

RESTRICTED, SENSITIVE (NORMAL)

Update on ECOS and Impact on IRB Studies and Forms During Transit Period

12 March 2024



Please regularly check the ECOS
Launch Support for the latest
information.



Agenda

- Why ECOS
- ECOS is Web-based
- Facilitating the Move
- Access to Research Studies
 - ROAM is accessible through 30 June
 - Critical Submissions
- Key Milestones
- Annex & Resources



ECOS - Ethics and Compliance Online System

ECOS is the new IRB IT System co-developed by NHG and SingHealth that will replace the current NHG ROAM system. The system is funded by NMRC to enhance the efficiency and quality of ethics reviews.



Question - Why do we need to move to **ECOS**?



iPhone 5 (2012)
ROAM (2012)

[Image credits: [iPhone 5 - Wikipedia](#)]



iPhone 16 (2024)
ECOS (May, July 2024)

[Image credits: [iPhone 16 Series To Have Two Major Upgrades, Tipster Hints They Are 'Quite Noteworthy'](#) ([wccftech.com](#))]

- Faster & agile
- Improved user interface
- Greater Capacity
- Stronger cybersecurity features
- Common Platform for DSRB & CIRB
- Promotes research collaborations



ECOS - Ethics and Compliance Online System

Benefits of



Current System - ROAM	Future System - ECOS
Addition/ removal of Study Administrator in the application form requires approval.	Addition/ removal of Study Administrator, Study Team member and Study Sponsor will not require IRB review and approval. Changes will be managed at site level.
Application questions different between DSRB (ROAM) and CIRB (iShare).	Most application questions are streamlined between DSRB & CIRB on ECOS.
Limitations to triaging of studies between IRB.	At submission, applications can be triaged across cluster IRBs or within the same IRB
Limitations to viewing revisions (i.e., track changes).	Able to compare revisions (i.e., track changes) made by study team.
Applicants need to scroll to the incomplete sections/ questions.	Research Office Checker able to check whether mandatory fields in the application form are completed. A pop-up window will show sections where mandatory fields are not completed or requirements were not fulfilled (e.g., study member did not complete Minimum Training requirement or FCOI requirement).

ECOS is Web-Based

Accessible to Public Healthcare Institutions (PHI) and non-PHIs users (e.g., Pharma Sponsors, Academic Institutions)

- 1 Common IRB Form
- Research Office Checker for institutions pre-endorsement checks
- Only PI, Site PI & Co-I roles in IRB applications
- Min training validation
- No need to upload CVs

- Report HBRA safety events & non-compliances to MOH
- Complete PI Self Assessment Forms

- Audit
- Monitoring



- Traction recruitment
- Accessible by **Sponsor, Study Team Members & Administrators**

ECOS for DSRB, CIRB
(Internet Web-based Application)

- For NHG & NUHS SDB applications



- FCOI declarations synced for DSRB applications

ECOS is Web-Based

Phase 1 IRB Launch - May 2024

Accessible to Public Healthcare Institutions (PHI) and non-PHIs users (e.g., Pharma Sponsors, Academic Institutions)

- 1 Common IRB Form
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- Traction on recruitment
- Accessible by **Sponsor, Study Team Members & Administrators**

- For NHG & NUHS SDB applications



- FCOI declarations synced for DSRB applications



Facilitating the Move

1. Only approved, ongoing studies will be migrated – 4100
2. Only profiles of PI, Site PI and Co-I of these active studies + key appointment holders (ex. DR, IR, IRB members) will be automatically ported into ECOS
3. DSRB has made 2 adjustments to reduce burden on researchers:
 - a) Automatic extension of study validity period by 6 months
 - b) Extended CY2023 FCOI declaration validity period by 6 months
4. New Requirements
 - a) HBRA Minimum Training to be uploaded in ECOS
 - b) GCP training is required for PI, Site PI and Co I + study team members involved in significant activities

Refer to
Annex &
Resources
(slide 14)

Accessing Studies

ROAM is accessible through 30 Jun 2024

Now to
01 April 2024



- Address DSRB queries on ROAM for submitted studies, amendments & Study Status Report Forms.
- Submit new Non-Compliance, UPIRTSO, Expected SAE reports and *Other Study Notification and address DSRB queries.
- DSRB aims to complete all reviews and ready the studies for ECOS in April.

