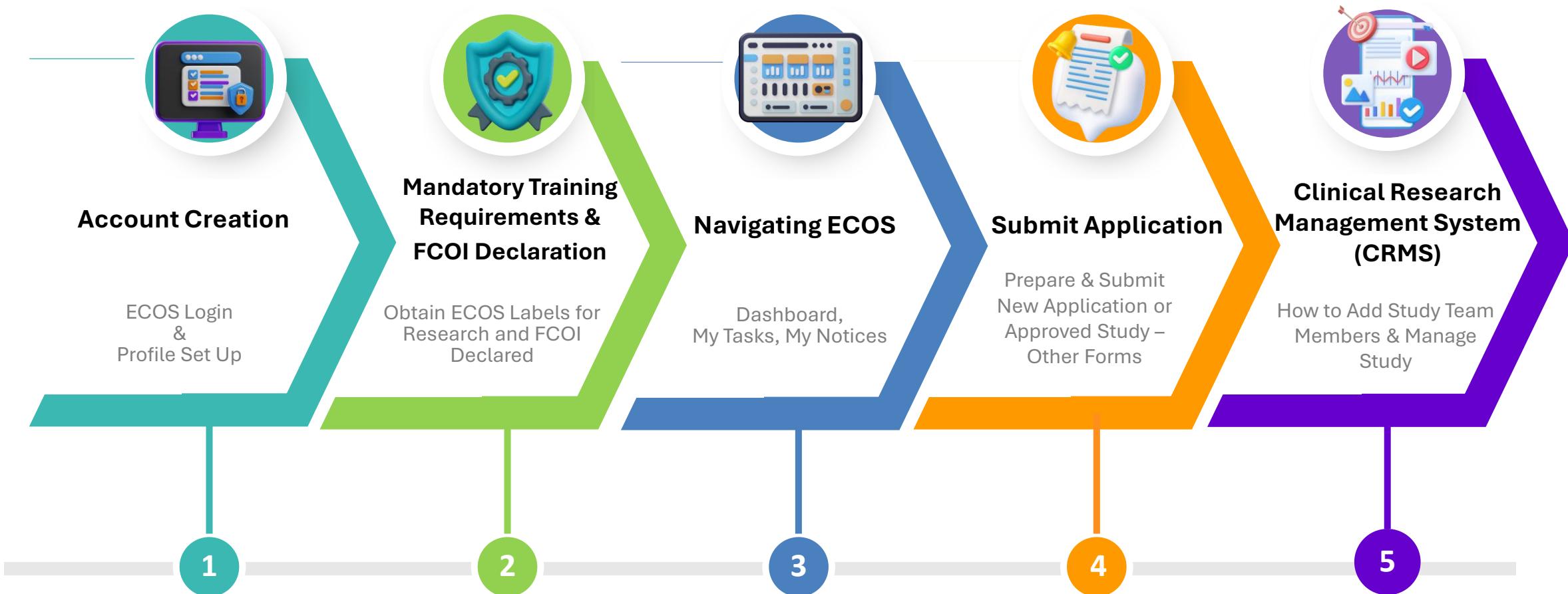


Quick Start Guide: Ethics & Compliance Online System (ECOS)

Getting Started - Ethics and Compliance Online System (ECOS)



ECOS, launched on 10 May 2024, is the new IRB IT system co-developed by NHG Health and SingHealth that supports the research lifecycle and provides centralised oversight for IRBs, institutions, and researchers.



Contents

1. Account Creation	ECOS Login User Profile Set Up	5. Clinical Research Management System (CRMS)	Overview How To Add My Team Members to My Studies on ECOS? How To Endorse / Reject / Deactivate My Team Members to My Studies on ECOS? Managing IRB Submission for Sponsored Study Managing Your Study Activities
2. Mandatory Training Requirements & FCOI Declaration	Complete Minimum Training Requirements To Receive ECOS Labels to Submit Studies FCOI Declaration		
3. Navigating ECOS	Navigating ECOS		
4. Submit Application	Who can make a submission on ECOS? Create New Application Create New Application/ Forms – PI/Site PI/Co-I Create New Application – STM/SA/SS Create New Other Forms for Approved Study	Resources	ECOS Modules User Guides Useful Contacts



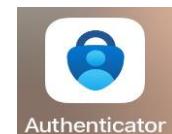
1

Account Creation

- ECOS Login
- User Profile Set-Up

Public Healthcare Institutions (PHI) Users – Login

- 1) PHI - Agency for Integrated Care (AIC), Ministry of Health (MOH), MOH Holdings (MOHH), National Healthcare Group (NHG), SingHealth, National University Health Systems (NUHS)
- 2) ECOS Login <https://www.ecos-research.com.sg/login/>
- 3) Login with your corporate M365 email address & Password
- 4) ECOS account will be automatically generated for users with corporate M365 email accounts
- 5) Two factor authentication (2FA) via Microsoft Authenticator is required




ECOS

[PHI User](#)

[Non-PHI User](#)

[LOG IN WITH CORPORATE EMAIL ADDRESS](#)

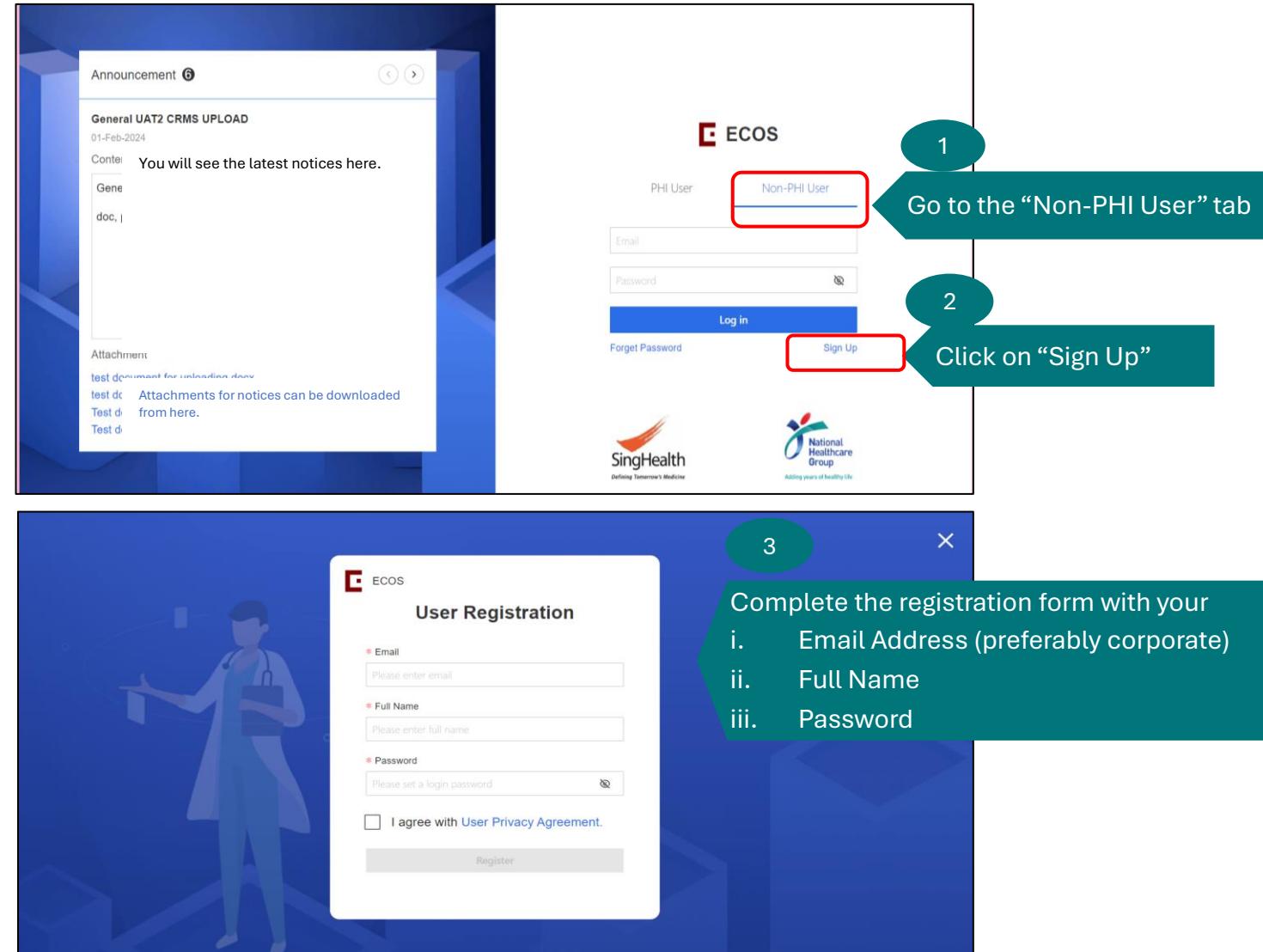
PHI: Public Healthcare Institutions


SingHealth
Defining Tomorrow's Medicine


National
Healthcare
Group
Adding years of healthy life

Non-Public Health Institution (PHI) Users – Login

- 1) Non-PHI - Pharma Sponsors, Academic Institutions (e.g. NUS)
- 2) ECOS Login
<https://www.ecos-research.com.sg/login/>



The diagram illustrates the user registration process for Non-PHI users on the ECOS platform. It consists of three main panels:

- Panel 1:** Announcement screen showing a general UAT2 CRMS UPLOAD notice. A red box highlights the "Non-PHI User" tab in the top navigation bar.
- Panel 2:** ECOS login screen. A red box highlights the "Sign Up" button. A callout bubble "1" points to the "Non-PHI User" tab, and a callout bubble "2" points to the "Sign Up" button.
- Panel 3:** User Registration screen. A red box highlights the "Email" input field. A callout bubble "3" points to the "Email" field, with the text "Complete the registration form with your" followed by a list of three items: i. Email Address (preferably corporate), ii. Full Name, iii. Password.



Non-PHI Users – Login (continued)

Microsoft Authenticator App

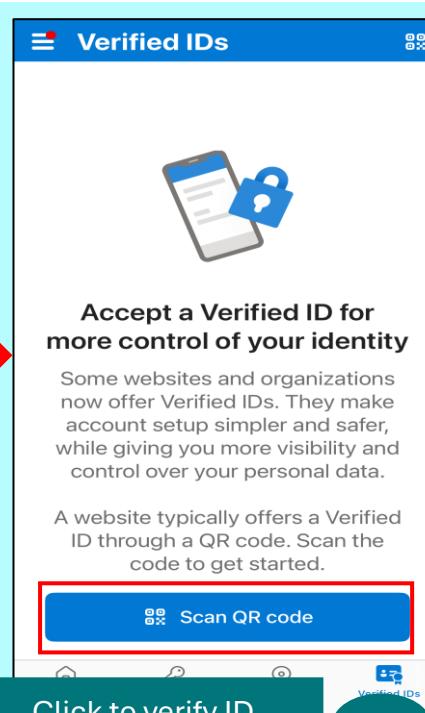
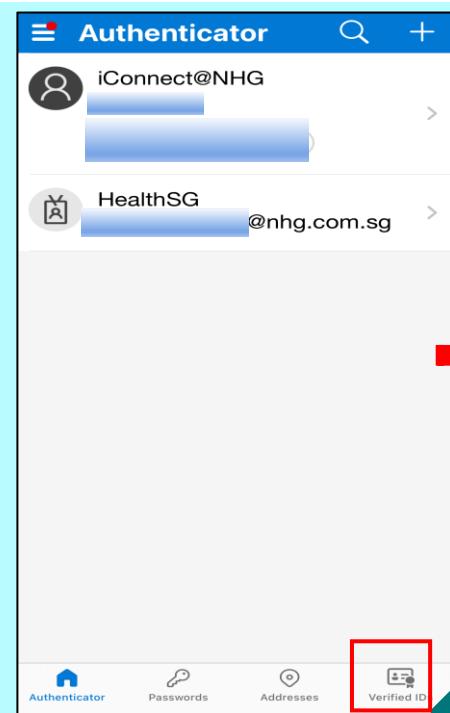
First-time users of ECOS with the App on your mobile device will need to pair it to this account, by clicking “Verify ID”

If you do not already have the App, you will need to Download it from Apple App Store or Google Play and create an account.



