Frequently Asked Questions (FAQ)

VERSION 1.0, DATED 30 DECEMBER 2025

Introduction

The Ethics and Compliance Online System (ECOS) was launched on 10 May 2024. It is the new IT system co-developed by NHG Health and SingHealth that supports the human research lifecycle from study initiation to completion, and provides centralised oversight for IRBs, institutions, and researchers. The ECOS system includes the following modules:

Module	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 and site milestones, and subject recruitment
3. Financial Conflict of Interest (FCOI)	For submission of annual FCOI declarations
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)

For the latest information & resources on ECOS, please refer to the NHG Health ECOS Website.

For more information on research requirements (e.g. IRB submission requirements, minimum training, FCOI), please refer to NHG Health Office of Human Research Protection Programme (OHRPP) Website.

Important Contacts

a) ECOS Technical Support	If you require any technical support, please contact the **ECOS Helpdesk**
b) NHG Health DSRB	**DSRB Contact List**
c) Minimum Training Requirements	For general enquires, contact **NHG Health Minimum Ethics Training Secretariat** For Human Biomedical Research Training enquiries, contact **NHG Health Research Course Admin** For institutions specific requirements and ECOS training verification, contact respective **Institutions' Minimum Training Secretariat (MTS)**
d) Financial Conflict of Interest (FCOI) Declarations	For any enquiries, contact the **NHG Health FCOI Declaration Secretariat**.

Table of Content

1 General

1.1 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 the ECOS Quick Start Guide for more details on how to login to ECOS and prepare for submissions to IRBs.

1.2 Where can I find ECOS training materials?

User guides are available for each ECOS module. You can access them here.

1.3 I am unable to login to ECOS. What should I do?

Please contact the ECOS helpdesk if you have issues logging into your account.

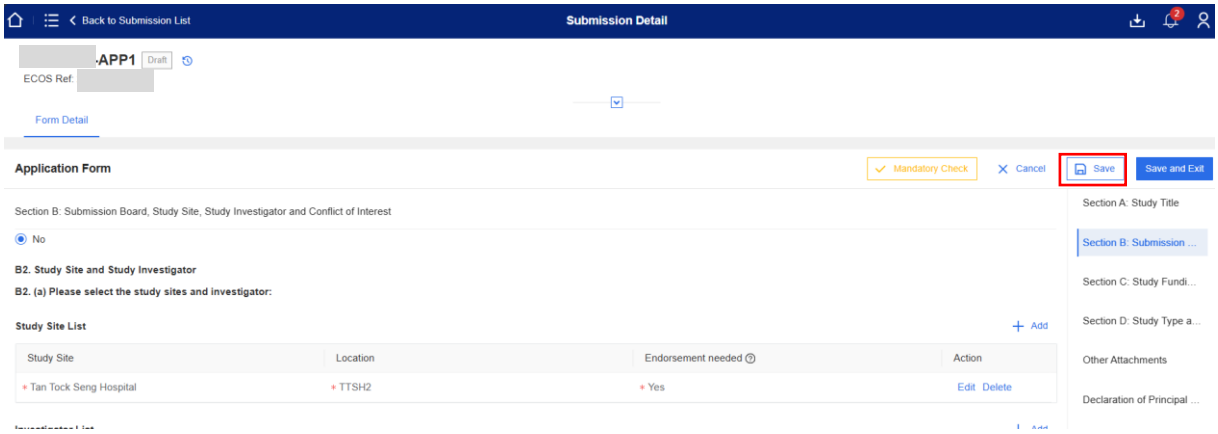
As part of a cybersecurity measure, your ECOS account will become disabled if you have not **logged into ECOS for > 90 calendar days**.

To reactivate your ECOS account, you will need to contact the ECOS helpdesk.

1.4 I am editing the IRB Application Form. Are my edits autosaved?

Edits to the IRB Application Form and Other Forms will **not** be autosaved. Only responses to queries in the IRB application form (e.g. site response to DSRB query) are autosaved.

To save, please click 'Save' located on the right-hand side of the form.

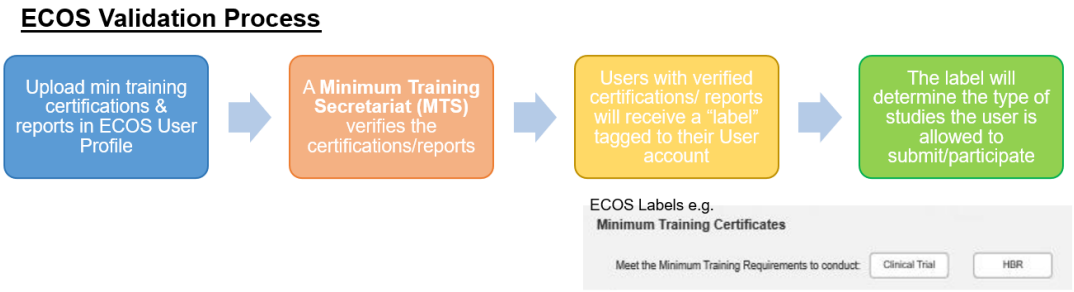


Note: User will be logged out of ECOS if there is inactivity for 60 mins.

