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

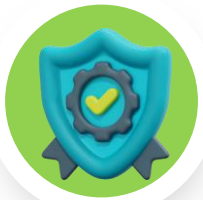
Getting Started - Ethics and Compliance Online System (ECOS)

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.

Account Creation

ECOS Login
&
Profile Set Up

1



Mandatory Training Requirements & FCOI Declaration

Obtain ECOS Labels for Research and FCOI Declared

2

Navigating ECOS

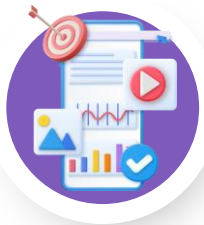
Dashboard,
My Tasks, My Notices

3

Submit Application

Prepare & Submit New Application or Approved Study – Other Forms

4



Clinical Research Management System (CRMS)

How to Add Study Team Members & Manage Study

5

Contents

1 Account Creation

- ECOS Login
- User Profile Set-Up

Public Healthcare Institutions (PHI) Users – Login

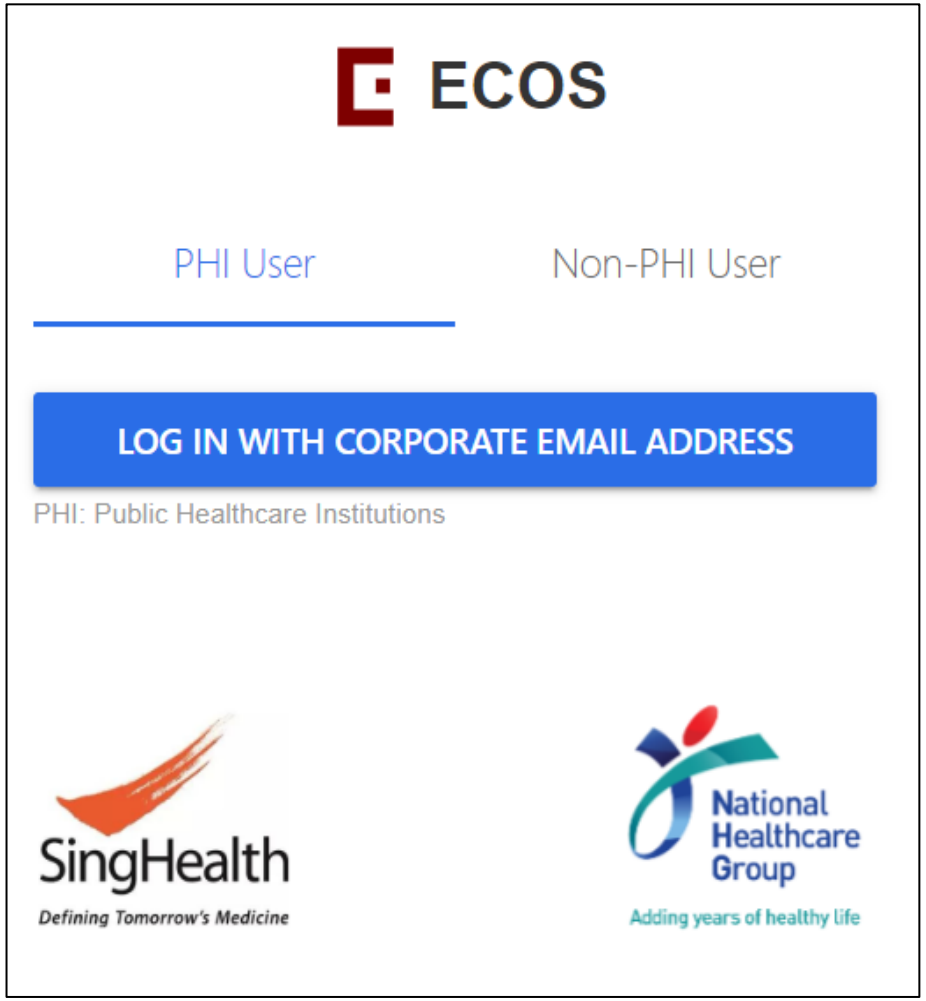
1) PHI - Agency for Integrated Care (AIC), Ministry of Health (MOH), MOH Holdings (MOHH), National Healthcare Group (NHG), SingHealth, National University Health Systems (NUHS)

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

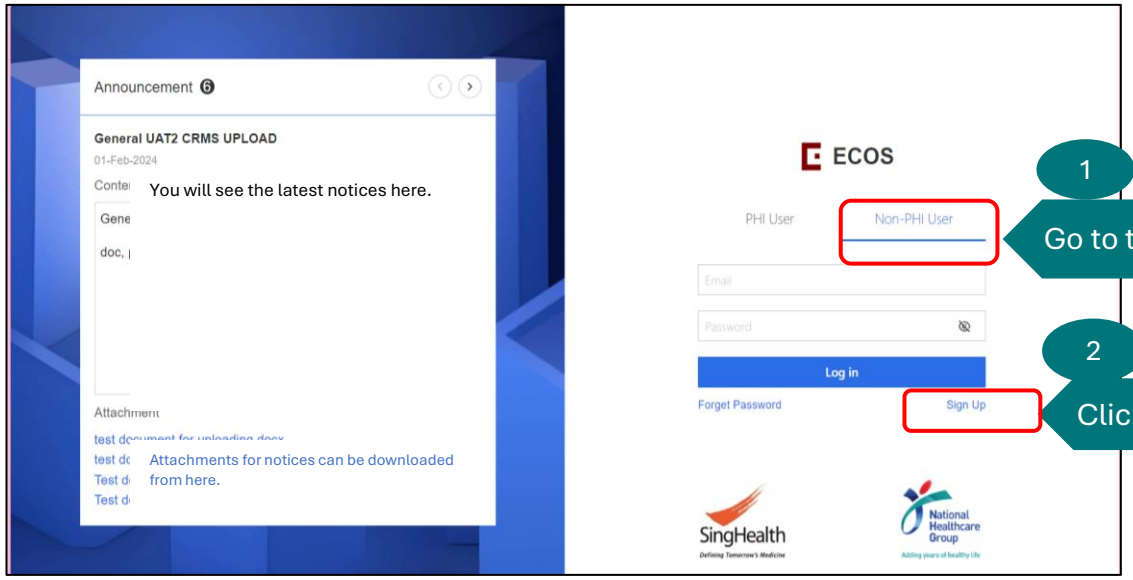
5) Two factor authentication (2FA) via Microsoft Authenticator is required

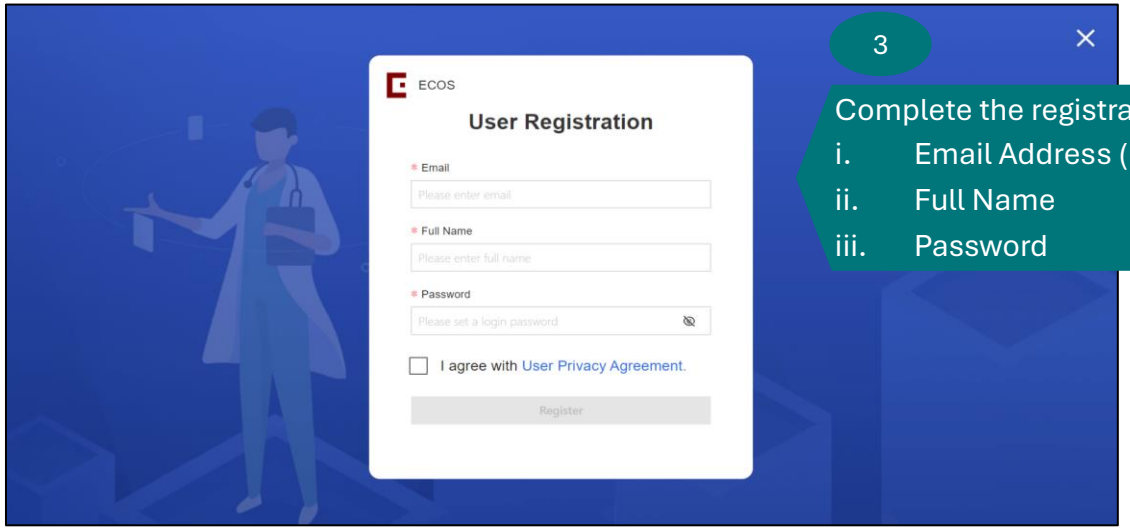


Non-Public Health Institution (PHI) Users – Login

1) Non-PHI - Pharma Sponsors, Academic Institutions (e.g. NUS)