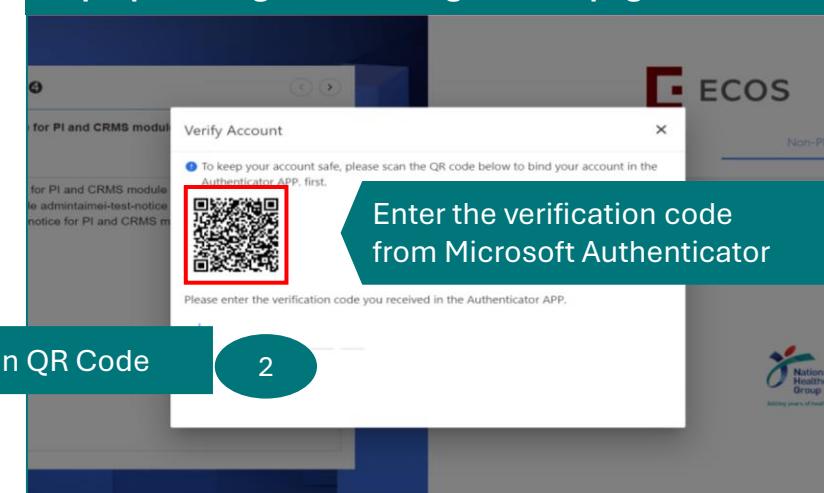
Authenticator

In Microsoft Authenticator



1

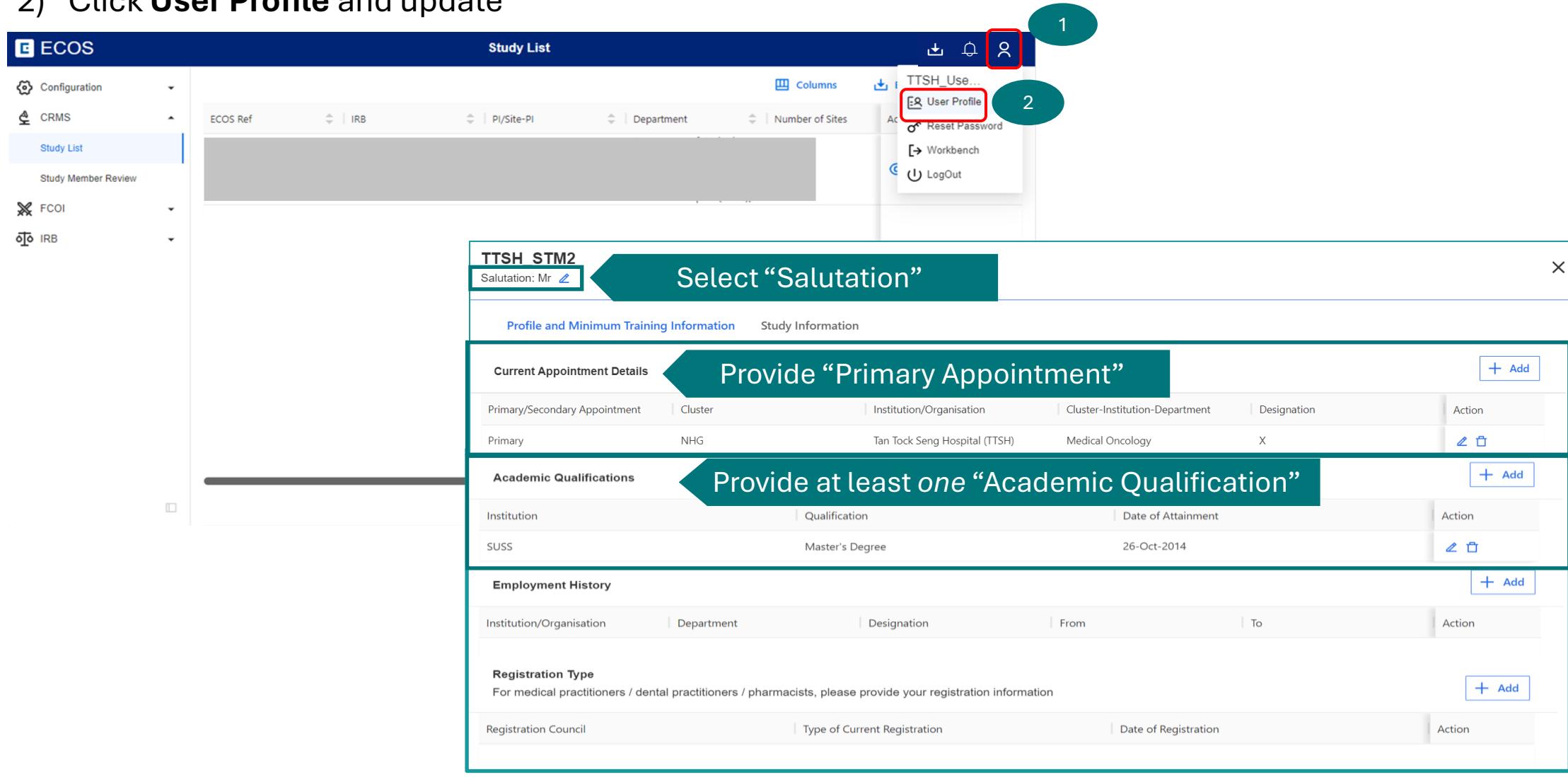
Pop-up message in ECOS registration page



3

User Profile Set Up

- 1) Click  **Profile icon** (top right corner)
- 2) Click **User Profile** and update



ECOS Study List

1

2

TTSH STM2

Salutation: Mr 

Select “Salutation”

Profile and Minimum Training Information Study Information

Provide “Primary Appointment”

Primary/Secondary Appointment	Cluster	Institution/Organisation	Cluster-Institution-Department	Designation	Action
Primary	NHG	Tan Tock Seng Hospital (TTSH)	Medical Oncology	X	 

Provide at least one “Academic Qualification”

Institution	Qualification	Date of Attainment	Action
SUSS	Master's Degree	26-Oct-2014	 

Employment History

Institution/Organisation	Department	Designation	From	To	Action
--------------------------	------------	-------------	------	----	--------

Registration Type

For medical practitioners / dental practitioners / pharmacists, please provide your registration information

Registration Council	Type of Current Registration	Date of Registration	Action
----------------------	------------------------------	----------------------	--------

Restricted, Sensitive - Normal



2

Mandatory Training Requirements & FCOI Declaration

- Complete Minimum Training Requirements To Receive ECOS Labels to Submit Studies
- FCOI Declaration



Overview

- 1) Only PIs, Site PIs, Co-Is are listed in the Application Form - Section B2(a) Investigator List. These investigators must submit their minimum training certificates for validation and issuance of **“ECOS Labels”**.
- 2) **ECOS Labels** allows users to submit studies they are qualified to conduct based on completed minimum training requirements. If the requirements are not met, the system will prompt, and no "label" will be issued.
- 3) All other study team members (Study Administrator, Study Member and Sponsors) are added in the **Clinical Research Management System (CRMS)** ([slide 25](#)).

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-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** (slide 11 for example)
- b) HBRA Training Certificate → Please upload the eCertificate

For more information, refer to [Overview of Minimum Training Requirements](#)



Example of CITI Completion Report

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)
COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

* Name: [REDACTED]
* Institution Affiliation: National Healthcare Group Pte Ltd. (ID: 527)
* Institution Email: [REDACTED]
* Institution Unit: [REDACTED]
* Phone: [REDACTED]

* Curriculum Group: [REDACTED]
* Course Learner Group: [REDACTED]
* Stage: [REDACTED]

* Record ID: [REDACTED]
* Report Date: [REDACTED]
* Current Score**: [REDACTED]

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES

	MOST RECENT	SCORE
Informed Consent (ID: 3)	25-Jan-2023	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 401)	26-Jan-2023	4/5 (80%)
Belmont Report and Its Principles (ID: 1127)	25-Jan-2023	3/3 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	25-Jan-2023	4/4 (100%)
The Federal Regulations - SBE (ID: 502)	26-Jan-2023	5/5 (100%)
Assessing Risk - SBE (ID: 503)	26-Jan-2023	5/5 (100%)
Records-Based Research (ID: 5)	25-Jan-2023	4/4 (100%)
Internet-Based Research - SBE (ID: 510)	26-Jan-2023	3/5 (60%)
History and Ethics of Human Subjects Research (ID: 498)	25-Jan-2023	5/5 (100%)
History and Ethical Principles - SBE (ID: 490)	26-Jan-2023	4/5 (80%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	25-Jan-2023	5/5 (100%)
Conflicts of Interest in Human Subjects Research (ID: 17464)	25-Jan-2023	4/5 (80%)
NHG-Singapore. Overview of the Regulatory Framework and Guidelines in Singapore (ID: 809)	25-Jan-2023	No Quiz
NHG - Singapore. Overview of Domain Specific Review Board (DSRB) Review Process (ID: 810)	25-Jan-2023	No Quiz
National Healthcare Group - Singapore (ID: 808)	25-Jan-2023	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Completion Date 28-Oct-2022
Expiration Date N/A
Record ID [REDACTED]

CITI PROGRAM



This is to certify that:

Has completed the following CITI Program course:

CITI Good Clinical Practice
(Curriculum Group)
CITI Good Clinical Practice Course
(Course Learner Group)
1 - Basic Course
(Stage)

X

Not valid for renewal of certification through CME.

Under requirements set by:

[REDACTED]

This GCP training contains all of the attested CITI Program modules from the GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) Version 2. This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Verify at www.citiprogram.org/verify/?w78b299b7-e656-43d4-a482-7a8274a6b921-51738529

