQ #2, 20 Dec 23, FAQ #5, 29 Jan 24, 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 #13, 6 Aug 24]

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.

[1st published: FAQ #2, 20 Dec 23, FAQ #6, 28 Feb 24, FAQ #7 15 Mar 24, FAQ #8, 28 Mar 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]

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)

[1st published: FAQ #1, 27 Nov 23, Refreshed: FAQ #2, 20 Dec 23, FAQ #6, 28 Feb 24, FAQ #7 15 Mar 24, FAQ #8, 28 Mar 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]

Qn 1.4: Will I still have access to ROAM?

- You will have **read-only access** to existing information on ROAM till **31 August 2024, 23:59** (extended from 31 July 2024). Please ensure you download all required information from ROAM by 31 August 2024.

[1st published: FAQ #2, 20 Dec 23 , 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]

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, FAQ #7, 15 Mar 24, FAQ #10, 10 May 24, FAQ #12, 1 July 24, FAQ #13, 6 Aug 24]

Qn 1.6: Is there a Deadline to submit Standing Database Applications (SDB)?

- New SDB applications will no longer be accepted **from 01 April 2024**. Submissions will only resume when ECOS SDB Module is launch in Phase 2 (estimated end September 2024).

- For queries pertaining to NHG Standing Database, please email **RDOCSecretariat@nhg.com.sg.**

[1st published: FAQ #3, 08 Jan 24, FAQ #9, 30 Apr 24, FAQ #10, 10 May 24, FAQ #11, 31 May 24, FAQ #12, 1 July 24]

Qn 1.7: Did DSRB conduct reviews after the initial submission cut-off date of 1 Feb 2024?

- Yes, the DSRB had received a 4-fold increase in submissions in the weeks leading to the initial submission cut-off date of **1 Feb 2024** for new study applications, amendments and study status reports.

- DSRB was working on the received submissions and had been committed to clear them in time for the migration to ECOS. DSRB also coordinated with other public and private sector IRBs to increase their capacity to accept new studies over the period.

- To manage the transition to ECOS, DSRB had also previously reached out to public grant funding agencies and local institutions to defer grant calls and awards over this period.

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

2. DATA MIGRATION FROM ROAM TO ECOS

Qn 2.1: Will all my approved DSRB studies be 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, Refreshed: 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]

Qn 2.2: Will Expired Studies be migrated to ECOS?

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

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

Qn 2.3: Will my ROAM User Account be automatically migrated over to the ECOS system?

- Unfortunately, **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.*

[1st published: FAQ #1, 27 Nov 23, Refreshed: FAQ #4, 19 Jan 24, FAQ #6, 28 Feb 24, FAQ #11, 31 May 24, FAQ #13, 6 Aug 24]

Qn 2.4: What happens to ROAM Account Profile 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** are required to be listed in the IRB application form.
- 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 and be added to the study in the ECOS Clinical Research Management System (CRMS) module. 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, Refreshed FAQ #7, 15 Mar 24, FAQ #10, 10 May 24, FAQ #11, 31 May 24, FAQ #13, 6 Aug 24]

Qn 2.5: I am an investigator (PI/ Site PI / Co-I) and all the studies I am involved in are completed. Will my ROAM Account Profile be 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, FAQ #11, 31 May 24, FAQ #13, 6 Aug 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, Refreshed: FAQ #7, 15 Mar 24]

Qn 3.2: What are the Minimum Training Certifications that have 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 are not loaded onto ECOS, you will not be allowed to submit new applications and study amendments (refer to Qn 3.6).

[1st published: FAQ #3, 08 Jan 24, Refreshed: FAQ #7, 15 Mar 24, FAQ #9, 30 Apr 2, FAQ #10, 10 May 24, FAQ #11, 31 May 24, FAQ #12, 1 July 24]

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, FAQ #12.1, 4 July]

Qn 3.4: My Research Institution requires that I complete HBRA minimum training. Do I need to upload my HBRA minimum training certificate on ROAM?

- You do not need to upload your HBRA minimum training certificate on ROAM. Instead, upload it on ECOS.