2 USER PROFILE - MINIMUM TRAINING REQUIREMENTS

2.1 What happens when I upload my training certificates on ECOS?

Your training certifications will go through the ECOS validation process shown below:



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 NHG Health Staff and Partner Institutions (Please refer to your cluster's/institution's minimum training policy/requirements)		
Type of Study	**Minimum Training Requirements**	**ECOS Labels** ✓ Non-HBR, HBR, SBE, Clinical Trials
Non-Human Biomedical Research	CITI Biomed CITI FCOI^	Non-HBR
Human Biomedical Research regulated by HBRA	CITI Biomed CITI FCOI^ HBRA Training*	HBR
Clinical Trials regulated by HSA	GCP CITI FCOI^	Clinical Trials
Social, Behavioural, Educational Research (applicable to submissions to NHG Health DSRB Domain F)	CITI SBE CITI FCOI^	SBE
^The FCOI declaration form will be given a "Reviewed and Completed" status. *Name of HBRA Training Certification might differ for different cluster/institution.		
Note: a) CITI Biomed, CITI FCOI, CITI GCP and CITI SBE → Please upload the **completion report showing all completed modules** b) HBRA Training Certificate → Please upload the eCertificate		

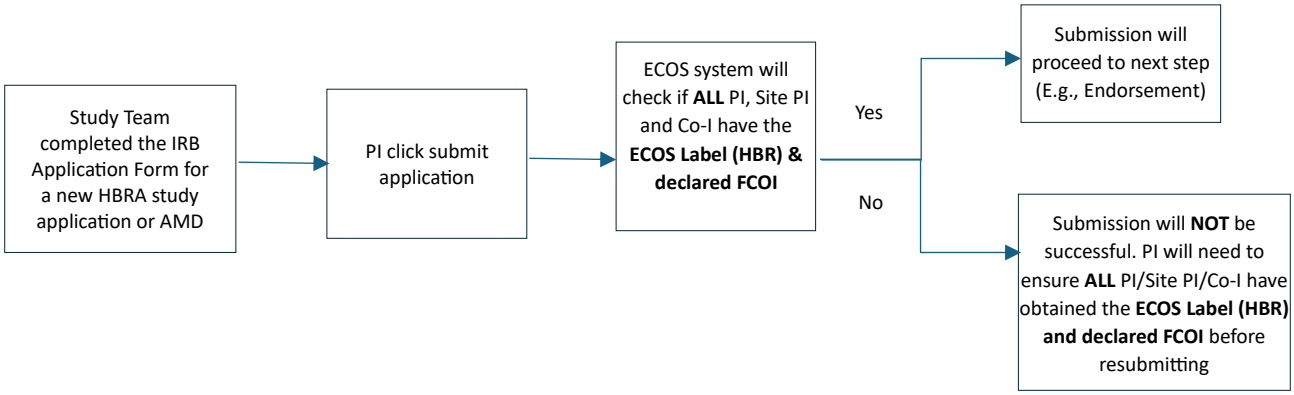
IMPORTANT

If you encounter any issues, please contact your respective Institution Minimum Training Secretariats to provide assistance.

2.2 What if the 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 for IRB review and approval.

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.



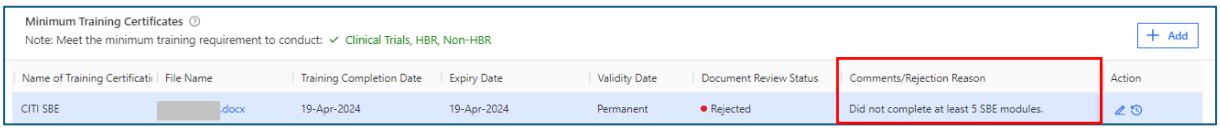
We strongly urge **PI, Site PI and Co-I** to **promptly check and submit** all minimum training requirements and FCOI declarations on ECOS.

Incomplete ECOS training records and FCOI declarations of non-investigator study roles listed in ECOS CRMS module [e.g., study coordinator or collaborator assigned as Study Team Member] 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.

2.3 Minimum training record submitted on ECOS was rejected. What must I do?

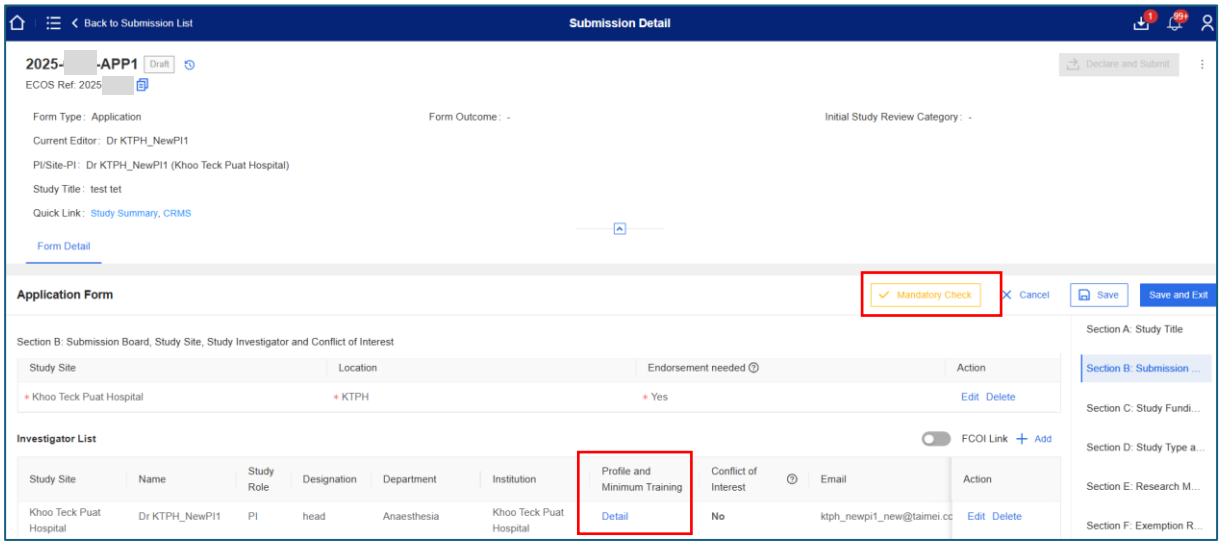
Check the 'Comments/Rejection Reason' column to see why the record was rejected. After addressing the issue, resubmit the training record.



Please refer to the **ECOS User Guide on Submitting Minimum Training Certification**.