How To: Upload/Update Minimum Training Certificates

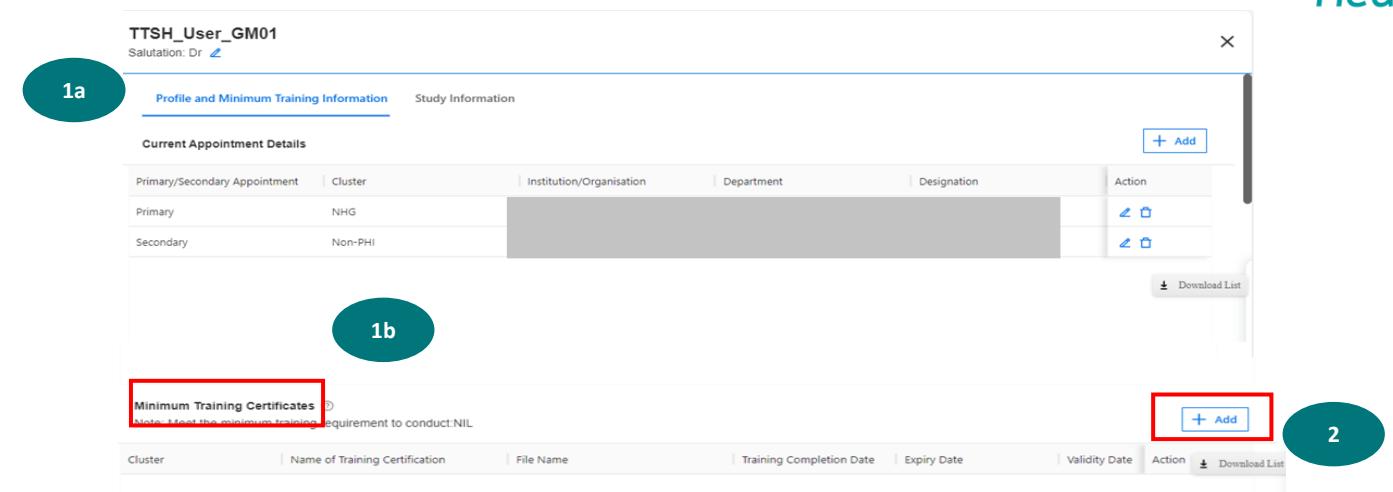
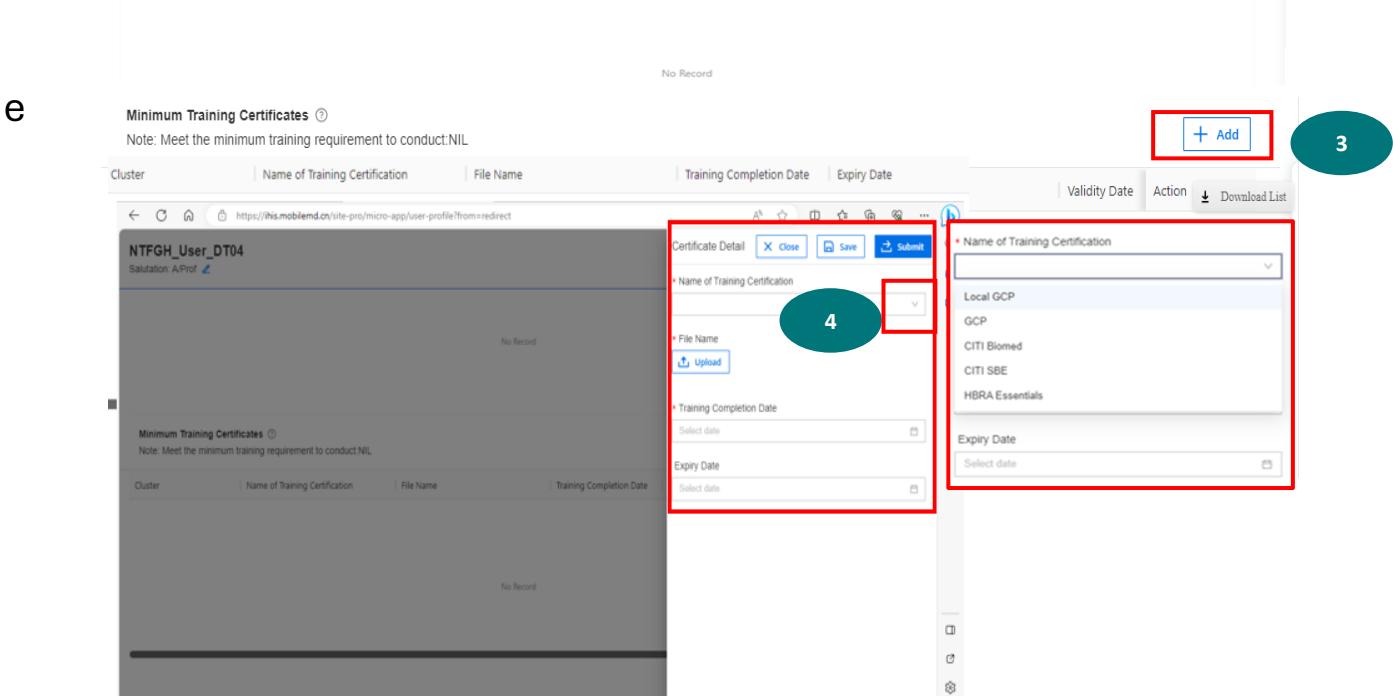
1(a) At “User Profile”, locate the “Profile and Minimum Training Information” tab

1(b) Scroll down to select “Minimum Training Certificates”

2) Click on  to upload/update certificate/s

3) Click on  for “Certificate Detail”

4) Click on  dropdown menu and to select the training certificate to be uploaded

How To: Upload/Update Minimum Training Certificates (continued)

- 4) Select “Name of Training Certification”
- 5) Click  to browse and upload the training certificate. (Limited to one file upload for each type of Training Certificate)
- 6(a) Click the **Calendar icon** for the calendar window
- 6(b) Select “Completion Date” on the training certificate
- 7) “Save” the Training Certificate and details
- 8) Click  to send certificates to your cluster / institution’s designated Minimum Training Secretariat for review

Certificate Detail

 Close
 Save
 Submit

*** Name of Training Certification**

*** File Name**

 Upload
 5

*** Training Completion Date**

Select date
 6a

Expiry Date

Select date
 6b

(Optional field)

*** Training Completion Date**

01-Sep-2023  6a

Sep 2023

Su	Mo	Tu	We	Th	Fr	Sa
27	28	29	30	31	1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
1	2	3	4	5	6	7

RECORD DETAILS

- Record ID: 58018505
- Completion Date: 01-Sep-2023
- Expiration Date: 01-Sep-2026
- Minimum Passing: 80
- Reported Score*: 96

REQUIRED AND ELECTIVE MODULES ONLY

DATE COMPLETED
SCORE



Review Training Certificate – Document Review Status

- 1) Upon submission of the Training Certificate view its status under the “**Minimum Training Certificates**” section
- 2) View “**Document Review Status**”: Pending Verification/Completed/ Rejected/Expired (*at the far right of the screen*)

Note: You will receive an email notification when there is a review outcome from the Minimum Training Secretariat

Minimum Training Certificates ? 1

Note: Meet the minimum training requirement to conduct: NIL

+ Add

Cluster	Name of Training Certification	File Name	Training Completion Date	Expiry Date	Validity Date	Action	Download List
NUHS	CITI Biomed	citiCompletionReport_12892325_601...	01-Sep-2023	-	31-Aug-2024	🕒	

Validity Date Document Review Status Comments/Reje Action

31-Aug-2024 Pending Verification 2 🕒

Document Review Status	Description
Pending Verification	Training Certificate is pending verification by your Cluster / Institution’s Minimum Training Secretariat
Completed	Training Certificate has been verified and accepted by your Cluster / Institution’s Minimum Training Secretariat
Rejected	Training Certificate is rejected by your Cluster / Institution’s Minimum Training Secretariat
Expired	Validity Date of Training Certificate has passed. Please complete the Refresher course and upload the new Training Certificate.



Edit & Review Training Certificate Status & ECOS Labels

Minimum Training Certificates

Note: Meet the minimum training requirement to conduct:  Clinical Trials, HBR, Non-HBR

 Add

Name of Training Certificate	File Name	Training Completion Date	Expiry Date	Validity Date	Document Review Status	Comments/Rejection Reason	Action
CITI SBE	.docx	19-Apr-2024	19-Apr-2024	Permanent	Rejected	Did not complete at least 5 SBE modules.	 

1

2

Profile and Minimum Training Information

Study Information

Minimum Training Certificates

Note: Meet the minimum training requirement to conduct:  Non-HBR, Clinical Trials, HBR

 Add

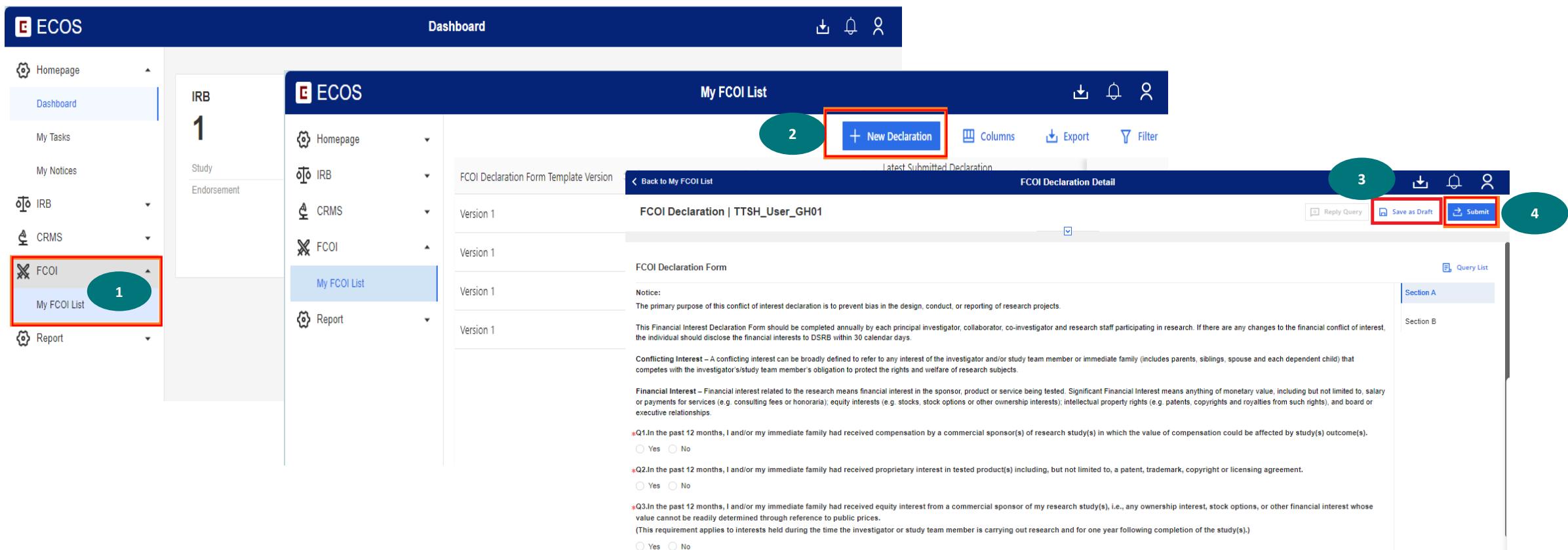
Name	Name of Training Certification	File Name	Training Completion Date	Expiry Date	Validity Date	Document Review Status	Comments/Rejection Reason	Action
NHG								
NHG	GCP	GCP Certific...	01-Apr-2023	-	Permanent	Completed		 
NHG	HBRA Essentials	HBR CERTIFI...	01-Dec-2022	-	Permanent	Completed		 
NHG	CITI FCOI	CITI CERTIFI...	01-Nov-2021	-	Permanent	Completed		 

3

- 1) Under “**Document Review Status**” field, the reason for a training certificate being “**Rejected**” will be indicated in “**Comments/Rejection Reason**”
- 2) To resubmit Training Certification
 - Click “**Edit**” 
 - Delete the incorrect Training Certificate
 - Re-do steps recommended in slides 12 to 14
- 3) The Minimum Training Secretariat will issue “**ECOS Labels**” (slide 9 – Type of Research) for the type of study that a user can conduct according to the training certificate that was submitted for verification. Do ensure that you have obtained the relevant ECOS Labels for your research.

How To Submit FCOI Declaration Form

- 1) On the “Dashboard” page, click “My FCOI List” (left sidebar)
- 2) Click **+ New Declaration** to submit a new FCOI Declaration Form & provide details of any Financial Conflict of Interest
- 3) Click “Save as Draft” if you are not ready to submit your FCOI Declaration yet
- 4) Click “Submit” when you are ready to submit to the FCOI Secretariat for review



ECOS Dashboard

My FCOI List

FCOI Declaration Form Template Version

FCOI Declaration Detail

FCOI Declaration Form

Section A

Section B

1

2

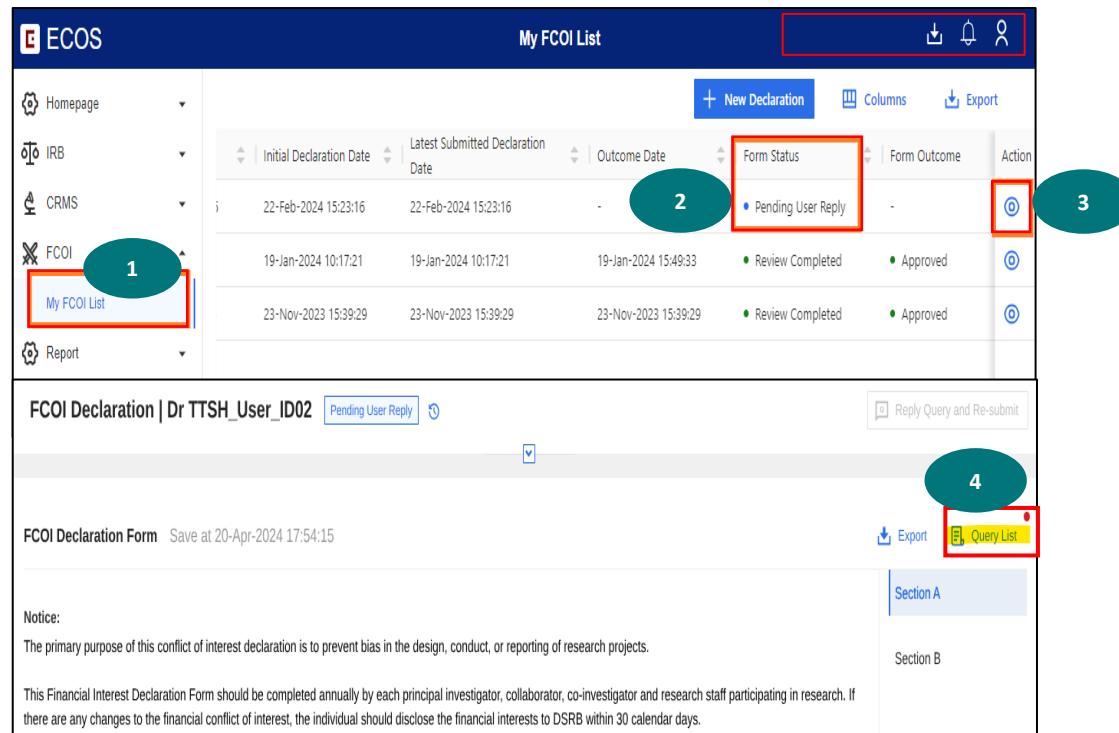
3

4

For more information, refer to [Financial Conflict of Interest \(COI\) Part 1:Declarations](#) & [Financial Conflict of Interest \(FCOI\) Part2: Training](#)