2) ECOS Login https://www.ecos-research.com.sg/login/

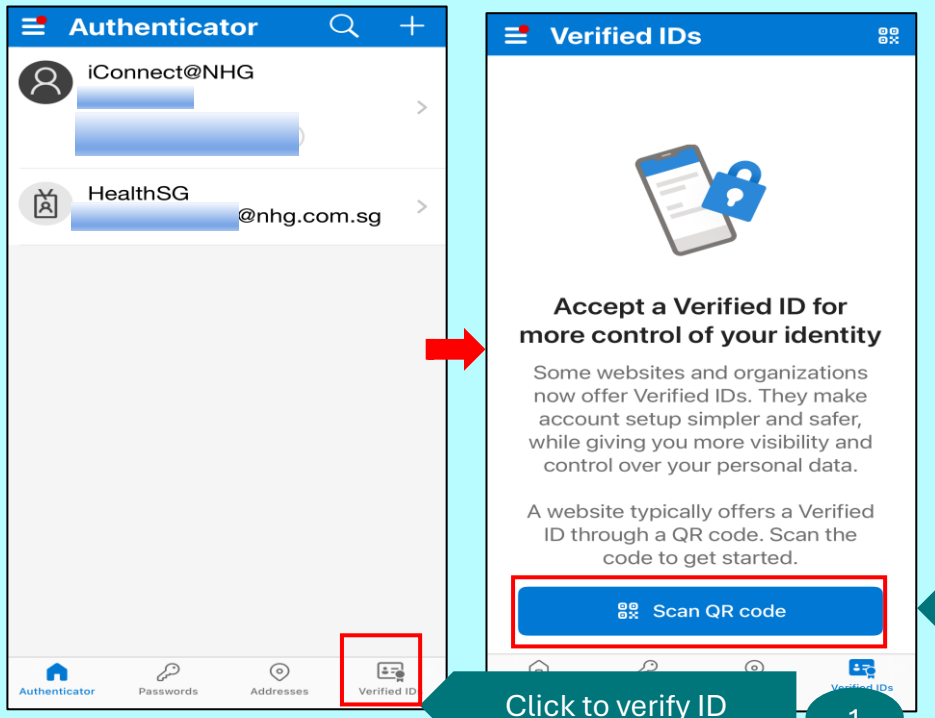




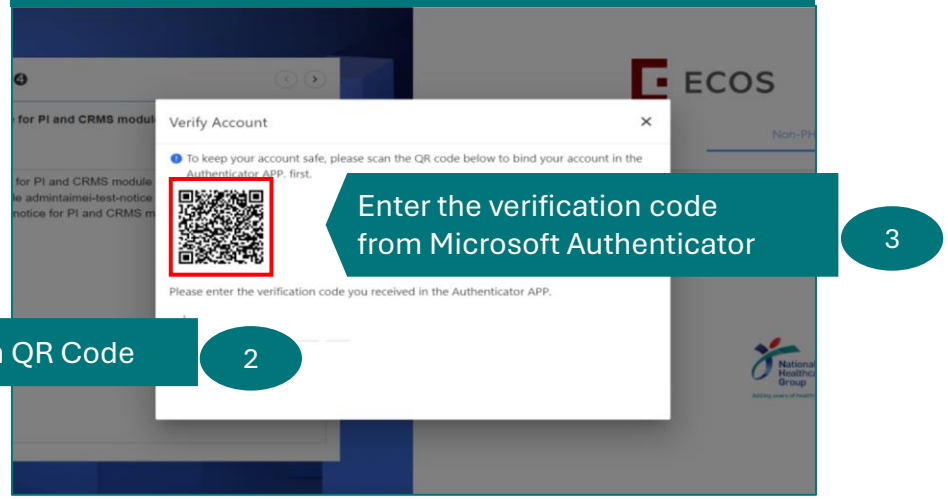
Non-PHI Users – Login *(continued)*

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.	

In Microsoft Authenticator

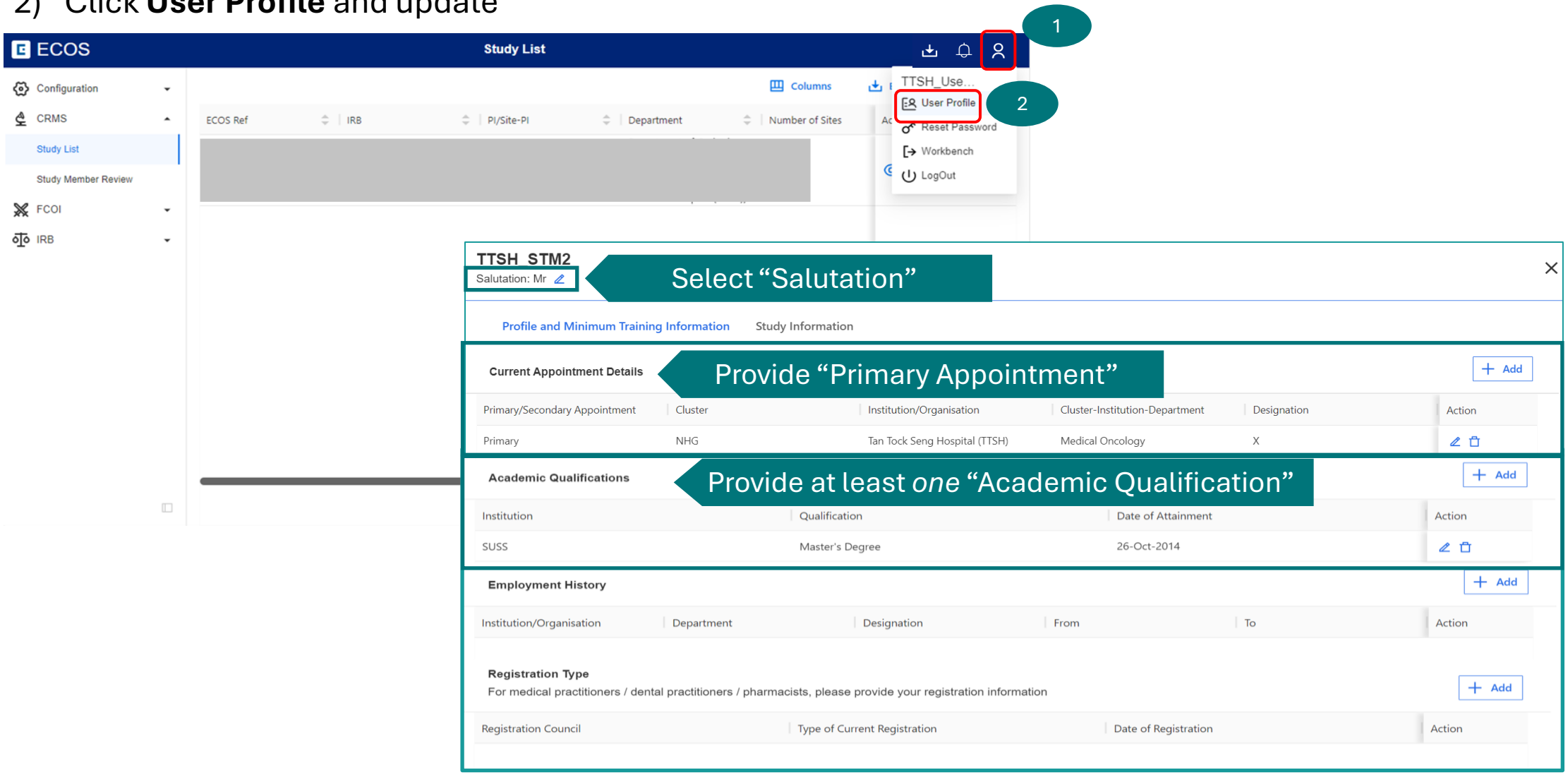


Pop-up message in ECOS registration page



User Profile Set Up

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



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-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** (slide 10 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:**
- **Phone:**