We strongly urge investigators to submit only critical OTH during this transition period. Non-critical miscellaneous documents under OTH can be submitted after ECOS is launched.

01 April 2024
to 30 Jun 2024




- ROAM users have **view access to ROAM study information** till **30 June 2024**.
- Please download all required information from ROAM **by 30 June 2024**.
- NCR, UPIRTSO, eSAE submissions may need to be submitted offline. More information to be released end March.

For studies to be readied for migration, all submissions must have a review outcome before 1 April 2024

Critical Submissions [1/2]

If I have an (a) international sponsor / funded / awarded study, (b) local funded / awarded study that are tied to business or whole of government strategies (c) hit or miss rare disease study proposals (d) pandemic / endemic studies (e) other funded and time sensitive studies, will I be able to submit them to DSRB after the submission cut-off date?

Do contact OHRPP@nhg.com.sg with the required information below if you have such critical submissions.

Submission Type	 Actions Required
New Studies	<ol style="list-style-type: none">1. Write to OHRPP@nhg.com.sg with: Email Subject: Seeking Exception Review of New Study<ol style="list-style-type: none">i. Name, Dept, Inst and Email of PIii. Name, Dept, Inst and Email of Site PI(s)iii. Strong justifications why new study cannot wait till ECOS launch2. Prof Benjamin Seet / designee will determine if the exception will be granted.3. DSRB will provide instructions to PI on submission process.
Study Amendments (AMD)	<ol style="list-style-type: none">1. Write to OHRPP@nhg.com.sg with: Email Subject: Seeking Exception Review AMD<ol style="list-style-type: none">i. DSRB Reference Numberii. Study Titleiii. PI Nameiv. List of changes in point-formv. Strong justifications why AMD cannot wait till ECOS launch2. Prof Benjamin Seet / designee will determine if the exception will be granted.3. DSRB will provide instructions to PI on submission process.

Critical Submissions [2/2]


If I have an (a) international sponsor / funded / awarded study, (b) local funded / awarded study that are tied to business or whole of government strategies (c) hit or miss rare disease study proposals (d) pandemic / endemic studies (e) other funded and time sensitive studies, will I be able to submit them to DSRB after the submission cut-off date?

Do contact OHRPP@nhg.com.sg with the required information below if you have such critical submissions.

Submission Type		i Actions Required
Study Status Report Forms (SRF)	Reactivation of a study which expired between 1 Nov 2023 & 31 Jan 2024	1. Write to OHRPP@nhg.com.sg with: Email Subject: Seeking Exception to Reactivate Study <ol style="list-style-type: none"> i. DSRB Reference Number ii. Study Title iii. PI Name 2. DSRB will provide instructions to PI on submission process.
	Suspended	1. Write to OHRPP@nhg.com.sg with: Email Subject: Seeking to Submit Notification of Suspension <ol style="list-style-type: none"> i. DSRB Reference Number ii. Study Title iii. PI Name 2. DSRB will provide instructions to PI on submission process.
	Completed / Terminated	1. Write to OHRPP@nhg.com.sg with: Email Subject: Seeking to Close Study (Completed / Terminated) <ol style="list-style-type: none"> i. DSRB Reference Number ii. Study Title iii. PI Name 2. DSRB will provide instructions to PI on submission process.

[1st published: FAQ #5, 29 Jan 24]