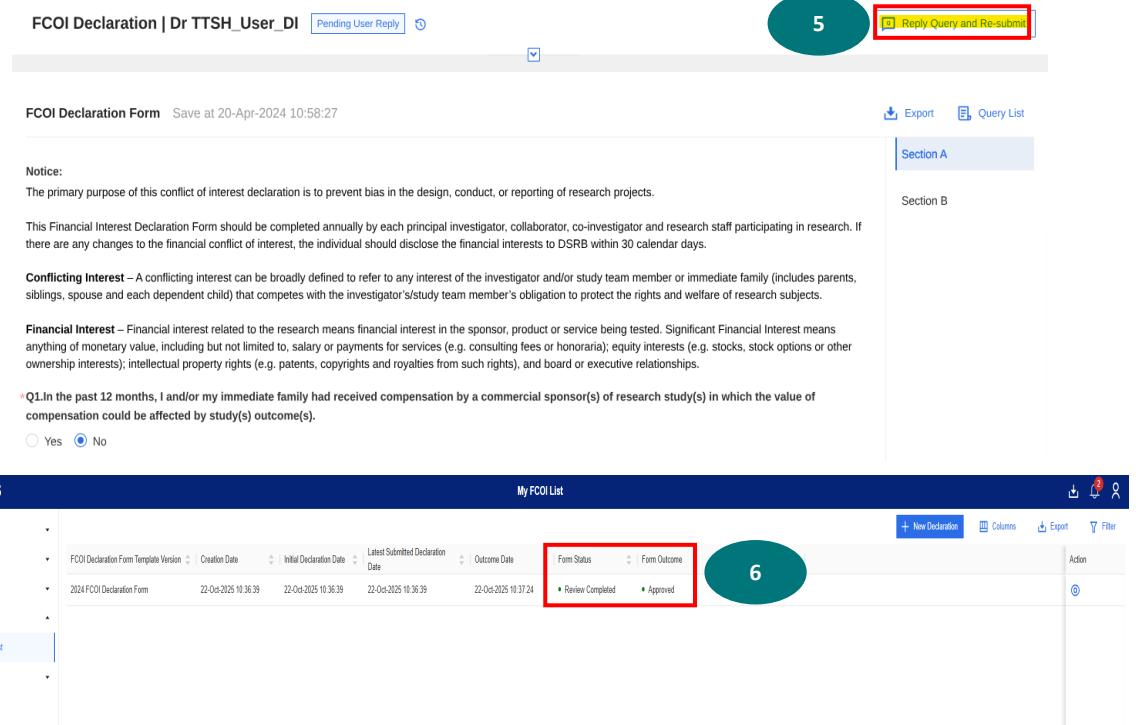


Respond to FCOI Secretariat's Queries



The image shows the ECOS interface. The top navigation bar includes 'ECOS', 'My FCOI List', and icons for download, bell, and user. The sidebar has links for 'Homepage', 'IRB', 'CRMS', 'FCOI' (which is highlighted with a red box and a green circle labeled 1), and 'Report'. The main content area shows 'My FCOI List' with a table. The table columns are 'Initial Declaration Date', 'Latest Submitted Declaration Date', 'Outcome Date', 'Form Status' (which is highlighted with a red box and a green circle labeled 2), 'Form Outcome', and 'Action' (which is highlighted with a red box and a green circle labeled 3). The 'Form Status' row for the first declaration shows 'Pending User Reply'. Below this is the 'FCOI Declaration' page for 'Dr TTSH_User_ID02' with a 'Pending User Reply' status. The declaration form includes sections A and B, and a 'Query List' button (highlighted with a red box and a green circle labeled 4) which has a red dot indicating a query.

- 1) Click “My FCOI List” (left sidebar)
- 2) At “Form Status” – “Pending User Reply”, your action is required
- 3) Click the  eye icon to view the “FCOI Declaration Form”
- 4) Click “Query List” to view the query/queries from the FCOI Secretariat. The  indicates that there is a query to be addressed.



The image shows the 'FCOI Declaration' page for 'Dr TTSH_User_ID1' with a 'Pending User Reply' status. It includes sections A and B, and a 'Reply Query and Re-submit' button (highlighted with a red box and a green circle labeled 5). Below this is the 'My FCOI List' page, which shows a table with columns: 'FCOI Declaration Form Template Version', 'Creation Date', 'Initial Declaration Date', 'Latest Submitted Declaration Date', 'Outcome Date', 'Form Status' (highlighted with a red box and a green circle labeled 6), and 'Form Outcome'. The 'Form Status' row for the declaration shows 'Review Completed'.

- After you have addressed the queries from the FCOI Secretariat and edited your FCOI Declaration Form, where applicable,
- 5) Click “Reply Query and Re-submit” to send the responses and FCOI Declaration Form back to the FCOI Secretariat
- 6) If the FCOI Declaration “Form Outcome” is “Approved”, “Form Status” will show “Review Completed”

After you have obtained (a) ECOS Label **and** received (b) FCOI Review Completed, you can now proceed to submit an application for the respective study.

Profile and Minimum Training Information **Study Information**

Minimum Training Certificates ?

Note: Meet the minimum training requirement to conduct:

ECOS Label

✓ Non-HBR, Clinical Trials, HBR

+ Add

Cluster	Name of Training Certification	File Name	Training Completion Date	Expiry Date	Validity Date	Document Review Status	Comments/Rejection Reason	Action
SingH...	GCP	GCP Certific...	01-Apr-2023	-	Permanent	● Completed		 
SingH...	HBRA Essentials	HBR CERTIFI...	01-Dec-2022	-	30-Nov-2023	● Expired		 
SingH...	CITI Biomed	CITI CERTIFI...	01-Nov-2021	-	31-Oct-2024	● Completed		 

ECOS

My FCOI List

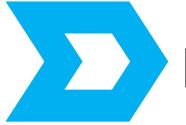
+ New Declaration **Columns** **Export** **Filter**

Form Status	Form Outcome	FCOI Status	Action
● Review Completed	● Approved	No	

 3

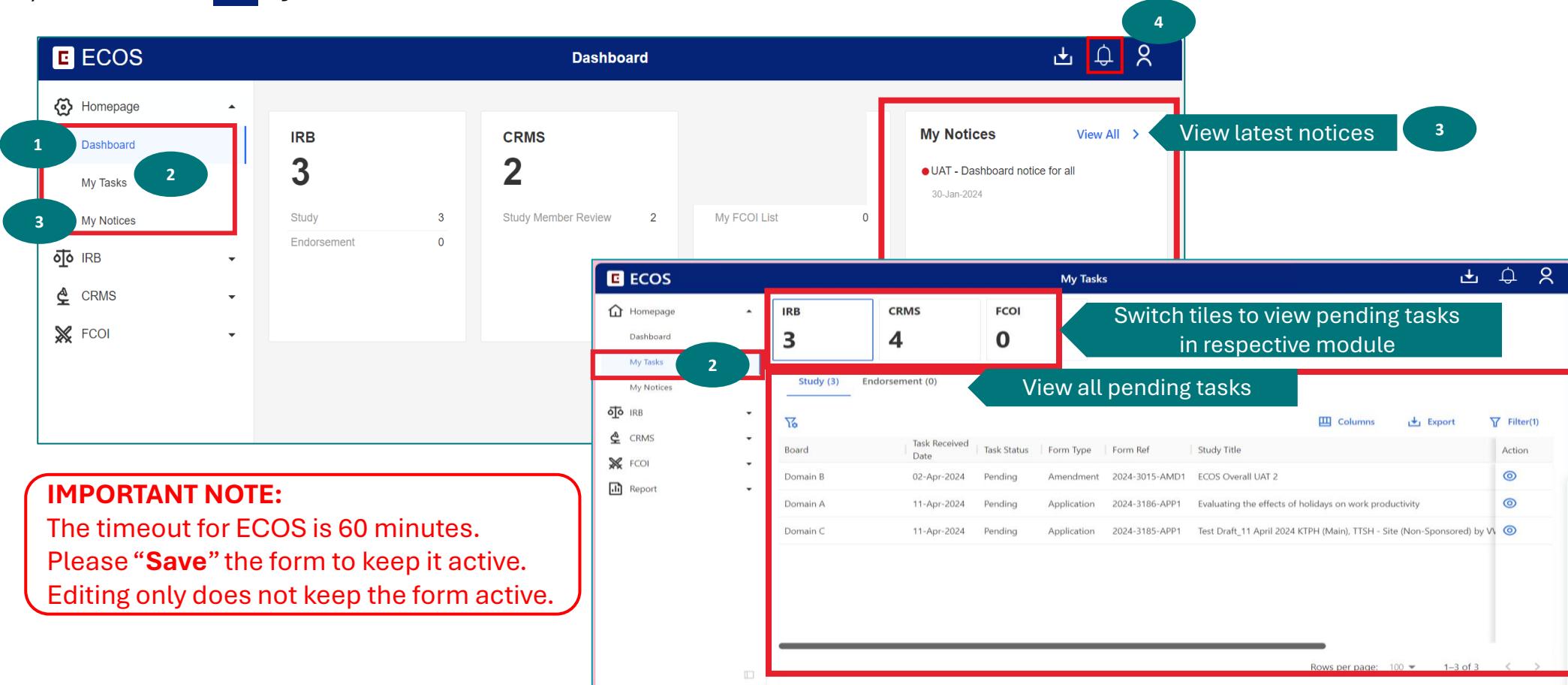
Navigating ECOS

- Dashboard - My Tasks / Notices / Study List



Navigating ECOS – Dashboard, My Tasks, My Notices

- 1) View pending tasks for each module on your “**Dashboard**”.
- 2) “**My Tasks**” – Switch tiles to review pending tasks in respective modules.
- 3) “**My Notices**” - View latest notices here. The ‘ ● ’ indicates that the notice has not been read.
- 4) Click to view  **System Notifications**.



The image displays two screenshots of the ECOS interface. The top screenshot shows the 'Dashboard' page with a red box around the 'My Tasks' and 'My Notices' sections. Callouts numbered 1, 2, 3, and 4 point to these sections respectively. The bottom screenshot shows the 'My Tasks' page with a red box around the 'IRB', 'CRMS', and 'FCOI' tiles. Callout 2 points to the 'My Tasks' tile. Callout 3 points to the 'View all pending tasks' button. Callout 4 points to the 'Switch tiles to view pending tasks in respective module' text. A red box highlights the 'Study (3)' and 'Endorsement (0)' sections. A red box also highlights the 'My Notices' section on the right, which contains a notice about UAT. A red box highlights the 'View latest notices' button. A red box highlights the 'System Notifications' bell icon in the top right corner.

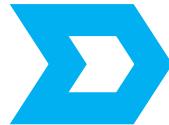
IMPORTANT NOTE:
The timeout for ECOS is 60 minutes.
Please “**Save**” the form to keep it active.
Editing only does not keep the form active.