- **Curriculum Group:** [redacted]
- **Course Learner Group:**
- **Stage:**

- **Record ID:** [redacted]
- **Report Date:**
- **Current Score**:**

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: 491)	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.

CITI PROGRAM

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

This is to certify that:

Not valid for renewal of certification through CME.

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)

Under requirements set by:
[redacted]

CITI
Collaborative Institutional Training Initiative

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

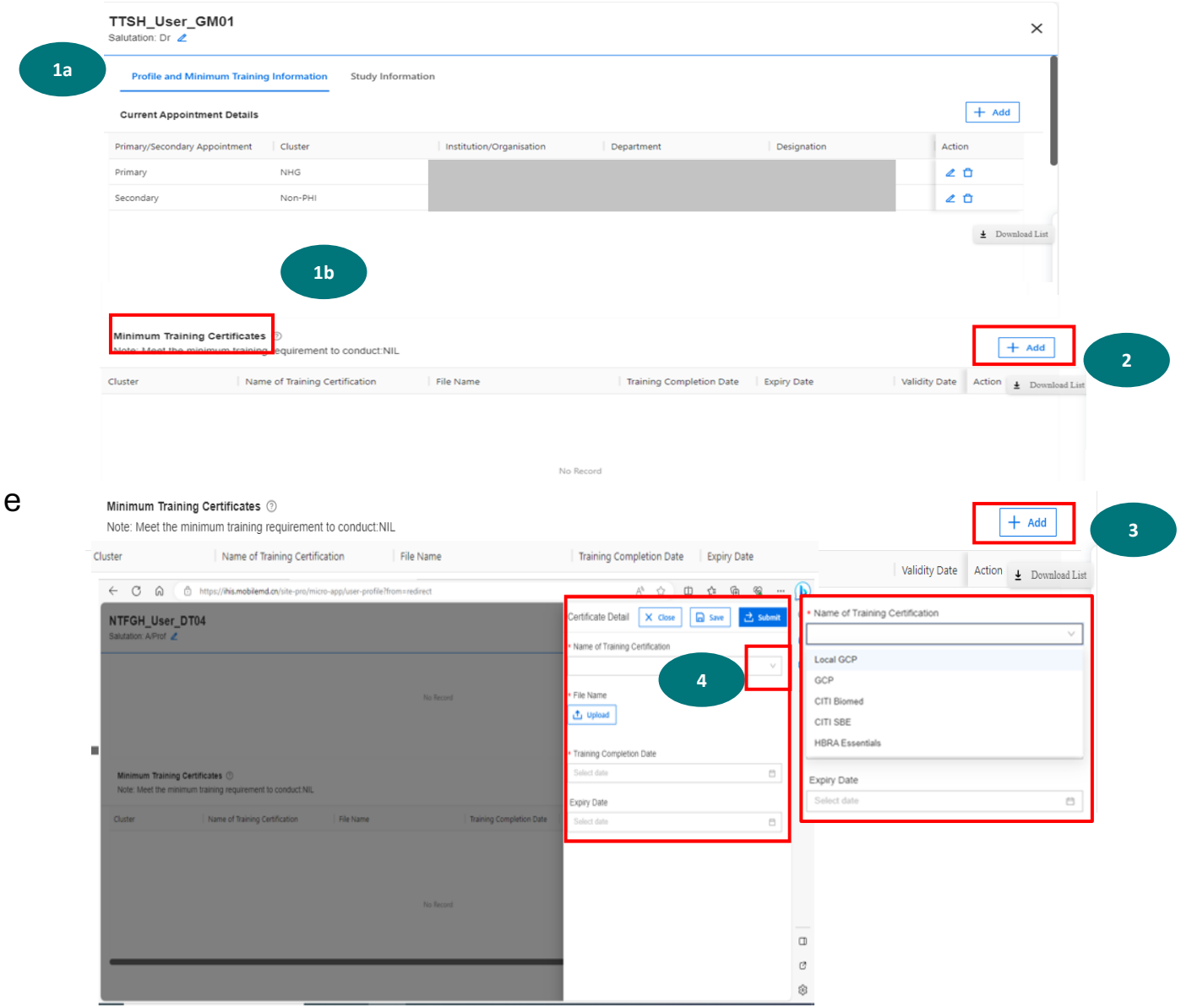
1(a) At **“User Profile”**, locate the **“Profile and Minimum Training Information”** tab

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

2) Click on + Add to upload/update certificate/s

3) Click on + Add 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"**

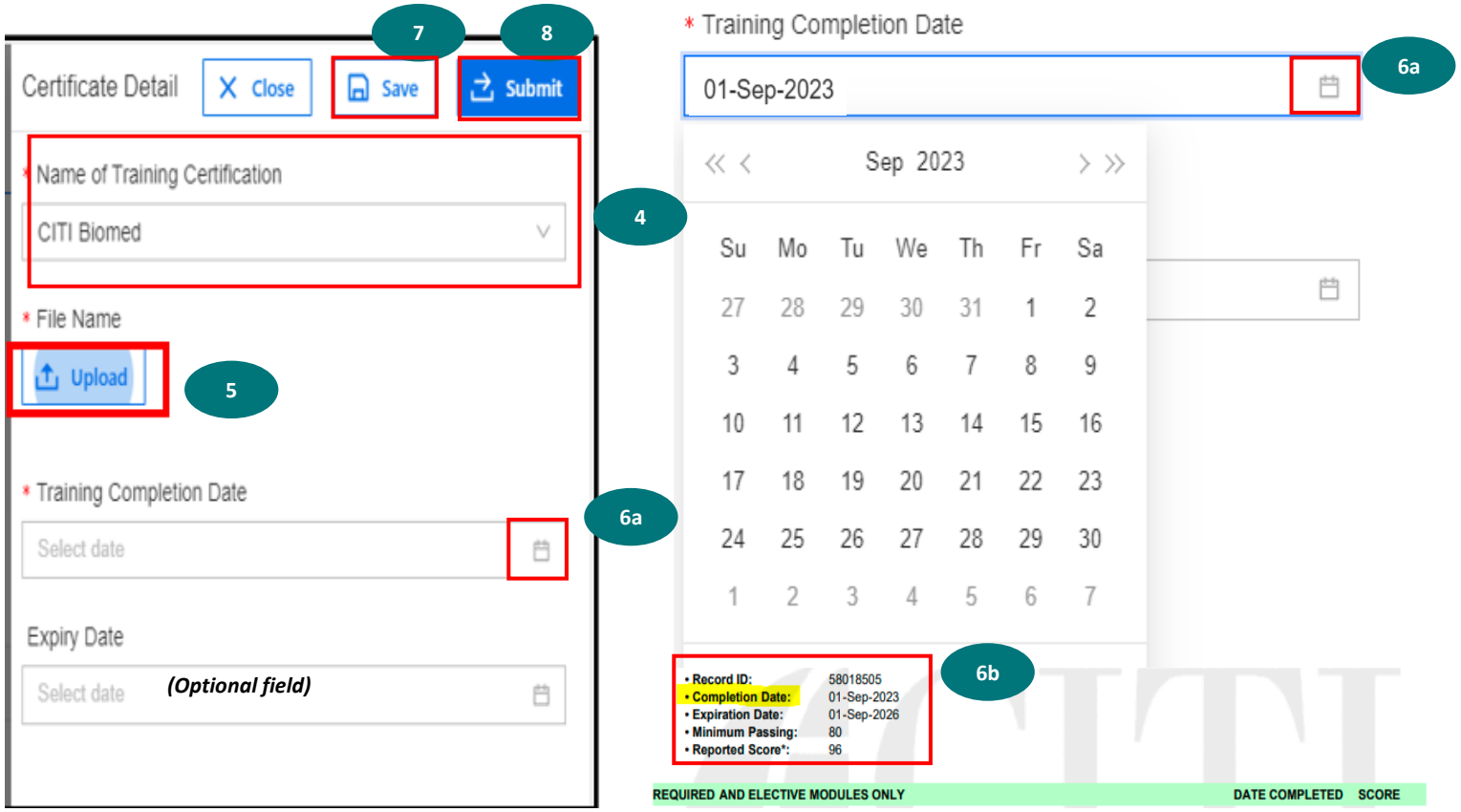
5) Click Upload to browse and upload the training certificate. (Limited to <u>one</u> file upload for each type of Training Certificate)