Key Milestones Ahead

	What will happen	 Actions Required
1 April 2024	<ul style="list-style-type: none"> DSRB confirms list of studies for migration into ECOS. <p>Studies with sup forms submitted after 16 March 2024 may be migrated at a later phase.</p>	<ul style="list-style-type: none"> NCRs, UPIRTSO, eSAE, OTH will still be reviewed. However, submission may be carried out offline. More details to follow. Submit only <u>CRITICAL OTH</u> during this transition period. Non-critical miscellaneous documents under OTH can be submitted after ECOS is launched.
	<ul style="list-style-type: none"> Profiles of Pls, Site-Pls and Co-Is involved in active studies will be extracted for ECOS pre-loading. 	<ul style="list-style-type: none"> Ensure your ROAM account is tagged with the corporate email address before 01 April 2024.
	<ul style="list-style-type: none"> DSRB / Standing Database secretariat will stop accepting new SDB applications. 	<ul style="list-style-type: none"> Submit new SDB applications or amendments on ROAM (non-NHG) or SDB Online System (NHG) before 01 Apr 2024.
May 2024	<ul style="list-style-type: none"> ECOS Gears Up! <p><i>Note: SDB module is targeted for launch in July 2024.</i></p>	<ul style="list-style-type: none"> For migrated accounts: Check that your user profile has been migrated & upload your training certificates (if applicable) prior to any new study submissions and AMD For non-migrated accounts: Create user profile and upload your training certificates prior to any new study submissions. <p>Note: Collaborators and Study Administrators who require access to the IRB documents and submissions will need to register for an ECOS User Account and be added in the new Clinical Research Management System (CRMS) module on ECOS upon launch. More details on CRMS will be provided later.</p>

* All dates are correct at the time of publication and may be subjected to further changes.

Contact OHRPP@nhg.com.sg if you have critical submissions after cut-off dates.



Agenda

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- ✓ ECOS is Web-based
- ✓ Facilitating the Move
- ✓ Access to Research Studies
 - ROAM is accessible through 30 June
 - Critical Submissions
- ✓ Key Milestones
 - Annex & Resources



Annex & Resources

- ◆ Data Migration
 - ◆ Migration of User Profile from ROAM to ECOS
 - ◆ Types of Studies for Migration
- ◆ DSRB Submission Deadlines
 - ◆ DSRB Extension for Status Report Form (SRF) Submission
 - ◆ FCOI Adjustments & Declarations
- ◆ Minimum Training Changes
- ◆ Resources to help you

Data Migration – Migration of User Profile from ROAM to ECOS [1/3]

To allow researchers to access their studies readily on ECOS, the following **ROAM accounts** will be preloaded into ECOS:

An individual who

- Is a **PI**, **Site-PI** or **Co-I** in an **Active Study** ^[A] or
- Is a **ROAM Key Appointment Holder** (such as *DR, IR, DSRB Chair/Members etc*)

AND

- Has a valid, complete ROAM Account Profile ^[B].

ACTION: Before 1 April 2024

Update your ROAM user profile to be migrated to ECOS

[A] What is an Active Study?

- A *DSRB-Approved Study, which is Ongoing*

[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.

Specific to NHG/Partner institutions only

*** 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.

All other existing ROAM users can create their ECOS profile when ECOS is launched.

Data Migration – Migration of User Profile from ROAM to ECOS [2/3]

To ensure studies are accessed by authorized research team members only, researchers with cross-PHI profiles will need to create different ECOS accounts to manage each PHI/Cluster's studies.

Example A: An individual who is a (1) **Senior Consultant in TTSH AND (2) Visiting Consultant in NUHS.**

- *Should create 2 ECOS Accounts*
- *(1) TTSH ECOS Account using XXX@TTSH.com.sg (2) NUHS ECOS Account using XXX@nuhs.com.sg*
- *To submit/access studies under TTSH, login using TTSH email. To submit/access NUHS studies, login using NUHS email.*

Example B: An individual who is a (1) **Senior Consultant in TTSH AND (2) Visiting Consultant in KTPH.**

- *1 ECOS Account suffice as both profiles are within the same PHI cluster - XXX@TTSH.com.sg*
- *Optional - Secondary Profile as KTPH VC on profile page*
- *May submit/access studies under TTSH/KTPH using same ECOS account.*

Segregation of ECOS accounts will ensure that access is promptly restricted access, e.g., when a VC ceases its appointment at another cluster.

Data Migration – Types of Studies for Migration [3/3]

Will all my approved DSRB studies be migrated?

- Only **Approved and Ongoing** studies will be migrated to ECOS.
- For **Ongoing** Studies, the following Study Status in ROAM will be 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
- Studies that are **Completed, Withdrawn** or **Terminated** will **NOT** be migrated to ECOS.
- For studies to be readied for migration, all submissions must have a review outcome **before 1 April 2024**.

Will Expired studies be migrated?