Switch tiles to view pending tasks in respective module

View all pending tasks

Board	Task Received Date	Task Status	Form Type	Form Ref	Study Title	Action
Domain B	02-Apr-2024	Pending	Amendment	2024-3015-AMD1	ECOS Overall UAT 2	
Domain A	11-Apr-2024	Pending	Application	2024-3186-APP1	Evaluating the effects of holidays on work productivity	
Domain C	11-Apr-2024	Pending	Application	2024-3185-APP1	Test Draft_11 April 2024 KTPH (Main), TTSH - Site (Non-Sponsored) by VV	

Rows per page: 100 ▾ 1–3 of 3 < >



Navigating ECOS – View “My Study List”

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

- 1) At , click “**My Study List**” to view the list of studies that you are involved in
- 2) At “**User Profile**”, click “**Study Information**”
- 3) Click view to go into the study

The screenshot displays the ECOS interface with two main windows. The left window is titled 'My Study List' and shows a table of studies. The right window is titled 'My Tasks' and shows study details. Annotations with numbered circles and arrows explain the navigation steps:

- 1**: A red box highlights the 'My Study List' button in the left sidebar. A teal circle with '1' points to this button. A green arrow points from the text 'View the list of studies that you are involved in' to this button.
- 2a**: A red box highlights the user profile icon in the top right corner of the main interface. A teal circle with '2a' points to this icon. A green arrow points from the text 'Click on the icon, then User Profile.' to this icon.
- 2b**: A red box highlights the 'Study Information' tab in the 'My Tasks' window. A teal circle with '2b' points to this tab. A green arrow points from the text 'View the list of studies that you are involved in' to this tab.
- 3**: A red box highlights the 'View' icon in the 'Action' column of the 'My Study List' table. A teal circle with '3' points to this icon. A green arrow points from the text 'View to go into the study' to this icon.

My Study List (Left Window):

ECOS Ref	IRB	Study Status	Study Title	PI/Site-PI Name	Initial Review Category	Action
2024-3186	NHG DSRB- Domain A	Pending IRB Review	NHG DSRB- Domain B	NHG DSRB- Domain B	Initial Review Category	(highlighted with a red box)
2024-3185	NHG DSRB- Domain C	Pending IRB Review	Test Draft_11 April 2024 KTPH (Main), TTSH - Site (Non-Sponsored) by VW			
2024-3189	NHG DSRB- Domain B	Approved	Test study - TTSH single site sponsored for dsrb approval			
2024-3188	NHG DSRB- Domain B	Approved	KTPH_SP1			

My Tasks (Right Window):

IRB	FCOI
0	0

TTSH_P1
Salutation: Dr

Profile and Minimum Training Information

Current Appointment Details

Primary/Secondary Appointment	Cluster	Institution/Organisation	Department	Designation	Action
Primary	National Healthcare Group	Tan Tock Seng Hospital	Medical Oncology	Senior Nurse	

Academic Qualifications

Institution	Qualification	Date of Attainment	Action
NUS	MSc Nursing	01-Apr-2023	



4 Submit Application

- Who can make a submission on ECOS?
- Create New Application / Forms



Who can make a submission on ECOS?

The Principal Investigator (PI) holds the overall responsibility for the preparation and completion of the submissions to the DSRB. The PI must maintain an overview of all submissions, even if tasks are delegated to other research staff.

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.

Please refer to the table below on the roles and responsibilities PI, Site PI and Co-I:

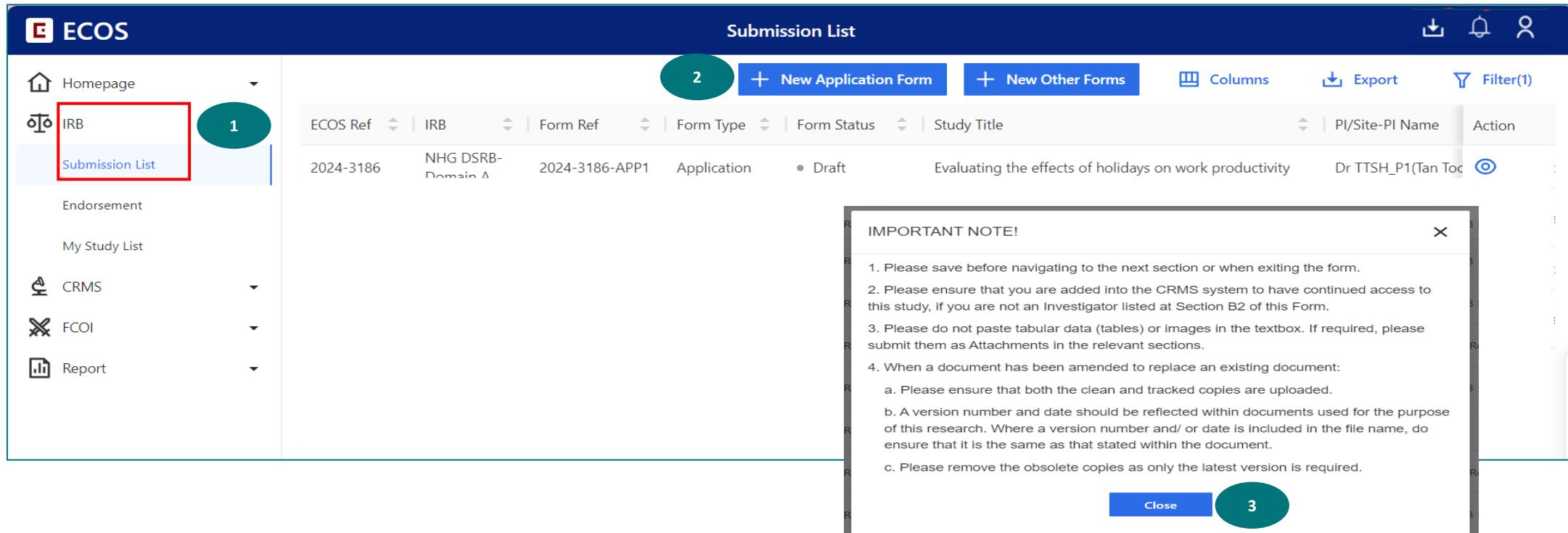
IRB Form	Who can submit on ECOS?		
	PI	Site PI	Co-I
➤ Initial IRB Application ➤ Amendment ➤ Study Status Report (SSR) ➤ Study Deviation or Non-Compliance Report (DNC) ➤ Other Study Notification (OSN)	✓	✗	✗
Serious Adverse Event (SAE)	✓	✓	✓
UPIRTSO (UPT)	✓	✓	✗

- All users who has access to IRB module will be able to create an IRB Application (APP) Form.
- Investigators (PI, Site-PI, Co-I) added to the IRB APP form will appear on the CRMS User Authorisation List following synchronisation between the IRB and CRMS modules. ([More information on CRMS in the later slides](#)).
- Investigators will be able to access CRMS pages for the study, in addition to the IRB APP Form.
- As for Study Team Members / Study Administrator / Study Sponsor (STM / SA / SS) since they cannot be added to the IRB APP Form, the system will prompt them to select their Study Site and Study Role when saving the form **for the first time**.
- Once completed, the STM / SA / SS will be added to the User Authorisation List in the study's CRMS. The STM / SA / SS will have access to CRMS and continue to have access to the IRB APP Form.



Create New Application – PI/Site PI/Co-I

- 1) Click  > “Submission List”
- 2) Create a “New Application Form”
- 3) Upon reading the “Important Note!”, “Close” the window to proceed with form creation.



The screenshot shows the ECOS Submission List interface. On the left, there's a sidebar with links for Homepage, IRB (with 'Submission List' highlighted), Endorsement, My Study List, CRMS, FCOI, and Report. The main area is titled 'Submission List' and shows a table with columns: ECOS Ref, IRB, Form Ref, Form Type, Form Status, Study Title, PI/Site-PI Name, and Action. One row is visible: ECOS Ref 2024-3186, IRB NHG DSRB-Domain A, Form Ref 2024-3186-APP1, Form Type Application, Form Status Draft, Study Title Evaluating the effects of holidays on work productivity, PI/Site-PI Name Dr TTSH_P1(Tan To), and Action (with a 'Close' button). A modal window titled 'IMPORTANT NOTE!' is open in the foreground, containing a list of instructions. The 'Close' button of the modal is also highlighted with a green circle labeled '3'.

Note:

Complete **Sections A (Study Title)** and **B (Submission IRB and Board)** and save to generate a new ECOS reference number for your study

For more information, please refer to [Overview of IRB Ethics Submissions](#) and [IRB Ethics Application Form - List of Sections & Questions](#)



Create New Application – PI/Site PI/Co-I

Submission Detail

2024-0193-APP1 Draft ①

ECOS Ref: 2024-0193 ②

Form Detail

Application Form

① A1. Please enter the Study Title for this Study.

CG23 - For Training Purposes

28 characters entered

② Mandatory Check ③ Save Save and Exit

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

Click the down arrow to collapse part of the top header

Submission Detail

2024-0193-APP1 Draft ①

ECOS Ref: 2024-0193 ②

Form Type: Application Form Outcome: -

Initial Review Category: -

Current Editor: -

PI/Site PI: Mrs SNEC_Basic1(Singapore National Eye Centre (SNEC))

Study Title: CG23 - For Training Purposes ⑤

Quick Link: [Study Summary, CRMS](#) ④

Click the down arrow to collapse part of the top header ⑥

Declare and Submit

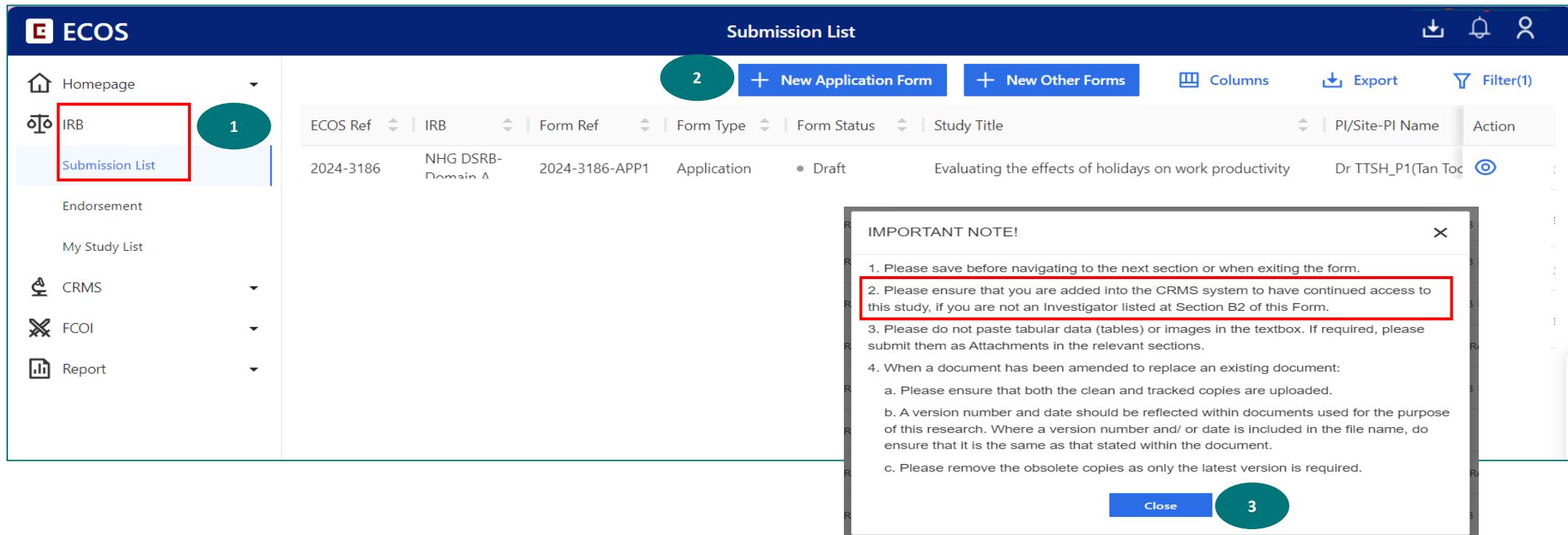
- 1) On the Application Form, click ‘Mandatory Check’ to ensure that all form fields are filled.
- 2) Use ‘Save’ frequently to ensure that all information are saved. Your form will not be autosaved.
- 3) Use ‘Save and Exit’ to save and exit editing mode.
- 4) View the ‘Study Summary’ such as Forms, Forms Attachments and Study Letter submitted for the study.
- 5) Refer to the CRMS section, slide 26 for more information.
- 6) For PI, the ‘[Declare and Submit](#)’ button will be displayed, and form will be ‘Pending Endorsement’ upon submission. For all other roles, the ‘[Finalise](#)’ button will be displayed, and form will be ‘Pending PI Declaration’ upon submission.