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

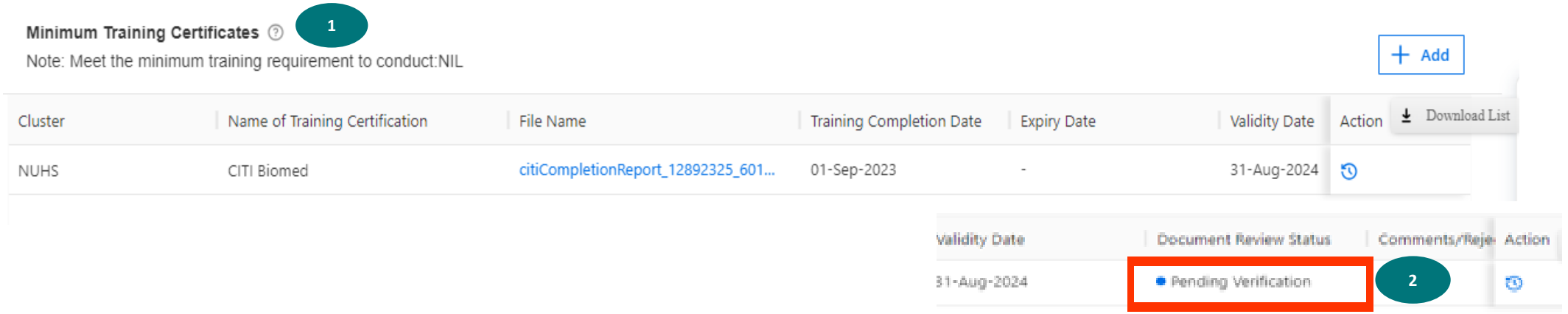
8) Click Submit to send certificates to your cluster / institution's designated Minimum Training Secretariat for review



Review Training Certificate – Document Review Status

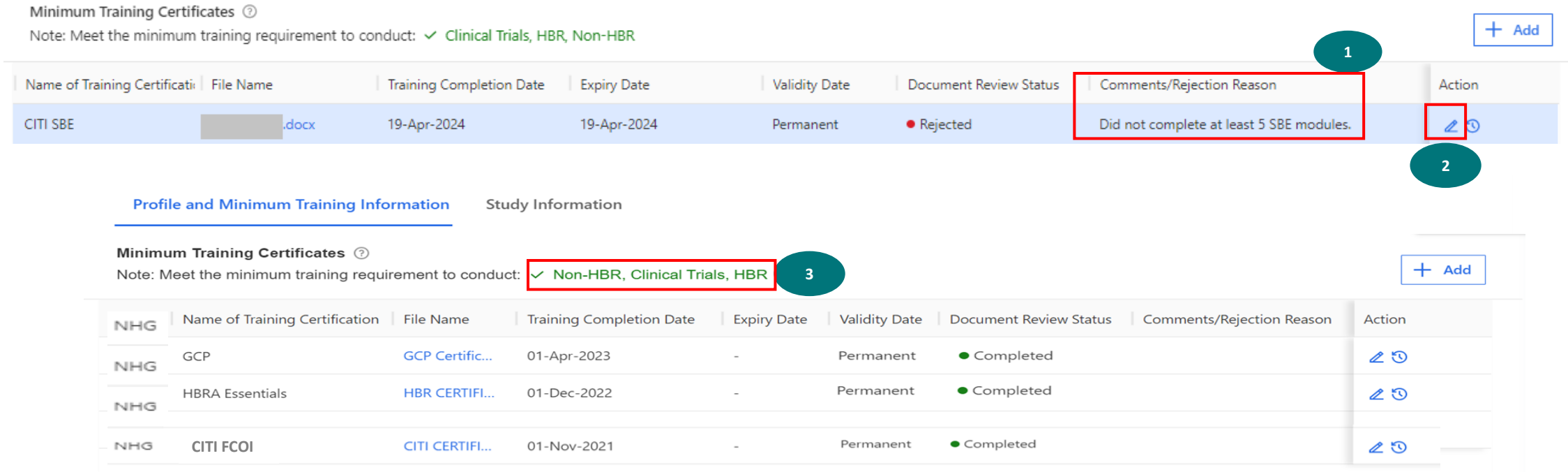
1) Upon submission of the Training Certificate view its status under the **“Minimum Training Certificates”** section
2) View **“Document Review Status”**: Pending Verification/Completed/ Rejected/Expired *(at the far right of the screen)*

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



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.

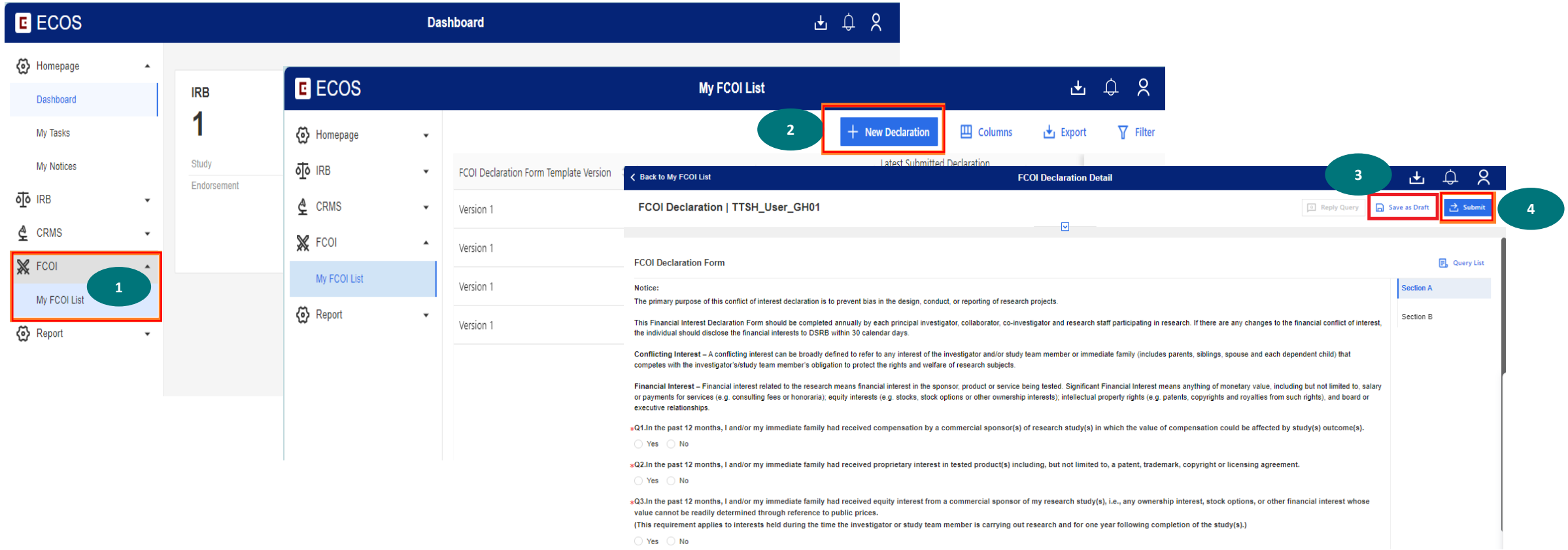
Edit & Review Training Certificate Status & ECOS Labels