2.4 My minimum training records under ECOS User Profile have been updated and verified. However, this update is not reflected in my draft IRB Application Form Section B - Investigator List.

Under Section B of the draft IRB application form, click on 'Mandatory Check' to update the most current training records in Section B - Investigator List.

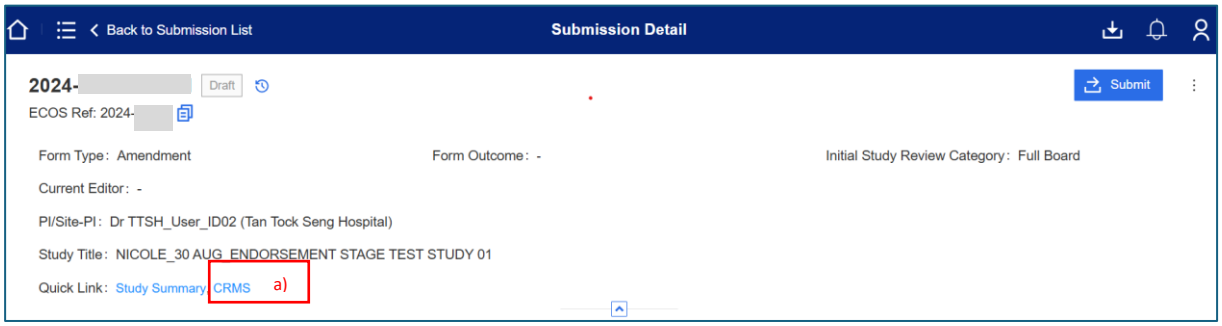


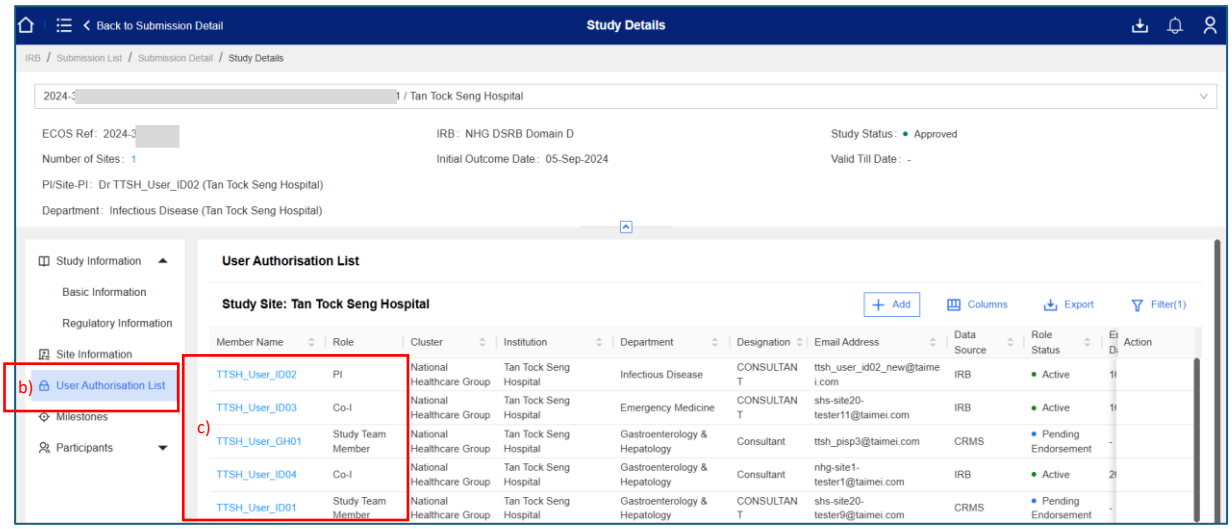
2.5 How do I obtain my Study Team Members' training Completion Reports / eCertificates?

Individuals listed in the CRMS User Authorisation List (UAL) for the study site can retrieve training records for other members under the same study site.

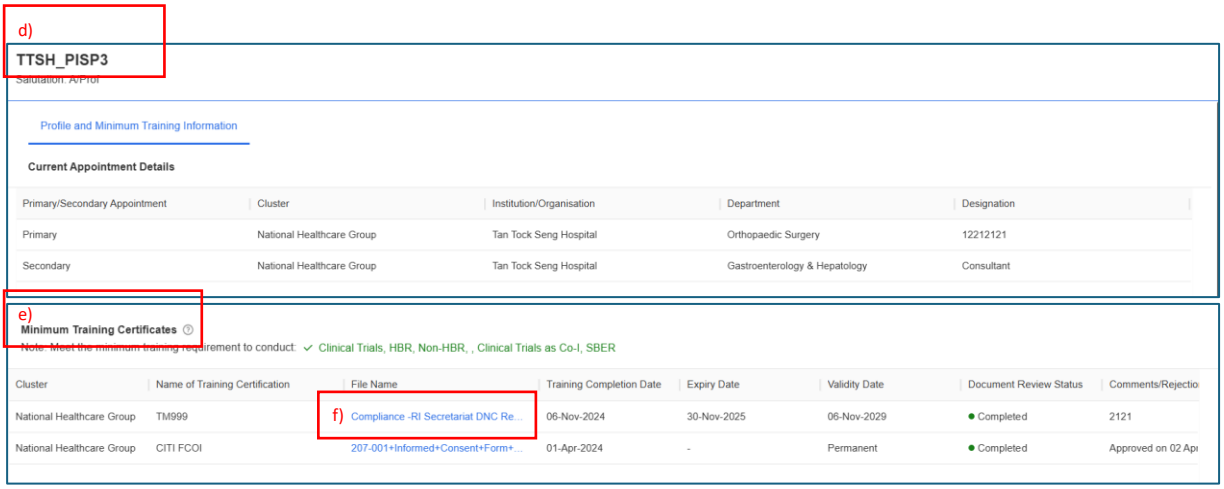
To retrieve the records, go to your study site and follow the steps below:

a) Click on 'CRMS
b) Click 'User Authorization List'
c) Click on the Member's Name





d) Open the Member's Profile Page
e) Scroll down to the Minimum Training Certificates section
f) Click on the File Name column for the respective Training Completion Report / Certificate



3 STUDY MANAGEMENT

3.1 Does my study require DSRB approval? If so, where do I submit?

Any study which involves systematic investigation, including research development, testing, and evaluation, and are designed to develop or contribute to generalizable knowledge is considered research and will require NHG Health DSRB review and approval if it involves patients, staff, premises or facilities of NHG Health institutions and other partner institutions under the oversight of NHG Health DSRB. Such studies must be submitted via ECOS for DSRB review.