IMPORTANT NOTE: The timeout for ECOS is 60 minutes. Please “Save” the form to keep it active. Editing only does not keep the form active.



Create New Application – STM/SA/SS

- 1) Click  > “Submission List”
- 2) Create a “New Application Form”
- 3) Upon reading the “Important Note!”, “Close” the window to proceed with form creation.



The screenshot shows the ECOS Submission List interface. On the left, there is a sidebar with links: Homepage, IRB (highlighted with a red box and circled '1'), Submission List, Endorsement, My Study List, CRMS, FCOI, and Report. The main area shows a table with columns: ECOS Ref, IRB, Form Ref, Form Type, Form Status, and Study Title. A row is selected with values: 2024-3186, NHG DSRB-Domain A, 2024-3186-APP1, Application, Draft, and Evaluating the effects of holidays on work productivity. A 'New Application Form' button is highlighted with a green circle '2'. A 'New Other Forms' button is also present. On the right, there are buttons for Columns, Export, and Filter. A 'IMPORTANT NOTE!' dialog box is open, containing the following text:

IMPORTANT NOTE!

1. Please save before navigating to the next section or when exiting the form.

2. Please ensure that you are added into the CRMS system to have continued access to this study, if you are not an Investigator listed at Section B2 of this Form.

3. Please do not paste tabular data (tables) or images in the textbox. If required, please submit them as Attachments in the relevant sections.

4. When a document has been amended to replace an existing document:

- Please ensure that both the clean and tracked copies are uploaded.
- A version number and date should be reflected within documents used for the purpose of this research. Where a version number and/ or date is included in the file name, do ensure that it is the same as that stated within the document.
- Please remove the obsolete copies as only the latest version is required.

Close

A green circle '3' is positioned next to the 'Close' button.

Note:

Complete **Sections A (Study Title)** and **B (Submission IRB and Board)** and save to generate a new ECOS reference number for your study

For more information, please refer to [Overview of IRB Ethics Submissions](#) and [IRB Ethics Application Form - List of Sections & Questions](#)



Create New Application – STM/SA/SS

Role used: Study Team Member (TTSH STM1)

1

Click the down arrow to collapse part of the top header

2

For continued access to the IRB Application Form, please select your Study Site and Study Role.

3

- 1) At the first save of the IRB APP Form, the system will recognise that (TTSH STM1) is not part of the Investigator List in Section B2 (a).
- 2) This will trigger a prompt.
- 3) Only 3 options for Role available for user to select: Study Administrator, Study Sponsor or Study Team Member.
- 4) Select the correct Site and Role, then click Save.
- 5) The system will register this and add (TTSH STM1) to the CRMS User Authorisation List (next slide).

IMPORTANT NOTE: The timeout for ECOS is 60 minutes. Please “Save” the form to keep it active. Editing only does not keep the form active.



Create New Application – STM/SA/SS

Role used: Study Team Member (TTS defence)

Submission Detail

2025-0196-APP1 Draft

ECOS Ref: 2025-0196

Form Type: Application

Form Outcome: -

Initial Study Review Category: -

Current Editor: -

PI/Site-PI: Dr TTS defence (Tan Tock Seng Hospital)

Study Title: Test

Quick Link: [Study Summary](#) [CRMS](#)

Form Detail

Application Form

Section A: Study Title

A1. Please enter the Study Title for this Study.

Test

Study Details

IRB / Submission List / Submission Detail / Study Details

2025-0196, Test / Tan Tock Seng Hospital

ECOS Ref: 2025-0196

IRB: NHG DSRB Domain E

Study Status: Draft

Number of Sites: 1

Initial Outcome Date: -

Valid Till Date: -

PI/Site-PI: Dr TTS defence (Tan Tock Seng Hospital)

Department: Geriatric Medicine (Tan Tock Seng Hospital)

User Authorisation List

Member Name	Role	Cluster	Institution	Department	Designation	Email Address	Action
TTS defence	PI	National Healthcare Group	Tan Tock Seng Hospital	Geriatric Medicine	doctor	tts_defence@taipei.com	IRB
TTS defence	Study Team Member	National Healthcare Group	Tan Tock Seng Hospital	Medical Oncology	TEST	tts_defence@taipei.com	CRMS

4) Click on CRMS

5) (TTS defence) added to the User Authorisation List. You can view PI added in Section B2 (a) of the application form.

6) Refer to [Slide 26](#) to continue filling up the Application Form.

IMPORTANT NOTE: The timeout for ECOS is 60 minutes. Please “Save” the form to keep it active. Editing only does not keep the form active.



► **Create New Other Forms for Approved Study**



- 1(a) Click  **IRB** > **“Submission List”**
- 1(b) Filter - Search for the Approved Study via ECOS Ref.
- 2) Click **“New Other Forms”** - Amendment, Study Deviation / Non-Compliance Report Form (DNC), Other Study Notification Form (OSN), Serious Adverse Event Report Form (SAE) and Study Status Report Form (SSR).
- 3) Search for Study with **“ECOS Ref or Study Title”**, click on the study
- 4) Select **“Form Type”** to be created

The screenshot shows the ECOS Submission List interface. The top navigation bar includes the ECOS logo, a download icon with '1' notifications, a bell icon with '99+' notifications, and a user profile icon. The main title is 'Submission List'. On the left, a sidebar lists 'Homepage', 'IRB' (highlighted with a red box and green '1a' circle), 'Submission List' (highlighted with a red box and green '1a' circle), 'Endorsement', 'My Study List', 'CRMS', 'FCOI', and 'Report'. The main content area shows a submission for '2024-3186' (NHG DSRB-Domain A) titled 'Evaluating the effects of holidays on work productivity' (Status: Draft, PI: Dr TTSH_P1/Tan Toc). A red box highlights the 'New Application Form' and 'New Other Forms' buttons. A green '2' circle highlights the 'Filter(1)' button. A modal window titled 'New Study Form' is open, containing fields for 'ECOS Ref or Study Title' (with a red box and green '3' circle) and 'Form Type' (with a red box and green '4' circle). The 'Form Type' dropdown is open, showing 'Amendment Form (Amendment)', 'Study Deviation/ Non-Compliance Report Form (DNC)', 'Other Study Notifications Report Form (OSN)' (highlighted with a red arrow), 'Serious Adverse Event Report Form (SAE)', and 'Study Status Report Form (SSR)'. A red box highlights the 'Confirm' button in the bottom right of the modal.

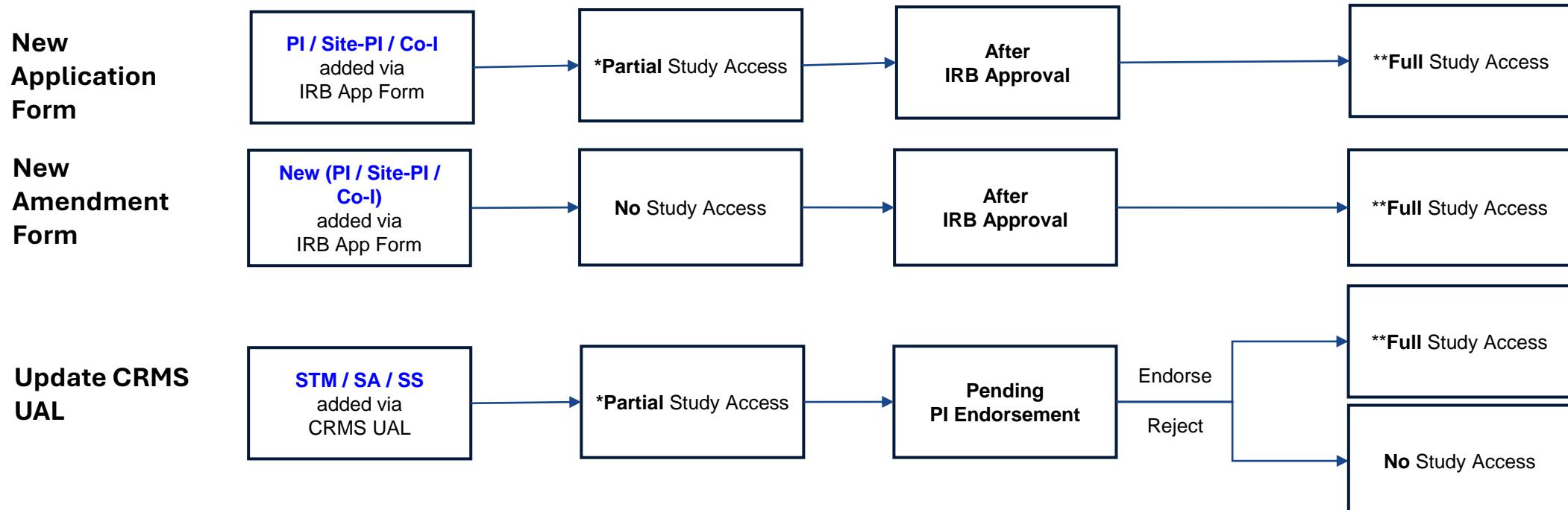


5

Clinical Research Management System (CRMS)

- How to Add Study Team Members
- Managing My Studies

Who Gets Access?	Form	Approval
PI / Site-PI / Co-Investigator (Co-I)	IRB Application Form Section B2.(a)	IRB
Study Team Member (STM) / Study Administrator (SA) / Study Sponsor (SS)	Update CRMS UAL	PI / Site PI
Institutional Research Office Administrators	Write in to OHRPP mailbox to get access	CRMS Module Admin (OHRPP)



***Partial Study Access**

Study Information / User Authorisation List

****Full Study Access**

Study Information / User Authorisation List
Site Information / Milestones / Participants / Participants – Study Configuration / Study Member Review



How To Add My Team Members to My Studies on ECOS?



1(a) Go to IRB > “Submission List”

1(b) Click “Filter” and search for the Study via “ECOS Ref.”

1(c) In the “Application Form” > “Section B: Submission Board, Study Site, Study Investigator and Conflict of Interest”, is updated in the “Dashboard” page

2) Go to CRMS, click dropdown menu

3) Click to view “Study List” available

4) Click “Filter” for your study

5) Click eye icon to view your study

The image displays three screenshots of the ECOS (Electronic Clinical Outcome System) interface, illustrating the steps to add team members to studies.

- Screenshot 1a:** The ECOS homepage shows the "Submission List" section. A red box highlights the "IRB" dropdown menu, and a green circle with "1a" indicates the step to click on "Submission List".
- Screenshot 1b:** The "Submission List" page. A red box highlights the "Filter" button, and a green circle with "1b" indicates the step to search for the study via "ECOS Ref." (2025-0145). The "Submission Detail" page is also shown below.
- Screenshot 1c:** The "Submission Detail" page for study 2025-0145-APP1. A green circle with "1c" indicates the step to check the "Section B: Submission" section, which shows the updated information from the dashboard.
- Screenshot 2:** The ECOS dashboard. A red box highlights the "CRMS" dropdown menu, and a green circle with "2" indicates the step to click on "Study List".
- Screenshot 3:** The "Study List" page. A red box highlights the "Filter" button, and a green circle with "3" indicates the step to filter studies. A red box highlights the "eye icon" in the "Action" column of the table, and a green circle with "4" indicates the step to click on it to view the study.
- Screenshot 4:** The "Study List" page with a red box highlighting the "Filter" button, and a green circle with "4" indicating the step to click on it to filter studies.
- Screenshot 5:** The "Study List" page with a red box highlighting the "eye icon" in the "Action" column of the table, and a green circle with "5" indicating the step to click on it to view the study.