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 10 to 12
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.

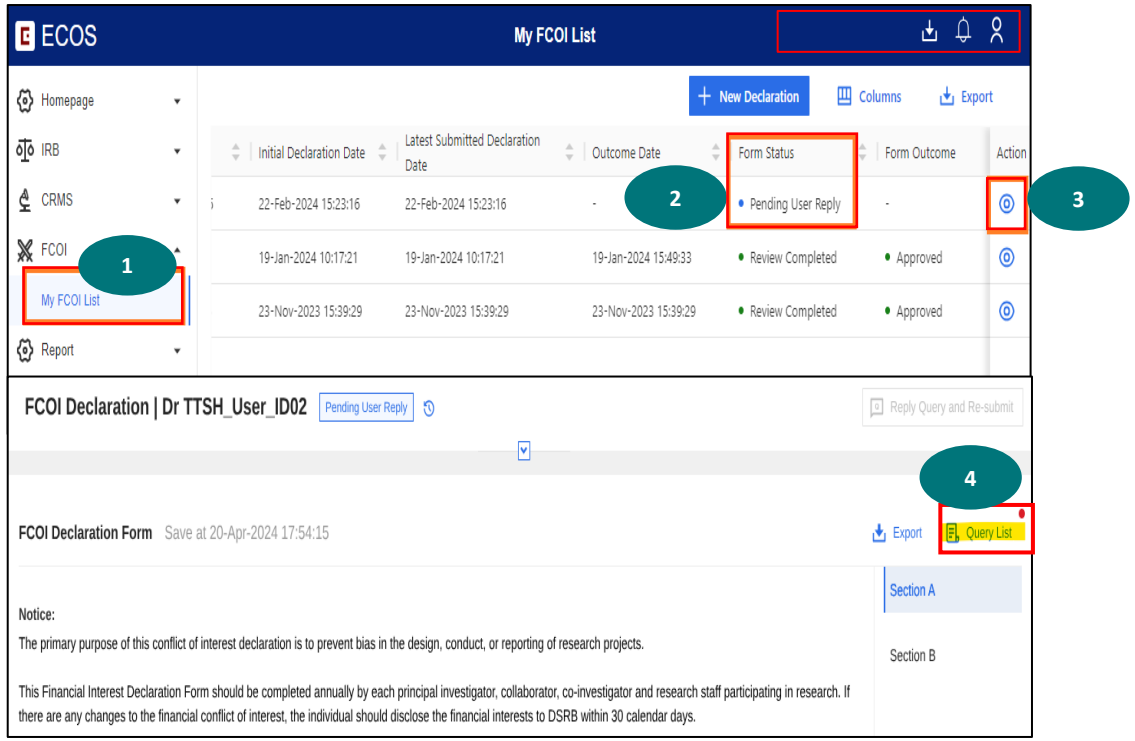
How To Submit FCOI Declaration Form

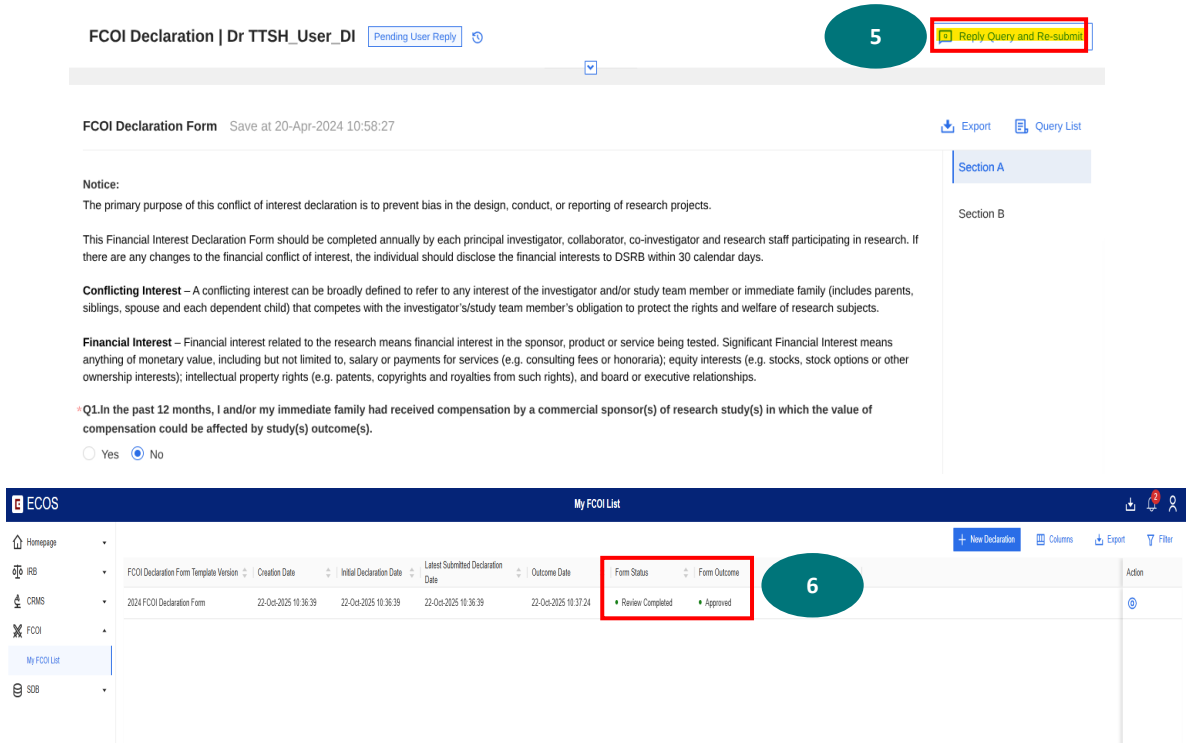
1) On the **“Dashboard”** page, click **“My FCOI List”** *(left sidebar)*
2) Click + New Declaration to submit a new FCOI Declaration Form & provide details of any Financial Conflict of Interest
3) Click **“Save as Draft”** if you are not ready to submit your FCOI Declaration yet
4) Click **“Submit”**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



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





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.