- Expired studies will not be eligible for migration to ECOS, except for studies that **are recently expired** (i.e., between 1 November 2023 – 31 January 2024).

If there is no intention to renew these expired studies, please inform DSRB.

DSRB Submission Deadlines – DSRB Extension for SRF

❑ One-Time Extension of DSRB Approval for Studies Expiring 1 Feb – 31 Jul 2024

- DSRB has extended study approvals **by 6 months** for studies whose DSRB approval is expiring between 1 February and 31 July 2024, both dates inclusive, to facilitate the data migration and transition activities to ECOS.
- PIs do not need to rush to submit SRFs and to minimise lapse in approvals during this transition period.
- The new approval expiry date will be updated backend.

Example A
Current Study Validity till: 1 Feb 2024



Auto-extension of Study Validity till:
1 Aug 2024

Example B
Current Study Validity till: 1 Jul 2024



Auto-extension of Study Validity till:
1 Jan 2025

DSRB Submission Deadlines – FCOI Declaration

❑ One-Time Extension of Validity Period for the 2023 and 2024 Annual FCOI Declaration

- The validity period for CY2023 FCOI Declarations has been **extended to 30 Jun 2024.**

➤ Study Team Members are **not required** to email CY2024 FCOI Declarations to the FCOI Secretariat, unless if there is a **change in FCOI** status.

(FCOI declaration forms received after 1 March 2024 may delay the study migration to ECOS)

➤ CY2024 FCOI Declaration will commence in ECOS from May 2024

❑ Data Migration of 2022 and 2023 Annual FCOI Declarations

- FCOI declarations of PI, Site PI or Co-I (active studies only) would be preloaded into ECOS

Minimum Training Requirement [1/4]

Migration of Minimum Training Completion Records into ECOS

What happens if PI/ Site PI/ Co-I's Minimum Training Certificate are not uploaded on ROAM before 1 March 2024?

- If your Minimum Training Certificates have not been uploaded before 1 March 2024, your training records will not be pre-loaded into ECOS.
- **i Action Required:** You will need to upload the training certificates on ECOS when it is launched.
- If your training certificates are not loaded onto ECOS, you will not be allowed to submit new applications and study amendments.

[Ref: ECOS Launch FAQ #5, 29 Jan 24, FAQ #6, 28 Feb 24]

Minimum Training Requirement [2/4]

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

1. Who needs to complete GCP Training

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 <u>PI, Site-PIs</u> and Co-Is to complete GCP prior to IRB submission.
Other Study Team Members (STM) (conducting clinical trial)	GCP training is <u>not mandatory</u> per DSRB requirements.	Mandatory for Study Team Members (STM) conducting <u>*significant trial related tasks</u> to complete GCP <u>before study involvement</u> . <i>* E.g. Informed consent, eligibility assessment, IP management, key efficacy and safety assessment, you may refer to HSA website for more details</i>

2. Acceptable GCP courses - DSRB will recognise generic GCP courses (e.g., CITI GCP) and training as acceptable minimum training.

Minimum Training Requirement [3/4]

For **HBRA** regulated studies

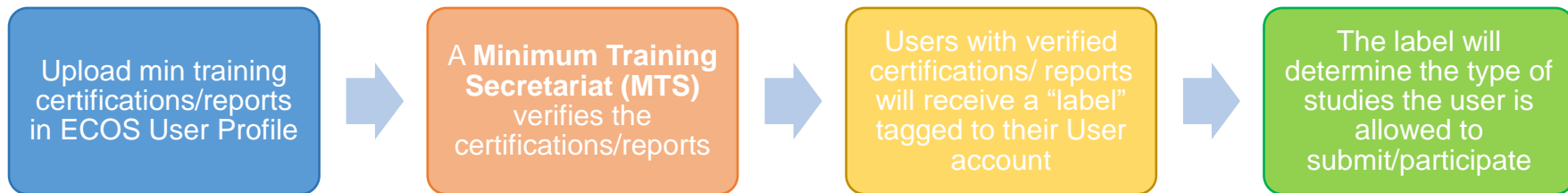
On ECOS, Researchers who want to conduct HBR study must obtain a “HBR” label before submission of new IRB submissions and amendments.