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

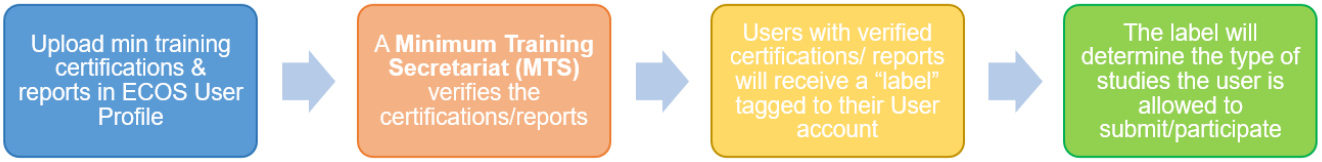
Please check with your specific Research Institution (RI) regarding the HBRA minimum training requirements, as these requirements may vary among different RIs.

[1st published: FAQ #3, 08 Jan 24, Refreshed: FAQ #6, 28 Feb 24, FAQ #9, 30 Apr 24, FAQ #10, 10 May 24, FAQ #13, 6 Aug 24]

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

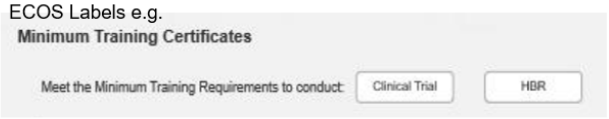
- Your training certifications will go through a validation process as per below.

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

[1st published: FAQ #6, 28 Feb 24, FAQ #9, 30 Apr 24, FAQ #13, 6 Aug 24]

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

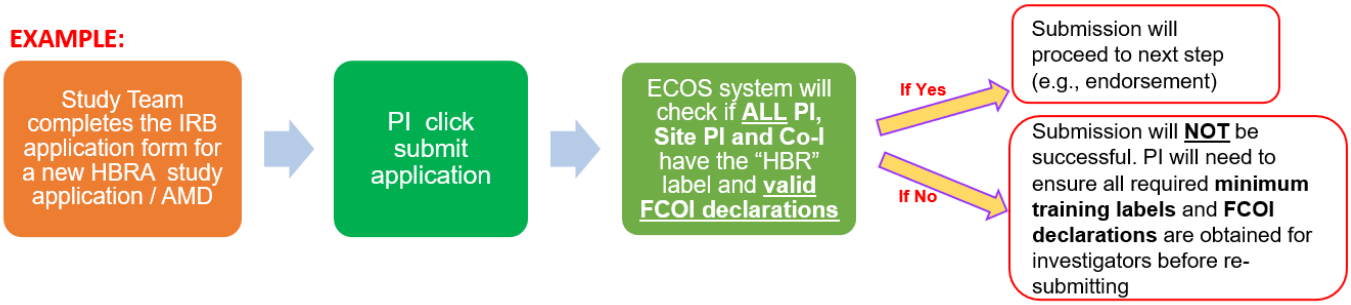
- The FCOI declaration will continue to be an annual exercise. However, to help with the transition to ECOS:
  - A one-time extension of the validity period of CY2023 FCOI Declarations had been given (up **till 30 June 2024).**
  - CY2022 and CY2023 annual FCOI declarations of PI, Site PI or Co-I (**in 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, 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** 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) 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.

[1st published: FAQ #6, 28 Feb 24, FAQ #9, 30 Apr 24, FAQ #10, 10 May 24, FAQ #13, 6 Aug 24]

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, 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 had been launched on 01 August 2024.

    For other ECOS Modules, more details will be provided later.

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

[1st published: 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 #13, 6 Aug 24]

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 Research website NHG :: RDO :: DSRB Frequently Asked Questions (FAQs).

[1st published: FAQ #7, 15 Mar 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 'ECOS Launch Support Portal > Training'

  - 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 Portal > User Guides'.**

  Do regularly check the ECOS Launch Support Website for the latest information.

[1st published: FAQ #7, 15 Mar 24, FAQ #9, 30 Apr 24, FAQ #10, 10 May 24, FAQ #12, 1 July 24]

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.

[1st published: FAQ #7, 15 Mar 24, FAQ #8, 28 Mar 24, FAQ #10, 10 May 24]