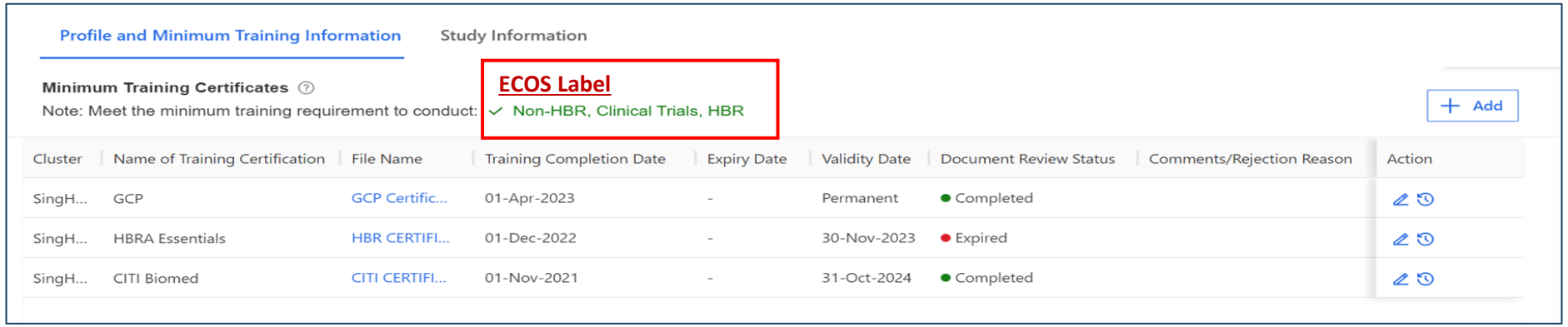
After you have addressed the queries from the FCOI Secretariat and edited your FCOI Declaration Form, where applicable,

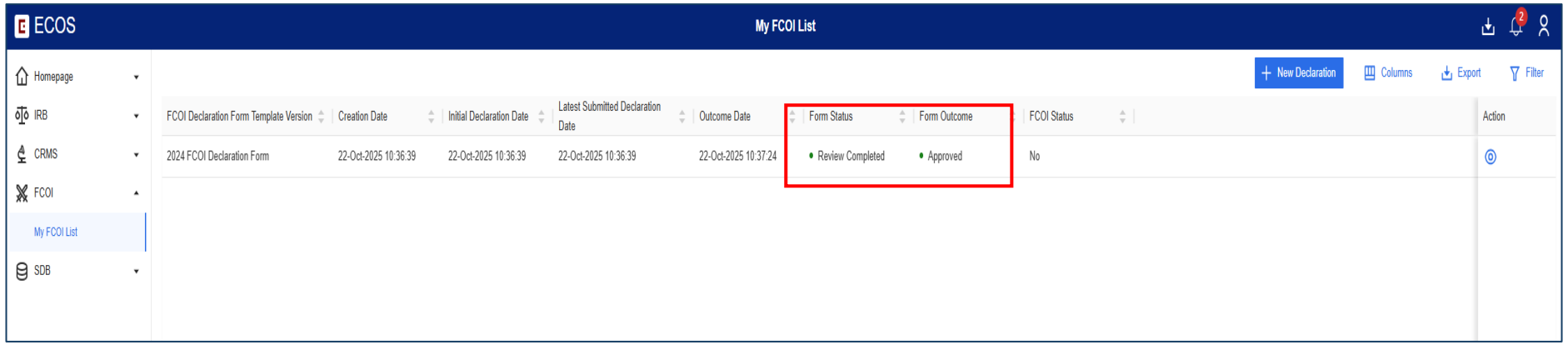
5) Click **"Reply Query and Re-submit"** to send the responses and FCOI Declaration Form back to the FCOI Secretariat

6) If the FCOI Declaration "Form Outcome" is "Approved", "Form Status" will show "Review Completed"

Summary

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.



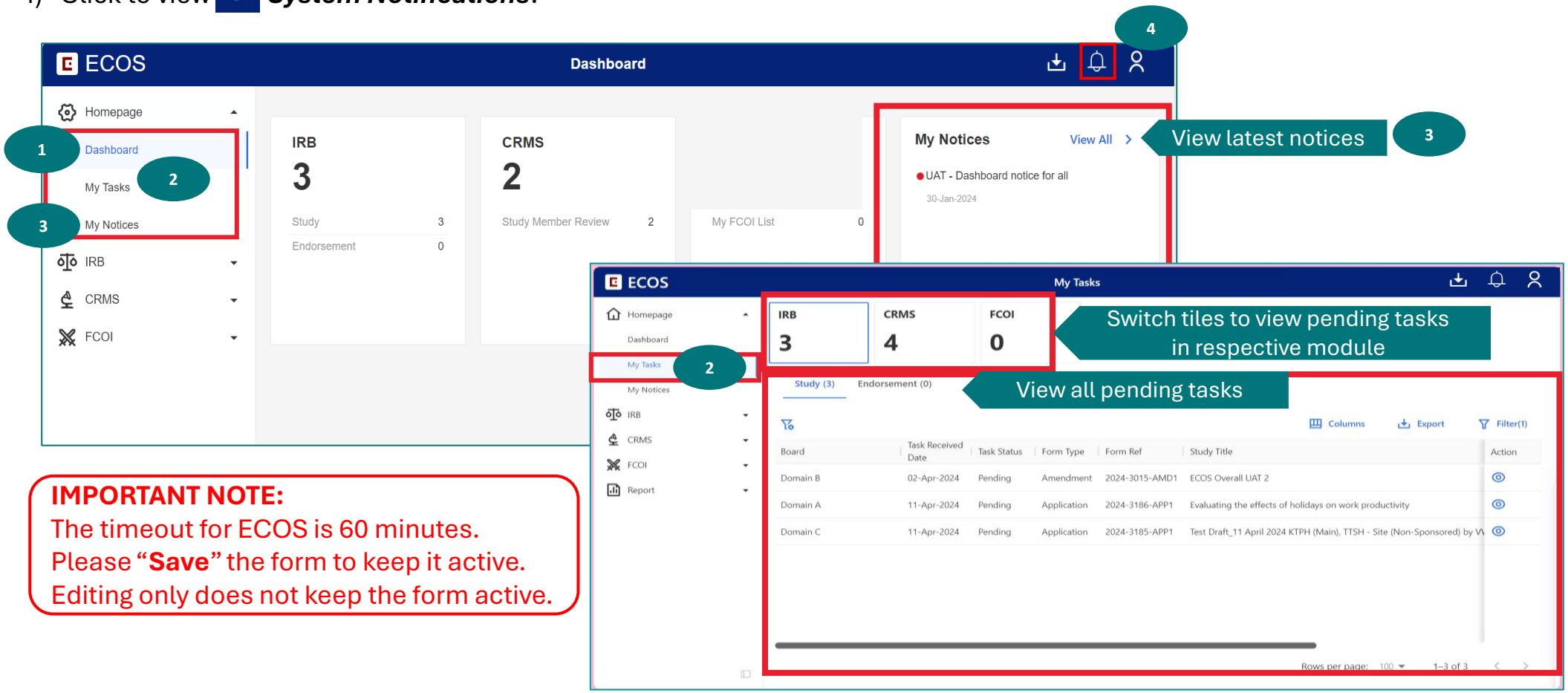


3 Navigating ECOS

- 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***.