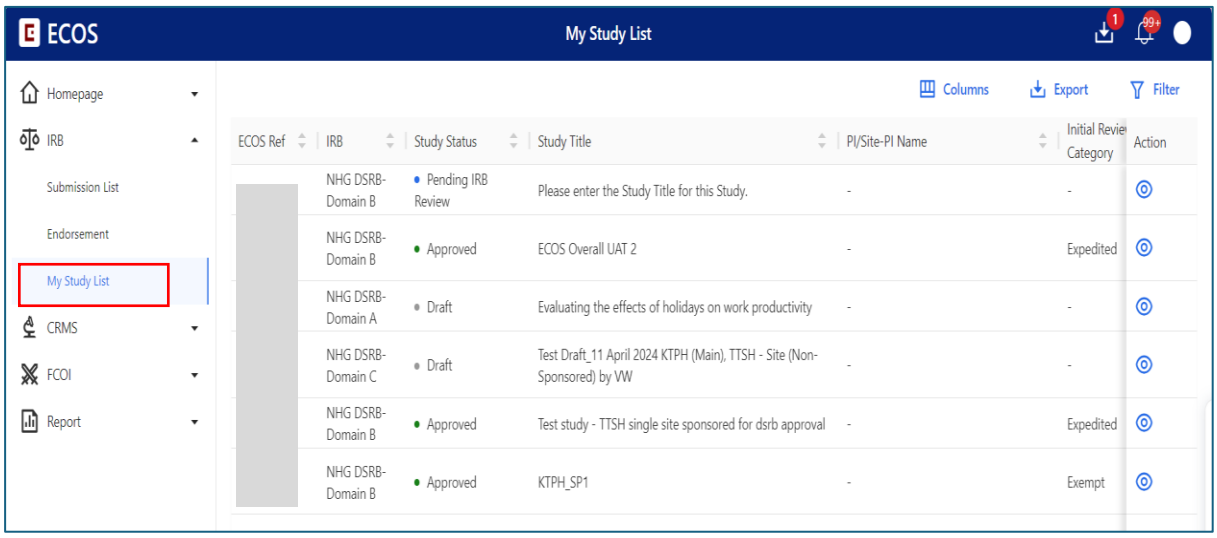
When in doubt whether an activity requires DSRB review and approval, you may contact the DSRB secretariat and provide a summary of the proposal for a preliminary assessment.

Please refer to NHG OHRPP Website - Ethics Review for more information.

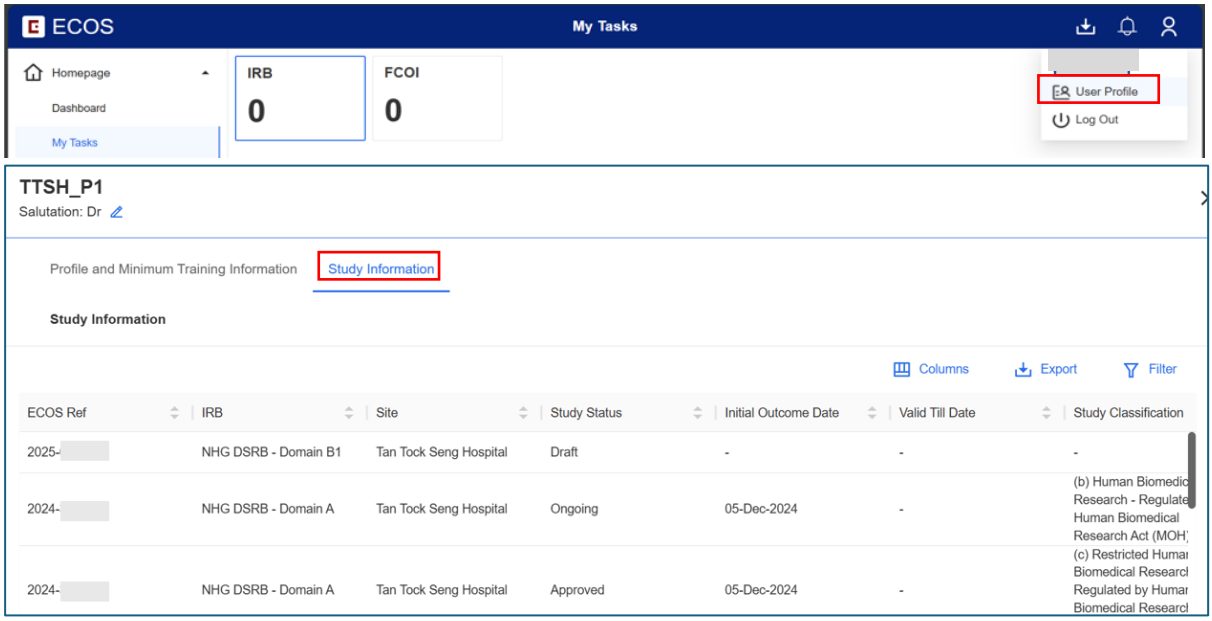
3.2 How to view the list of studies I am involved in on ECOS?