ECOS Process	New HBR Min Training Requirement	i Action Required
PI/ Site PI and Co-I	Complete HBR Training <u>before new IRB submissions and amendments.</u>	Important Upon ECOS launch, investigators will need to upload HBR minimum training (records /certificate) directly into ECOS for verification , prior to submitting new IRB applications and amendments.
Other study team members	Complete HBR Training <u>before study involvement.</u>	

Minimum Training - ECOS Minimum Training Validation Check [4/4]

Training certificates will go through a validation process

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.

Minimum Training Certificates

Meet the Minimum Training Requirements to conduct:

Clinical Trial

HBR

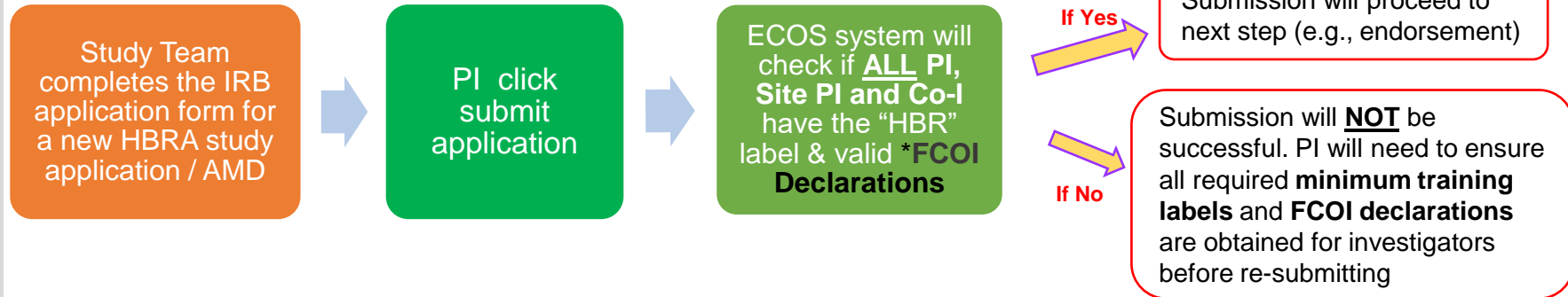
[Ref: 1st published: FAQ #6, 28 Feb 24]

REMINDER**FCOI Declaration Process**

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 will be given (up till 30 June 2024). CY2024 FCOI Declaration will commence in ECOS upon launch in mid-2024.

CY2022 and CY2023 annual FCOI declarations of PI, Site PI or Co-I (in active studies only) would also be preloaded into ECOS.

When ECOS is launched, the FCOI declarations will be submitted via ECOS.

Submission Process to DSRB**EXAMPLE:**

*For more information on FCOI, refer to the NHG research website: <https://www.research.nhg.com.sg> > Conducting Research > Minimum Training Requirements > Financial Conflict of Interest (FCOI) Training Requirements

[Ref: ECOS Launch FAQ #5, 29 Jan 24]

Resources on ECOS

Home > Research Ethics Framework > ECOS Launch Support for NHG

<https://www.research.nhg.com.sg> > Ethics & Quality > ECOS Launch Support

ETHICS & QUALITY



Introduction to Ethics >

Apply for Ethics Approval >

DSRB Announcements

DSRB FAQ

Standing Databases & Tissue Banks▶

Research Quality >

Quality Improvement

ECOS Launch Support >

ECOS Launch Support for NHG

ECOS Home

ECOS Announcements

ECOS FAQs

ECOS Migration Prep

ECOS User Guides

LATEST ECOS ANNOUNCEMENTS & NEWS

- **NEW** 28 Feb 2024: [ECOS FAQs \(Version #6 dated 28 Feb 2024\) is now available.](#)
- **NEW** 26 Feb 2024: [\[ECOS Announcement #5A\] Study PI, Site-PI & Co-I Minimum Training Checklist - FOR ACTION BEFORE 1 MARCH 2024](#)
- **NEW** 26 Feb 2024: [\[ECOS Announcement #5B\] ROAM Study Supplementary Report Form Submission Cutoff-date Extended to 1 April 2024](#)
- [8 Feb 2024: \[ECOS Announcement #4\] Debunking Myths](#)

Do you wish to receive our ECOS Announcements over Email? [Subscribe to the ECOS Mailing List here.](#)
(<https://for.sg/ecos-mailing-list>)

For More Information



Any Questions?