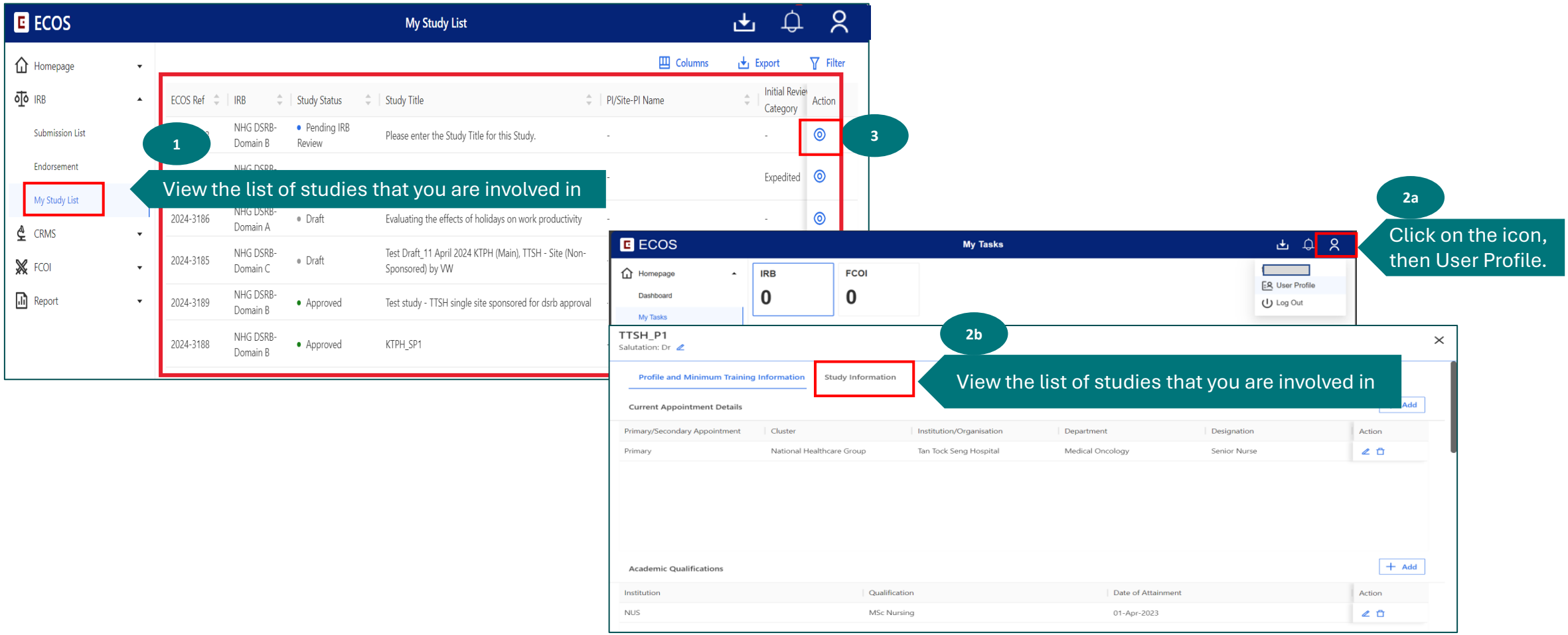


IMPORTANT NOTE:
The timeout for ECOS is 60 minutes.
Please "**Save**" the form to keep it active.
Editing only does not keep the form active.

Navigating ECOS – View "My Study List"

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

1) At IRB , 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



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)	✓	✓	✗

Create New Application

- 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).

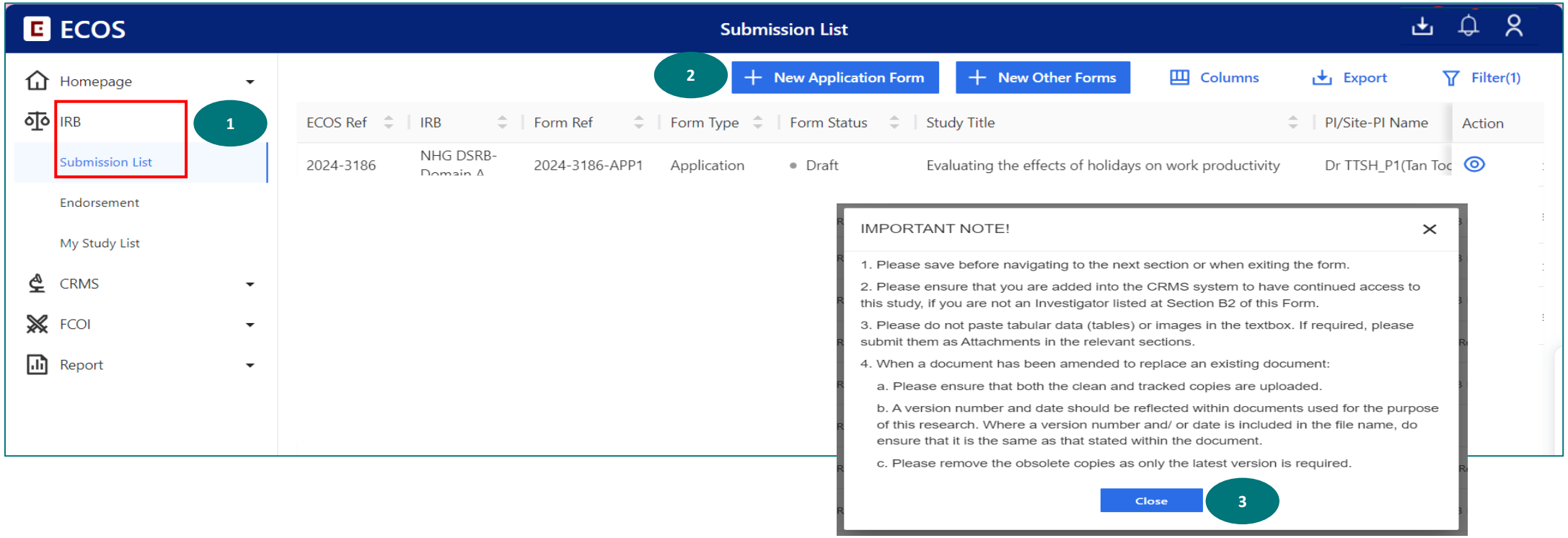
- Investigators will be able to access CRMS pages for the study, in addition to the IRB APP Form.

- 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

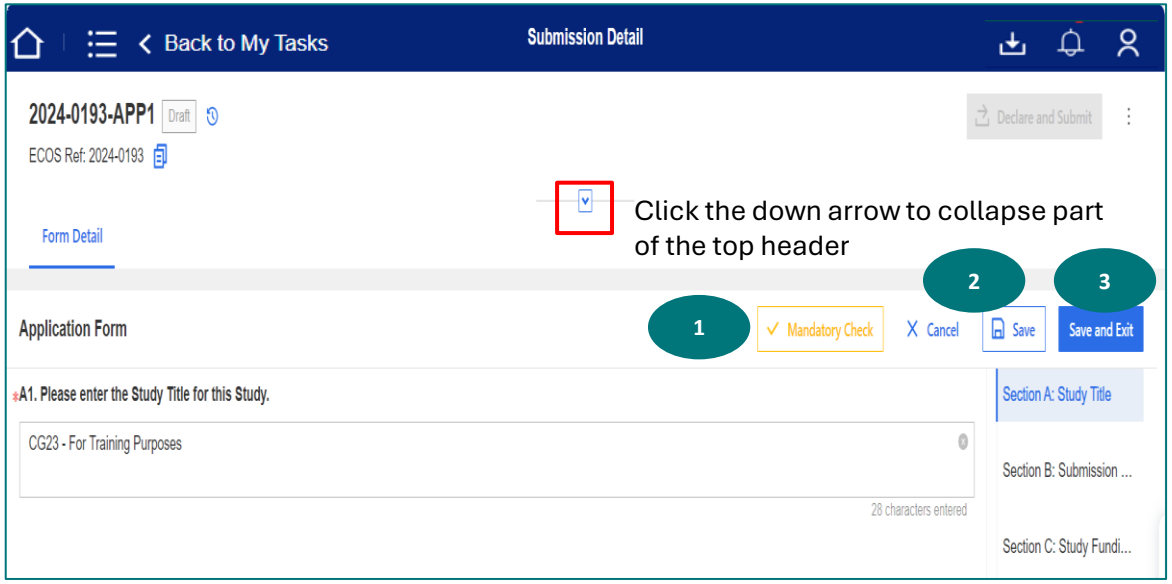
1) Click IRB > **"Submission List"**
2) Create a **"New Application Form"**
3) Upon reading the **"Important Note!"**, **"Close"** the window to proceed with form creation.