There are two ways to view the studies you participate in:

- At IRB tab, click 'My Study List' to view the list of studies in which you are involved.



- Under 'User Profile', click 'Study Information' and you will see the list of your studies.



3.3 How do I manage access to my study site information on ECOS?

Different user roles on ECOS will have different access rights to the ECOS modules.

The following ECOS user roles are available to study sites:

ECOS User Roles	How to Assign	Approval
1) **PI** 2) **Site PI** 3) **Co-I**nvestigator	In **IRB Application Form -** Section B2. (a) Investigator List: ➢ Search for the individual on ECOS using their email address or full name ➢ Assign the ECOS roles (PI, Site PI or Co-I)	IRB approval is required to include these roles into the study site
Non-Investigator Roles: **1) Study Administrator (SA)**[i] **2) Study Team Member (STM)**[ii] **3) Sponsor** [iii]	In the **study site specific CRMS - User Authorisation List (UAL):** ➢ Search for the individual on ECOS using their email address or full name ➢ Assign the ECOS roles (SA, STM or Sponsor)	PI / Site PI endorsements are required to include these roles into the study site **Endorsements not required if roles are added by the PI / Site PI*

[i] *Site personnel **not directly involved** in the research but provides administrative support only, e.g., Department Manager, Clinical Research Coordinators (CRC) not involved in the conduct of research.*
[ii] *Site personnel **directly involved** in the research conduct e.g., CRCs, Study Nurses, Pharmacists, Collaborators etc.*
[iii] *Sponsor/CRO personnel, e.g., Clinical Research Associates (CRA), Submission Specialist, Research Administrators etc.*

All users must have an ECOS account before they can be assigned roles on ECOS.

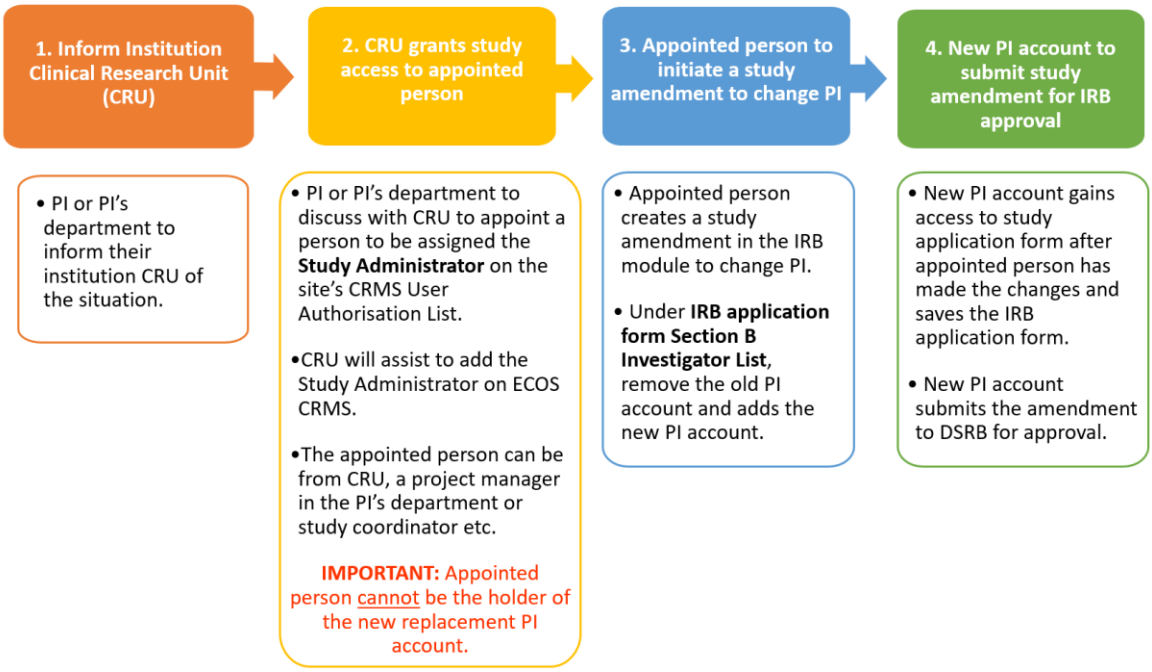
PI is overall responsible for ensuring appropriate access to their study site information. If changes are required (e.g. addition or removal of investigators, study team members), please edit the IRB application form / CRMS UAL.

For more information on how to manage access to your study site, please refer to the **ECOS User Guide for CRMS**.

3.4 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 @nhghealth.com.sg) and is unable to use the old account profile to access his / her studies.



3.5 Who needs 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 NHG Health Research & Quality Management (RQM).

Please refer to the **ECOS User Guide on Research Quality Programmes: How to complete the PISAF & SCC** for more information on how to navigate the Compliance PISAF module.

4 IRB SUBMISSIONS

4.1 Who can view, edit and submit IRB forms on ECOS?

The Principal Investigator (PI) is overall responsible for the preparation and completion of the submissions to the DSRB. Even if tasks are delegated to other research staff, the PI should retain oversight of all submissions.

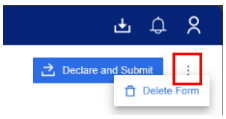
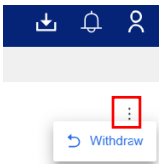
For submissions on ECOS, Study Sponsors and site staff (i.e. Study Administrators or Study Team Member) can all view and edit the IRB forms.