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ECOS FREQUENTLY ASKED QUESTIONS

The ECOS FAQ Document will be periodically updated with latest information as they become available. We recommend that you check back here regularly to obtain the latest version available.

You may download the latest ECOS FAQ Document for answers to the questions listed below.



[ECOS FAQ Document Version # 6](#) (Updated as of 28 Feb 2024) **UPDATED**

Do you have questions about ECOS or the transition over to ECOS?
[Submit your Questions here.](https://for.sg/ecos-submit-questions) (<https://for.sg/ecos-submit-questions>)

(1) DSRB SUBMISSION DEADLINES

Qn 1.1: When is the Deadline for Researchers to submit their IRB Applications to DSRB for review & approval?

Qn 1.2: Is there a Deadline to submit Study Renewals to DSRB?

Qn 1.3: Is there a Deadline to submit Safety Events (NCR, UPIRTSO, Expected SAE) to DSRB?

Qn 1.4: Will I still have access to ROAM after the submission cut-off dates?

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

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

Qn 1.7: If I have an (a) international sponsor / funded / awarded study, (b) local funded / awarded study that are tied to business or whole of government strategies (c) hit or miss rare disease study proposals (d) pandemic / endemic studies (e) other funded and time sensitive studies, will I be able to submit them to DSRB after the submission cut-off date?

Qn 1.8: Is DSRB still conducting reviews after the submission cut off dates? **NEW**

ATTENTION!

DSRB will cease accepting the following reports via the ROAM System **from 1 April 2024.**

(extended from 1 March 2024)

1. **Non-Compliance/Study Deviation Reports (NCR)**
2. **Unanticipated Problems involving Risks to Subjects or Others (UPIRSTOs)**
3. **Expected Serious Adverse Events (SAE)**
4. **Other Study Notifications (OTH)***

**We strongly urge investigators to submit only critical OTH during this transition period. Non-critical miscellaneous documents under OTH can be submitted after ECOS is launched.*



TO NOTE

Studies with forms submitted after 16 Mar 2024 may be migrated into ECOS at a later date.

Details on reporting of safety events in April will be provided later.

Please continue to address DSRB queries promptly to achieve a review outcome before 1 April 2024, to facilitate the timely migration of your study to ECOS.

MINIMUM TRAINING CHECKLIST

Tip! Use this checklist to ensure you are well-prepared for the transition to ECOS!



**For Your Action Now
Before 01 March 2024**

For: [Active, Ongoing Studies] PI, Site PI, Co-I

01 Ensure that your minimum training statuses (Biomedical CITI¹, FCOI CITI², GCP³, SBE CITI⁴) are updated to Completed on your ROAM Profile.

- Biomedical CITI** - If incomplete, please upload a CITI training completion report.
- FCOI CITI** - If incomplete, please upload a FCOI CITI training completion report.
- GCP** (applicable only if you are actively involved in clinical trials) - If incomplete, please upload a GCP training certificate
- SBE CITI** (applicable only if you are actively involved in Population Health studies submitted to Domains F1 & F2) - If incomplete, please upload a CITI training completion report with completion records of 5 SBE modules

02 If your status is reflected as Pending Verification, you may email min_ethics_training@nhg.com.sg to enquire on review progress.

03 PI, Site PI, Co-I can refer to the min training requirements on the NHG Research Website: <https://for.sg/mintraining>

¹ Biomedical Collaborative Institutional Training Initiative (CITI) Training Completion Report

² Financial Conflict of Interest (FCOI) CITI Training Completion Report

³ Good Clinical Practice (GCP) Training Certificate

⁴ Social-Behavioural-Education CITI Training Completion Report

Please note that only the latest uploaded document under the 4 training categories above will be migrated to ECOS.

NOTE: Only training certificates updated to Completed on ROAM by 1 March 2024 will be migrated into ECOS. For researchers who need more time to complete their training, please submit the certificates directly on ECOS when it launches in mid-2024.

ARE YOU READY?

For More Information

Any Questions?

Mailing List Subscription



Thank You.

Please regularly check the ECOS
Launch Support for the latest
information.