How To Add My Team Members to My Studies on ECOS?

- 1) Click “CRMS”, on the “Submission Detail” page
- 2) Click “User Authorization List”
- 3) Click “Add”
- 4) Enter “Member name/ email” to search for correct user. (User must have a valid ECOS Account)
- 5) Select the relevant role: Study Administrator/Study Member/ Study Sponsor.
- 6) Click “Submit”

The screenshot shows the ECOS User Authorization List interface. It consists of two main windows: a 'Submission Detail' window on the left and a 'User Authorization List' window on the right.

Submission Detail Window (Left):

- Header: 'Submission Detail' with a 'Back to Submission List' link.
- Form Type: Application.
- Current Editor: -
- PI/Site-PI: A/Prof TTSH_User_ID04 (Tan Tock Seng Hospital)
- Study Title: Test
- Quick Link: Study Summary (highlighted with a red box and circled 1)
- Form Detail tab is selected.
- Application Form tab is visible.
- Section A: Study Title

User Authorization List Window (Right):

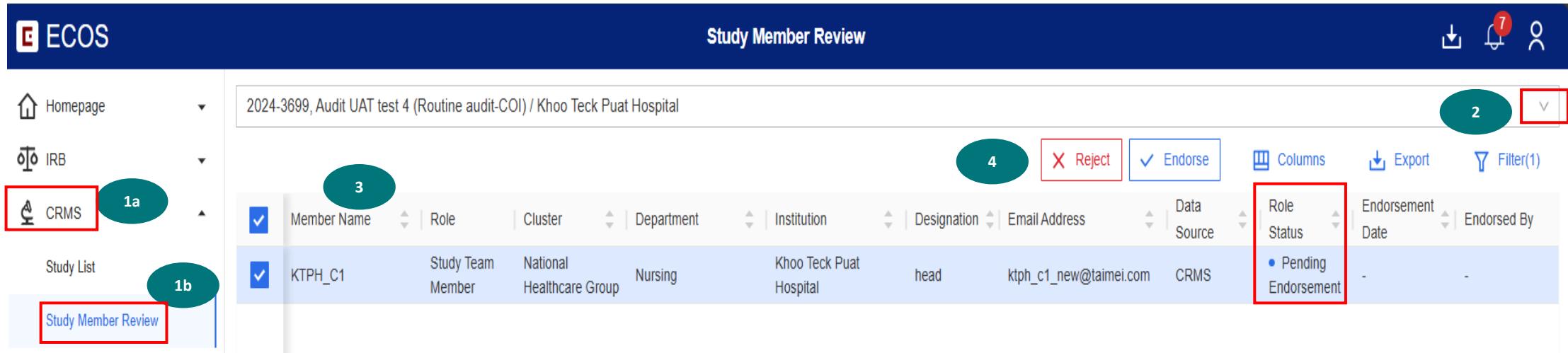
- Header: 'User Authorization List' with a 'Back to Submission Detail' link.
- Study Site: Tan Tock Seng Hospital
- Table: Shows a single row for TTSH_User_ID04 with the role 'PI'.
- Buttons: '+ Add' (highlighted with a red box and circled 3), 'Edit', and 'Submit' (highlighted with a red box and circled 6).
- Form fields: 'Member Name/Email' (highlighted with a red box and circled 4) and 'Role' (highlighted with a red box and circled 5).
- Buttons: 'Export' and 'Filter(1)'.

IMPORTANT NOTE:

Each participant for the study should only have one role in ECOS.

Team Members	ECOS Defined Role Definition
Study Team Member	Site personnel directly involved in the research conduct e.g. CRCs, Study Nurses, Pharmacists, etc.
Study Administrator	Site personnel NOT directly involved in the research but provides administrative support only e.g. Dept Manager providing research administrative support.
Study Sponsor	Sponsor / CRO personnel, e.g. CRAs.

How To Endorse / Reject / Deactivate My Team Members to My Studies on ECOS?



The screenshot shows the ECOS Study Member Review interface. The top navigation bar includes the ECOS logo, a search bar with the study ID '2024-3699, Audit UAT test 4 (Routine audit-COI) / Khoo Teck Puat Hospital', and various icons for download, help, and user profile. The left sidebar has links for Homepage, IRB, CRMS (highlighted with a red box), Study List, and Study Member Review (highlighted with a red box). The main content area displays a table of study members. The table columns are: Member Name (highlighted with a teal circle labeled 3), Role, Cluster, Department, Institution, Designation, Email Address, Data Source, Role Status (highlighted with a red box and a teal circle labeled 4), Endorsement Date, and Endorsed By. A member named 'KTPH_C1' is selected, showing the role 'Study Team Member', cluster 'National Healthcare Group', department 'Nursing', institution 'Khoo Teck Puat Hospital', designation 'head', email 'ktph_c1_new@taimei.com', data source 'CRMS', and role status 'Pending Endorsement'. Action buttons 'Reject' (red) and 'Endorse' (blue) are located above the table. A 'Columns' button, a 'dropdown arrow' (highlighted with a teal circle labeled 2), an 'Export' button, and a 'Filter(1)' button are also visible.

1(a) Click 

1(b) Go to “Study Member Review”

- 2) Click  to Select your study
- 3) Select “Member Name” requiring PI Endorsement. This appears as “Role Status” - “Pending Endorsement”
- 4) PI can either “Reject” or “Endorse” the addition of the team member that are added by non-PI (e.g., Co-I, Study Administrator). (The option to “Endorse” is only available for IRB approved studies - Give Study Team Member and Study Administer roles additional access to Site Information, User Authorisation List, Site Information, Milestones and Participants.).

PI to **Deactivate**, if access was not appropriately given.

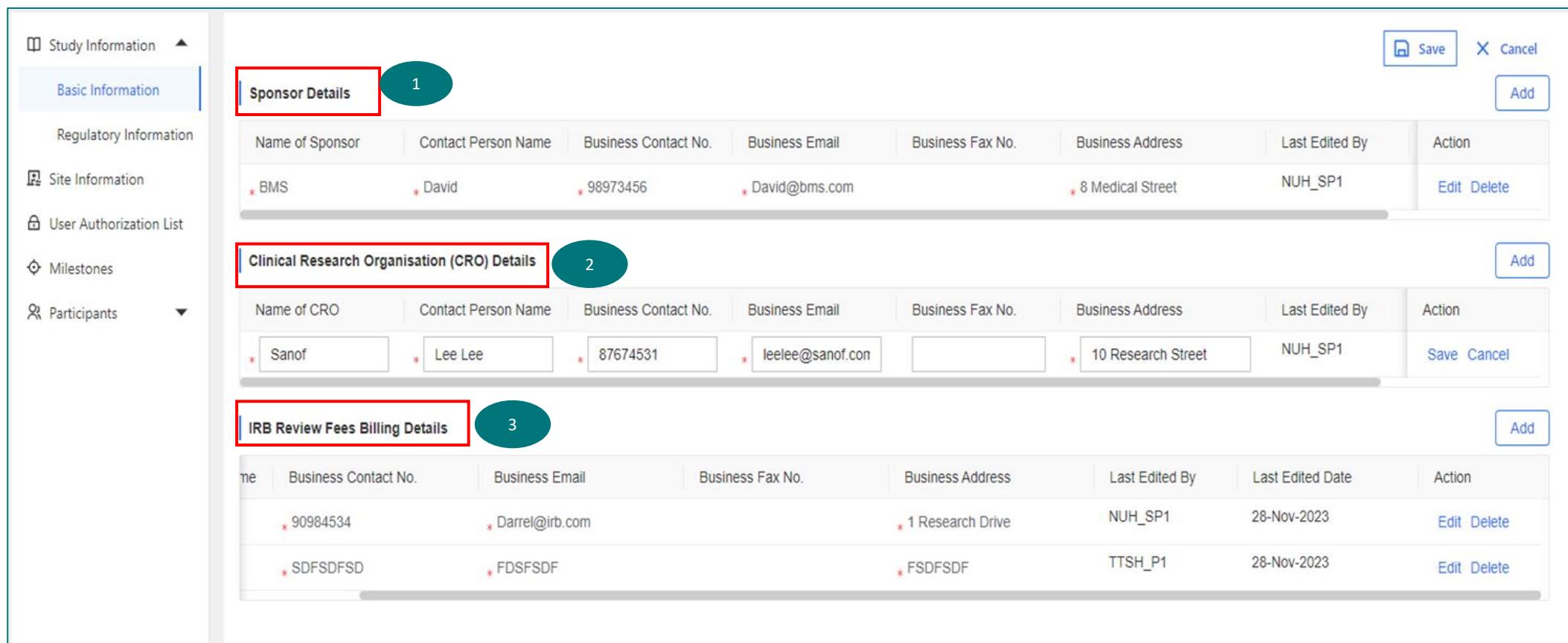
IMPORTANT NOTE: PI Endorsement is a pre-requisite for assigning team members in ECOS.



Managing IRB Submission for Sponsored Study

The following CRMS sections in “**Study Information > Basic Information**” will need to be completed to support the IRB application, if Section C1 (funding information) “Pharmaceutical / Industry Sponsored” was selected:

- 1) Sponsor Details
- 2) CRO Details and,
- 3) IRB Review Fees Billing Details



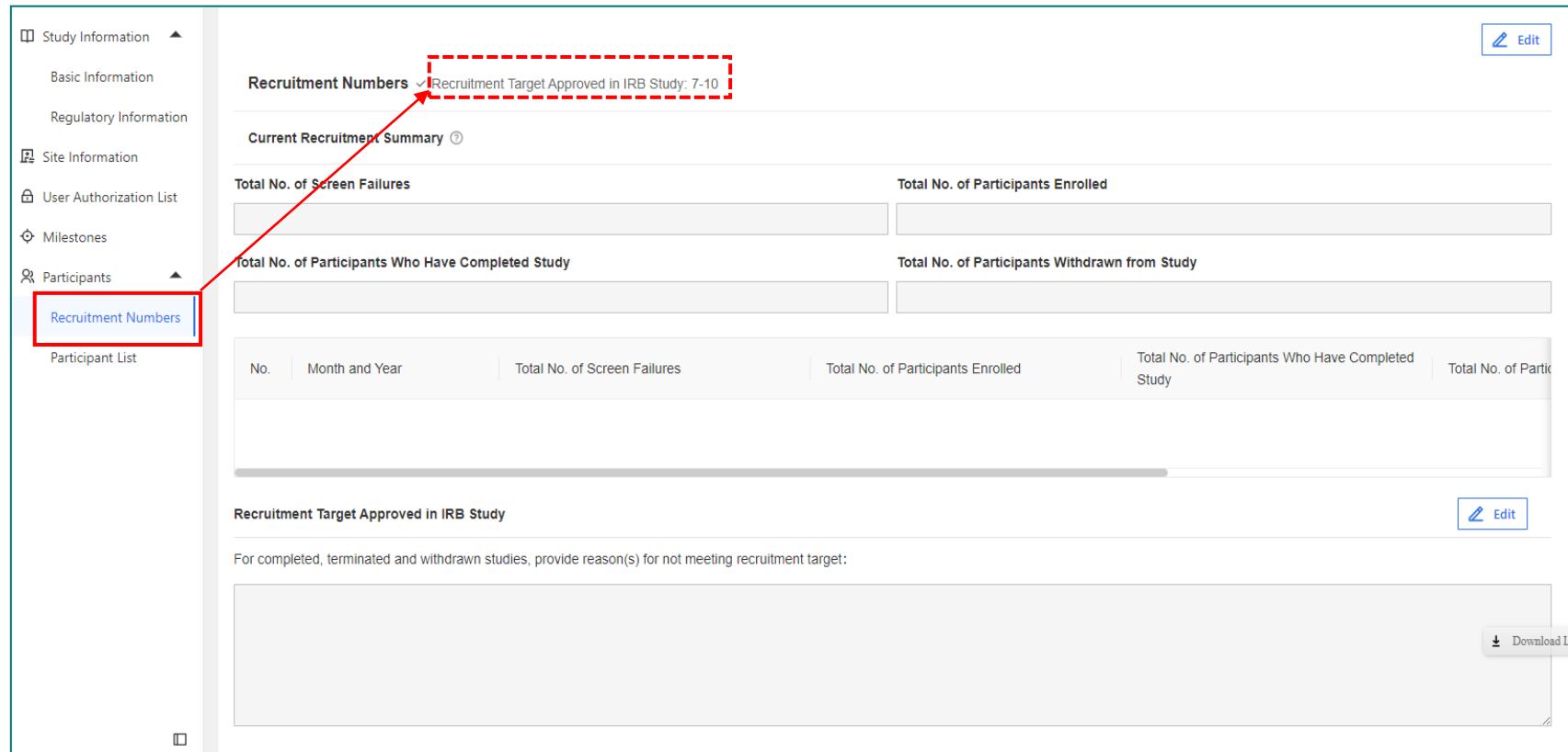
The screenshot shows the 'Basic Information' tab under 'Study Information' in the CRMS interface. The page is divided into three main sections, each with an 'Add' button in the top right corner:

- Sponsor Details (Section 1):** Contains fields for Name of Sponsor, Contact Person Name, Business Contact No., Business Email, Business Fax No., Business Address, Last Edited By, and Action. A single record is listed: BMS, David, 98973456, David@bms.com, 8 Medical Street, NUH_SP1.
- Clinical Research Organisation (CRO) Details (Section 2):** Contains fields for Name of CRO, Contact Person Name, Business Contact No., Business Email, Business Fax No., Business Address, Last Edited By, and Action. A single record is listed: Sanof, Lee Lee, 87674531, leelee@sanof.com, 10 Research Street, NUH_SP1.
- IRB Review Fees Billing Details (Section 3):** Contains fields for Name, Business Contact No., Business Email, Business Fax No., Business Address, Last Edited By, Last Edited Date, and Action. Two records are listed: 90984534, Darrel@irb.com, 1 Research Drive, NUH_SP1, 28-Nov-2023; and SDFSDFSDF, FDSFSDF, FSDFSDF, TTSH_P1, 28-Nov-2023.



Managing Your Study Activities

You can now track and enter recruitment number



The screenshot shows a software interface for managing study activities. On the left, a sidebar lists categories: Study Information (Basic Information, Regulatory Information), Site Information, User Authorization List, Milestones, Participants (with 'Recruitment Numbers' highlighted by a red box and arrow), and Participant List. The main content area is titled 'Recruitment Numbers' and includes a note: 'Recruitment Target Approved in IRB Study: 7-10'. Below this is a 'Current Recruitment Summary' table with four rows: 'Total No. of Screen Failures' (empty), 'Total No. of Participants Enrolled' (empty), 'Total No. of Participants Who Have Completed Study' (empty), and 'Total No. of Participants Withdrawn from Study' (empty). At the bottom, there is a section for 'Recruitment Target Approved in IRB Study' with a text input field and a 'Download List' button.

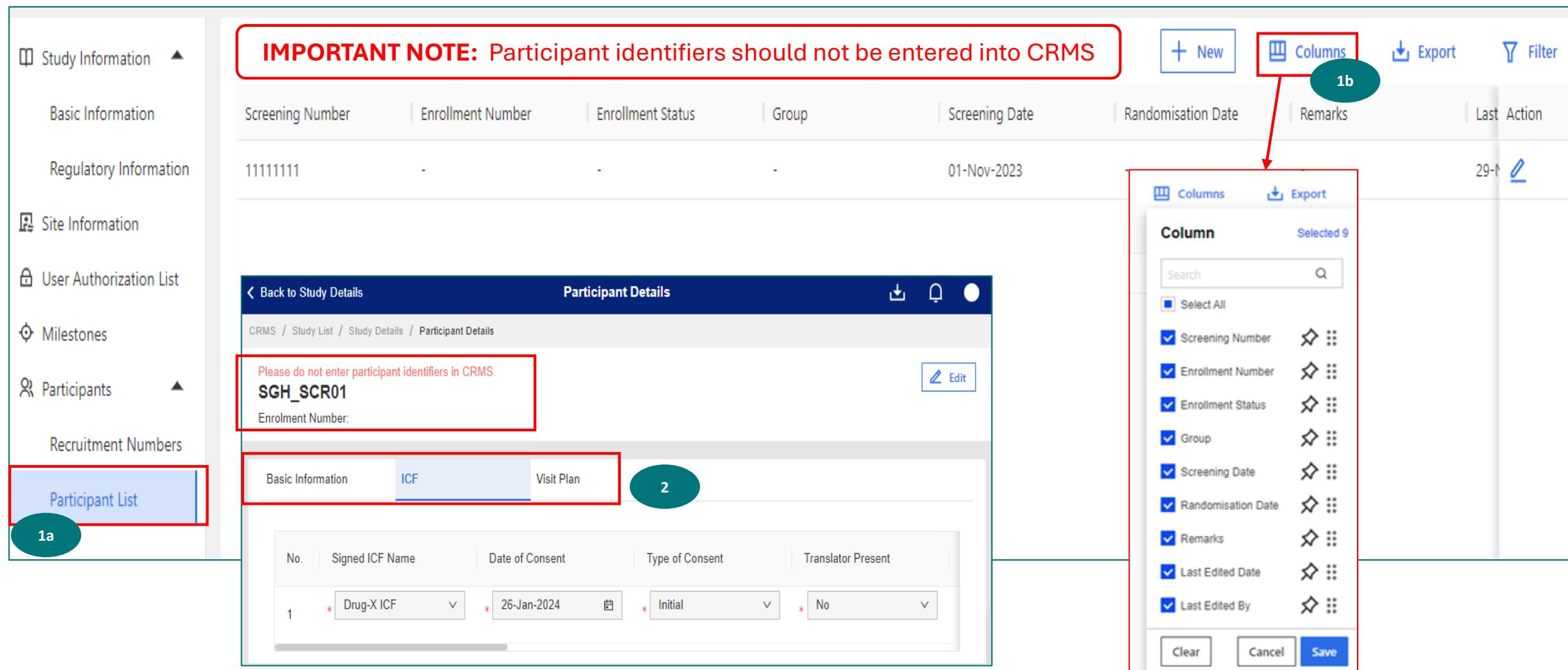
For step-by-step training on the navigation of Managing Your Research Activity, please refer to CRMS module guide in [ECOS User Guides](#)



Managing Your Study Activities

(1a) Study “Participant List” may be sorted by (1b)“Columns” and selected fields such as “Screening Number”, “Enrollment Status” and “Randomization Date”.

2) “Participant Details” can be entered into three sub-pages - Basic Information/ICF Details/Visit Plan.



The screenshot illustrates the CRMS software interface for managing study activities. On the left, a sidebar lists various study details: Study Information, Basic Information, Regulatory Information, Site Information, User Authorization List, Milestones, Participants (with a red box around the 'Participant List' sub-page), and Recruitment Numbers. The 'Participant List' sub-page is highlighted with a red box and a teal '1a' callout. The main content area shows a table of participant details with a red box around the header row. A prominent red box highlights the 'IMPORTANT NOTE: Participant identifiers should not be entered into CRMS' message. The 'Columns' button in the top right is circled in teal and labeled '1b', with a red arrow pointing to a detailed 'Columns' configuration dialog box. This dialog lists 9 selected columns: Screening Number, Enrollment Number, Enrollment Status, Group, Screening Date, Randomisation Date, Remarks, Last Edited Date, and Last Edited By. The 'ICF' tab in the 'Participant Details' sub-page is highlighted with a red box and a teal '2' callout, showing a form for basic information, ICF, and visit plan.

Resources

- ECOS Modules User Guides
- Useful Contacts

ECOS Modules User Guides



View the [User Guides](#) here.

1. General ECOS Functionality & Overview	<ul style="list-style-type: none">• Quick Start Guide: Ethics & Compliance Online System (ECOS)• ECOS User Guide: Minimum Training Module• ECOS User Guide: Financial Conflict of Interest (FCOI) Module
2. IRB Ethics Submissions	<ul style="list-style-type: none">• ECOS User Guide: Institutional Review Board (IRB) Module• IRB Guidebook: Application Form• Mastering IRB Submissions: Key Points to Note for Effective Response
3. Managing Your Research Activity	<ul style="list-style-type: none">• ECOS User Guide: Clinical Research Management System (CRMS) Module
4. Responding to the NHG Health Research Institution for Deviation/ Non-Compliance & Serious Adverse Events from HBR Studies	<ul style="list-style-type: none">• ECOS User Guide: Compliance Module - Deviation / Non-Compliance & Serious Adverse Event (For PI)
5. Standing Database (SDB) Submissions	<ul style="list-style-type: none">• ECOS User Guide: SDB Module For Custodians and Database Team Members• ECOS User Guide: SDB Module For Endorsers• SDB Form Guidebook: Application, Non-Compliance & Status Report Form
6. For ECOS Institution & Department Representatives	<ul style="list-style-type: none">• ECOS User Guide: For Department Representative (DR) / Institution Representative (IR)
7. Research Quality Programmes	<ul style="list-style-type: none">• ECOS User Guide: Compliance Module - Principal Investigator Self-Assessment Form (PISAF)• ECOS User Guide: Compliance Module - Principal Investigator Self-Assessment Form – Study Closure Checklist (PISAF – SCC)• ECOS User Guide: ECOS Monitoring Module• ECOS User Guide: ECOS Audit Module

Useful Contacts

Institutions' Minimum Training Secretariat

To contact your Institutions' Minimum Training Secretariat (MTS) or NHG Health Research Course Admin (for HBR ERC), please refer to the following:

Institution	Institutional MTS Contact Information
Geriatric Education & Research Institute (GERI)	Ms Qiu Shijia: qiu.shijia@geri.com.sg ↗
Institute of Mental Health (IMH)	Ms Jenny Tay: Jenny.am.tay@nhghealth.com.sg ↗
	Ms Jaclyn Ong: Jaclyn.yy.ong@nhghealth.com.sg ↗
Khoo Teck Puat Hospital (KTPH)	Ms Vimala: vimala.sadaiyappan@nhghealth.com.sg ↗ ktph.cru.admin@nhghealth.com.sg ↗
NHG Polyclinics	nhgp.cru@nhghealth.com.sg ↗
National Skin Centre (NSC)	nsc.research@nhghealth.com.sg ↗
Tan Tock Seng Hospital (TTSH)	ttsh.CRIO@nhghealth.com.sg ↗
Woodlands Health (WH)	Ms Liang Shanying: shanying.liang@nhghealth.com.sg ↗

NHG Health Minimum Ethics Training Secretariat

nhggroup.min.ethics.training@nhghealth.com.sg

NHG Health Research Course Admin (HBR only)

nhggroup.research.courseadmin@nhghealth.com.sg

FCOI Secretariat

Nhggroup.DSRB.FCOI@nhghealth.com.sg

Useful Contacts *(continued)*



If you require any ECOS technical support, please contact your Institution's ITD Helpdesk, using the [**ECOS Support Request Form**](#) found on the ECOS Homepage.

For PHI Users

NHG users

nhggroup.ITSHELP@nhghealth.com.sg

(1800-483-4357)

NUHS users

ITSHELP@nuhs.edu.sg

(1800-483-4357)

SingHealth users

it.helpdesk@singhealth.com.sg

(1800-666-7777)

For Non-PHI Users

<https://for.sg/acos-support-request>

You can email synapxe.ecossupport@synapxe.sg with the ticket number for any updates on the tickets raised.



Thank You

Tan Tock Seng Hospital • Khoo Teck Puat Hospital • Woodlands Hospital • Yishun Community Hospital • TTSH Integrated Care Hub
Institute of Mental Health • National Skin Centre • National Centre for Infectious Diseases • NHG Cancer Institute • NHG Eye Institute • NHG Heart Institute
Population Health • NHG Polyclinics • Diagnostics • Pharmacy • Community Care • NHG College • Centre for Healthcare Innovation