However, submissions can only be performed by the PI, Site PI and Co-Is as follows:

IRB Form	Who can submit on ECOS?		
	PI	Site PI	Co-I
➢ Initial IRB Application ➢ Amendment ➢ Study Status Report (SSR) ➢ Study Deviation/ Non-Compliance Report (DNC) ➢ Other Study Notification (OSN)	✓	✗	✗
Serious Adverse Event (SAE)	✓	✓	✓
UPIRTSO (UPT)	✓	✓	✗

4.2 How do I withdraw my IRB Application Form and Other Forms submission on ECOS?

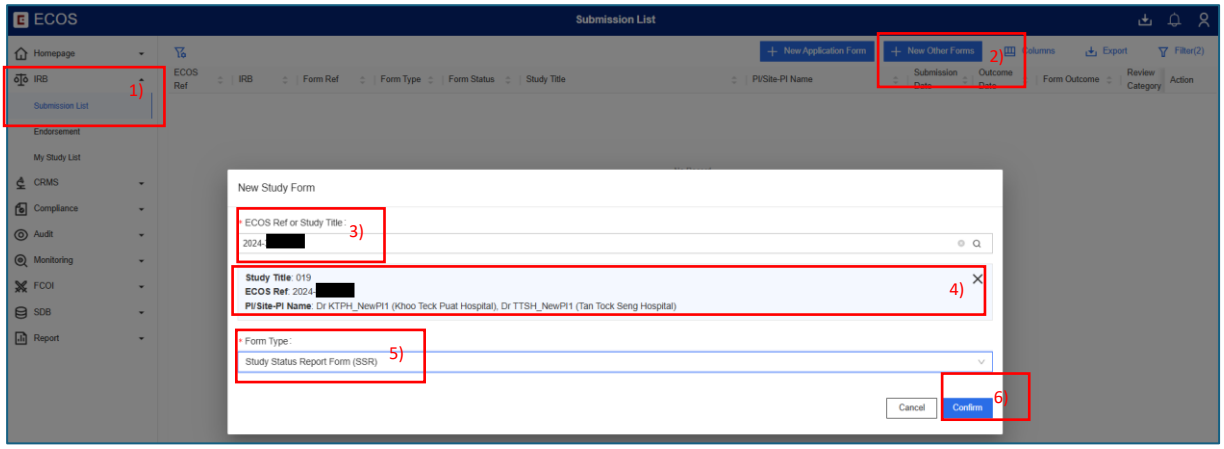
Only the PI can withdraw a submission on ECOS. To withdraw, please follow the steps below:

IRB application form & all other forms that have yet to be submitted by PI (i.e. have not Click 'Declare and Submit' in submission page)	1. Click on the 3 dots at the top right of the IRB application form submission page. 2. Click 'Delete Form' 
IRB application form and amendment form that have been submitted by PI and is at Endorsement stage Note: Application form will be locked, no edits can be made by study site	1. To unlock the form for editing by study site, you can either - a) Contact one of the endorsers to post a query and send the form back to the study site. <u>OR</u> b) Wait for the submission to reach DSRB. After which, you may contact the respective Domain Secretariat to query the application to unlock the form for editing. 2. Once the form is unlocked, please click on the 3 dots at the top right of the IRB application form submission page. 3. Click 'Withdraw' 

4.3 How do I terminate 1 study site for a multi-site study on ECOS?

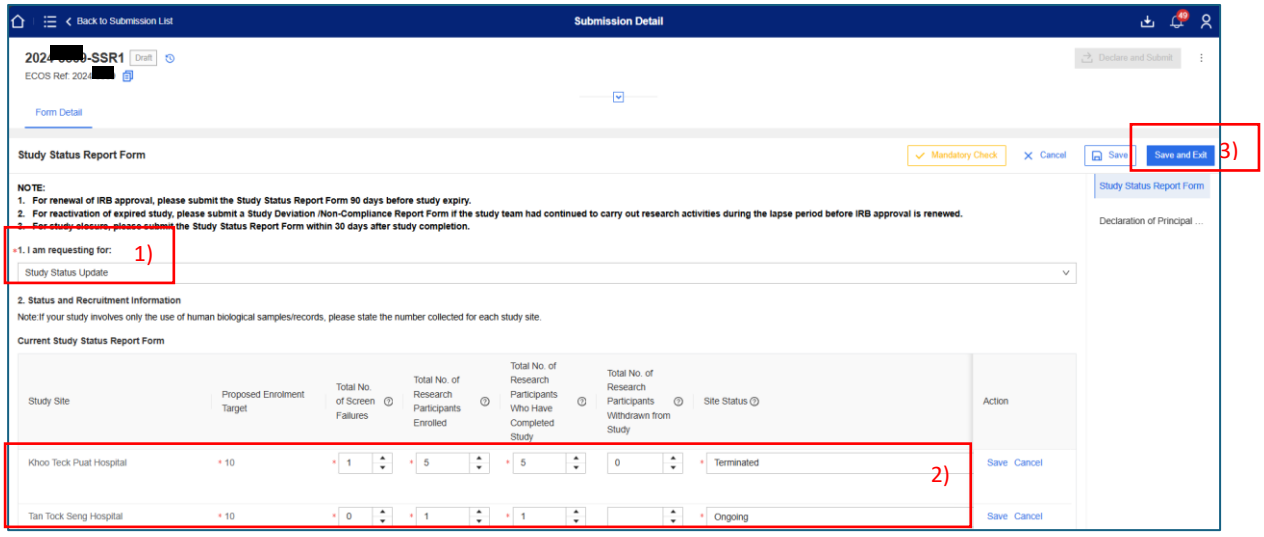
To terminate a study site, submit a Study Status Report (SSR) for your study:

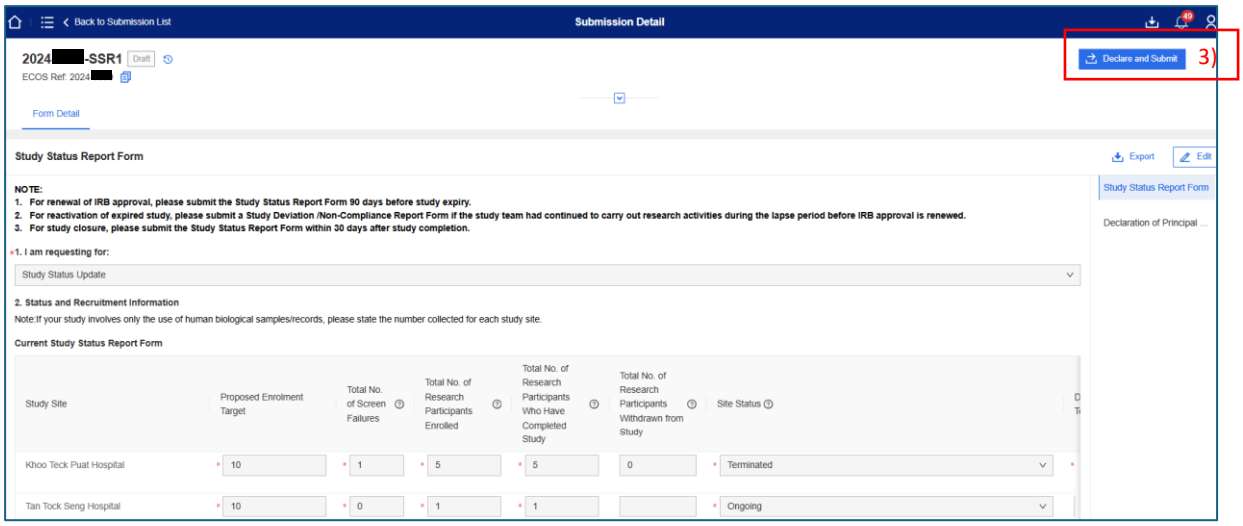
1) Go to IRB tab > Submission List
2) Select 'New Other Forms'
3) Enter the ECOS Reference No. or Study Title and click Search
4) Select your study from the results
5) Under Form Type, choose 'Study Status Report (SSR) Form'
6) Click Confirm



Study Status Report Form

1) Question 1 - Select "Study Status Update" from the dropdown list
2) Question 2 - Update and fill up the necessary information under the specific study site. Select 'Terminated' under the Site Status for the site you wish to terminate.
3) Complete the remaining sections in the SRR and Click 'Save and Exit' and 'Declare and Submit'.





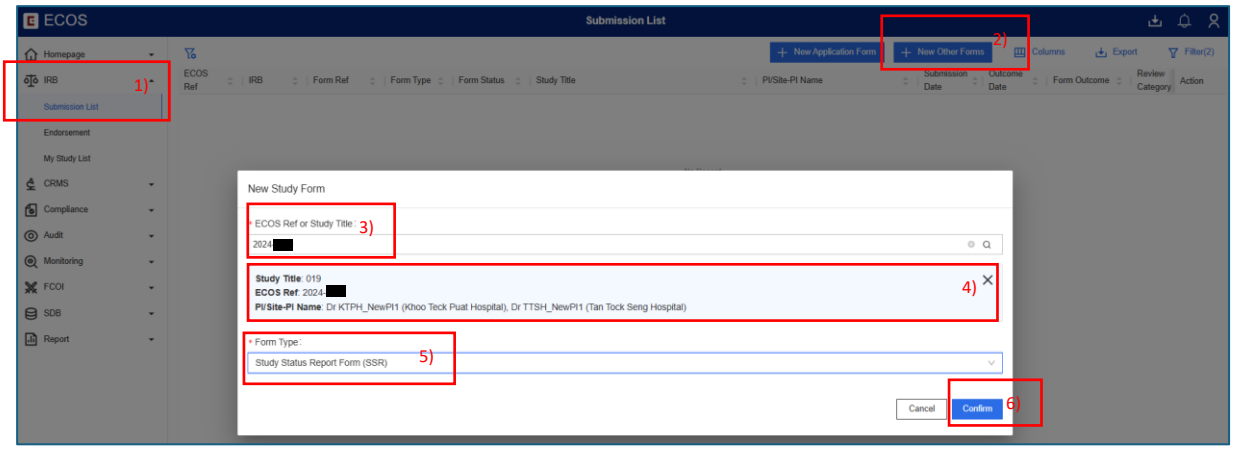
4.4 How do I close a study on ECOS?

Please submit a Study Status Report (SSR) for your study on ECOS.

For multi-site studies, you only need to submit 1 SSR to close all sites under the study.

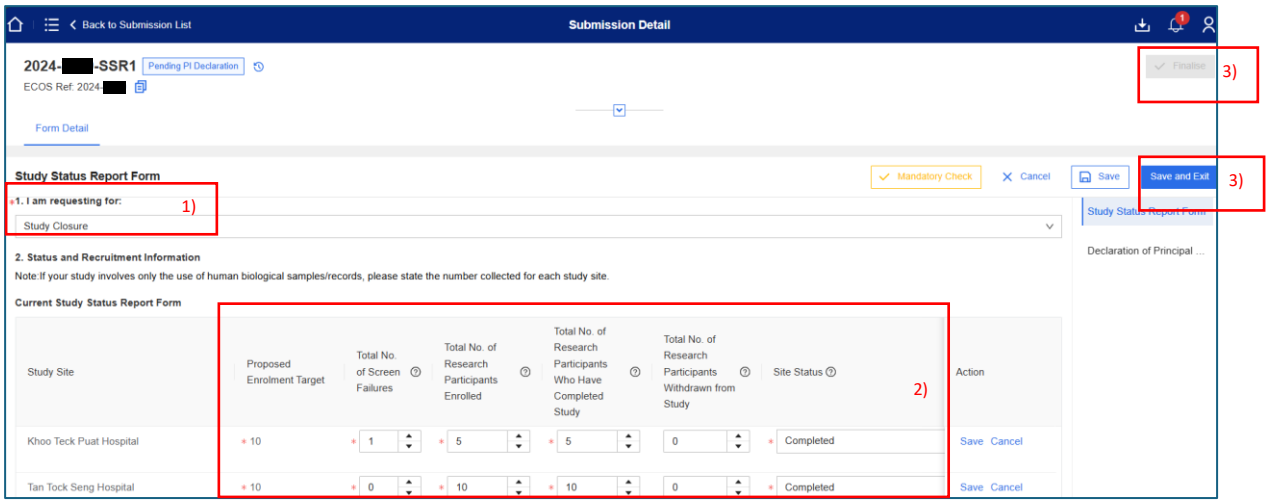
To submit:

1. Go to IRB tab > Submission List
2. Select 'New Other Forms'
3. Enter the ECOS Reference No. or Study Title and click Search
4. Select your study from the results
5. Under Form Type, choose 'Study Status Report (SSR) Form'
6. Click Confirm



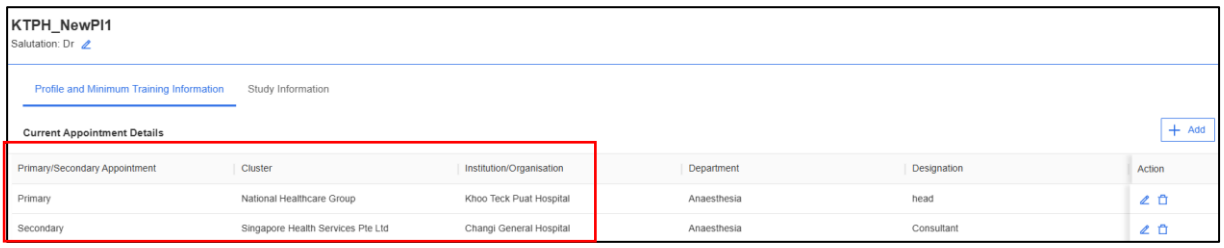
Study Status Report Form

1. Question 1 - Select 'Study Closure' from the dropdown list.
2. Question 2 - Update & fill up the necessary information under the respective study sites.
3. Complete the remaining sections in the SRR and Click 'Save and Exit' and 'Finalise'.

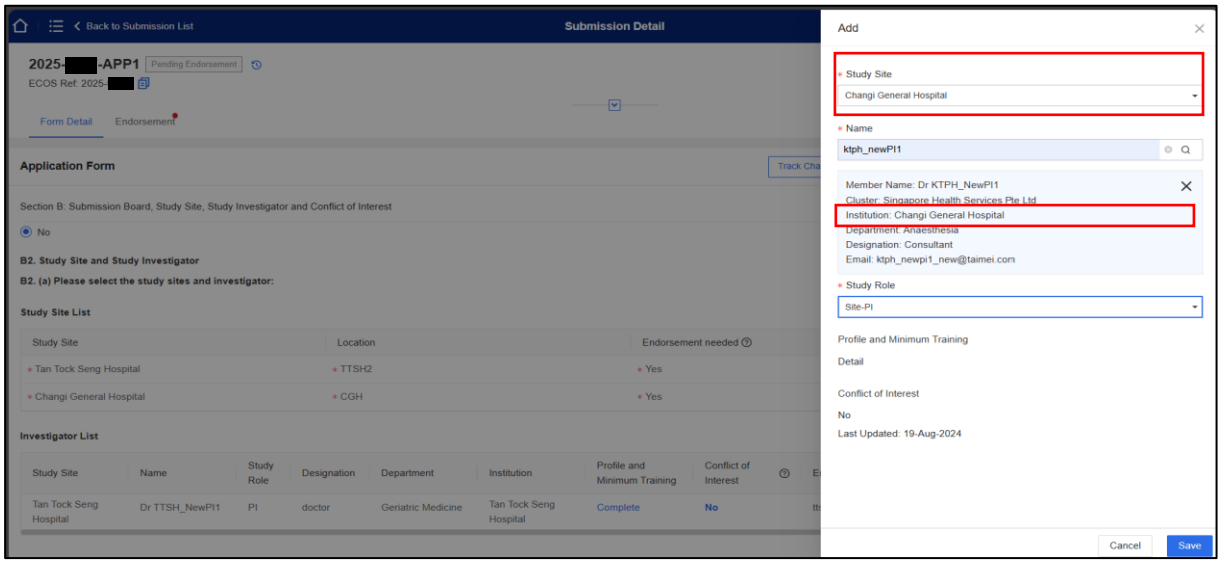


4.5 I received the error "The selected PI / Site PI should be from the study site" when I try to add them to the IRB Application Form. What should I do?

ECOS Users should ensure that all relevant primary and secondary appointments are in their ECOS User profile.



When adding a PI or Site PI in Section B of the IRB application form (Under 'Investigator List'), select the investigator's primary / secondary appointment that corresponds to the 'Study Site'. For example, if the study site is Changi General Hospital (CGH), select the PI / Site PI's appointment at CGH.



5 OTHERS

5.1 What is the difference between Research Office Checker & Research Office Administrator (IRB Module)?

Access Level	IRB Module Role Functions	IRB Module Roles	
		Research Office Checker (optional)	Research Office Administrator
Institution Level	▪ Performs checks to ensure completeness of submission before it is routed for endorsement	✓	X
	▪ Manage institution's DR & IR endorsement list	✓	✓
	▪ Assign nominated DR & IR for endorsement	✓	✓
	▪ To re-assign endorsements tasks when the RO Checker / DR/ IR is away or takes too long to complete the endorsement tasks (e.g., when DR / IR is a study team member)	✓	✓
	▪ Generate reports for their institution's studies	✓	✓

5.2 How to change the Department Representative (DR) / Institution Representative (IR) on ECOS?

The Institution's Research Office (RO) is managing the Institutions' DR / IR assignments or changes. Please approach your respective Institution RO.