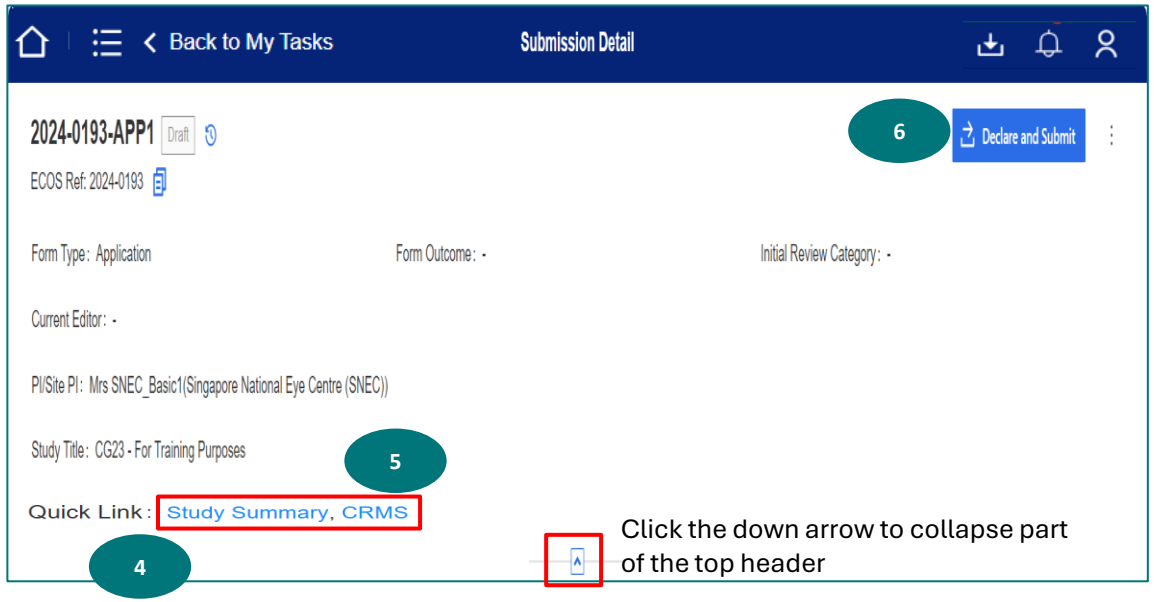


Note:
Complete **Sections A (Study Title)** and **B (Submission IRB and Board)** and save to generate a new ECOS reference number for your study

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





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.

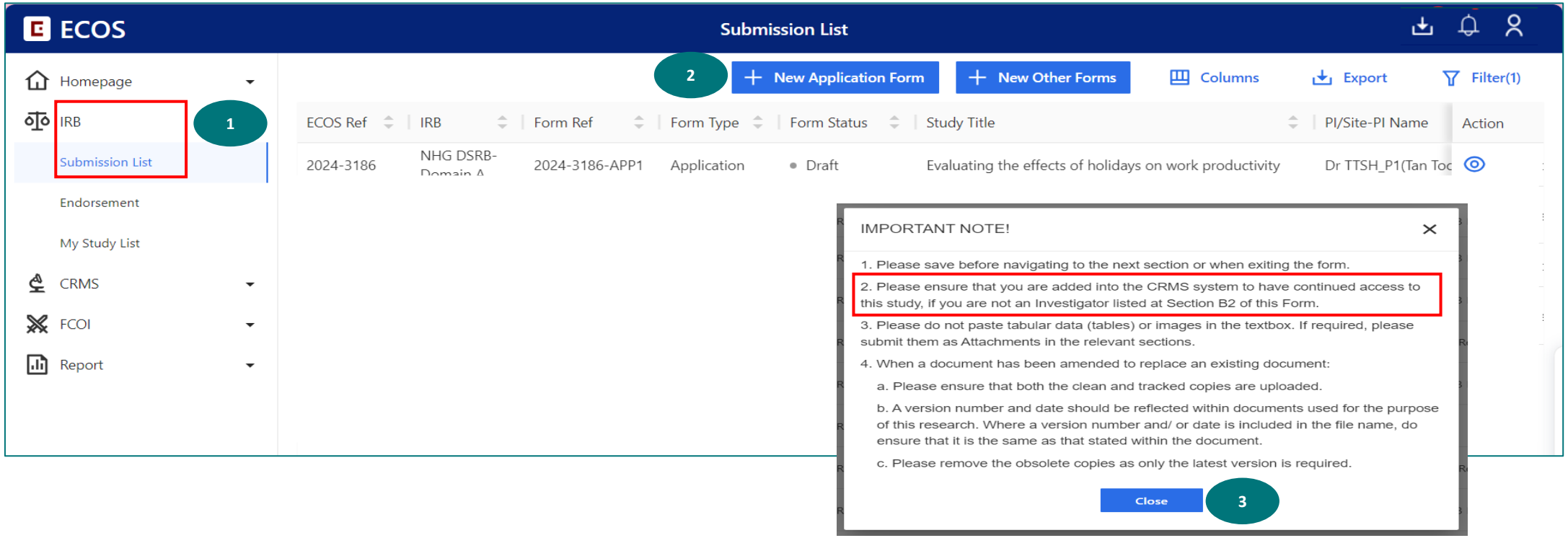
5) Refer to the CRMS section, slide 26 for more information.

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 IRB > **"Submission List"**
2) Create a **"New Application Form"**
3) Upon reading the **"Important Note!"**, **"Close"** the window to proceed with form creation.

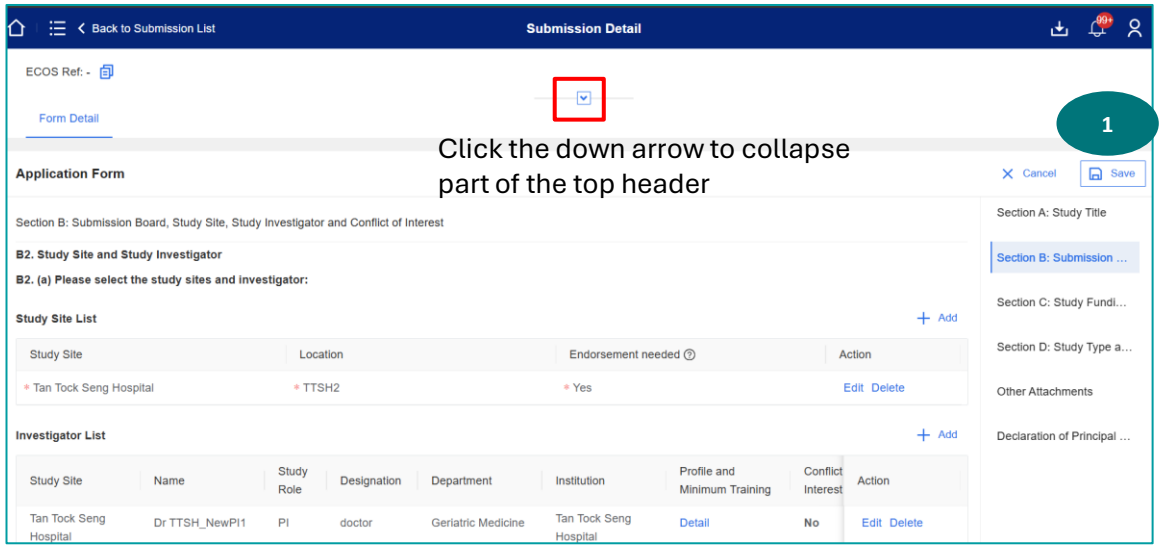


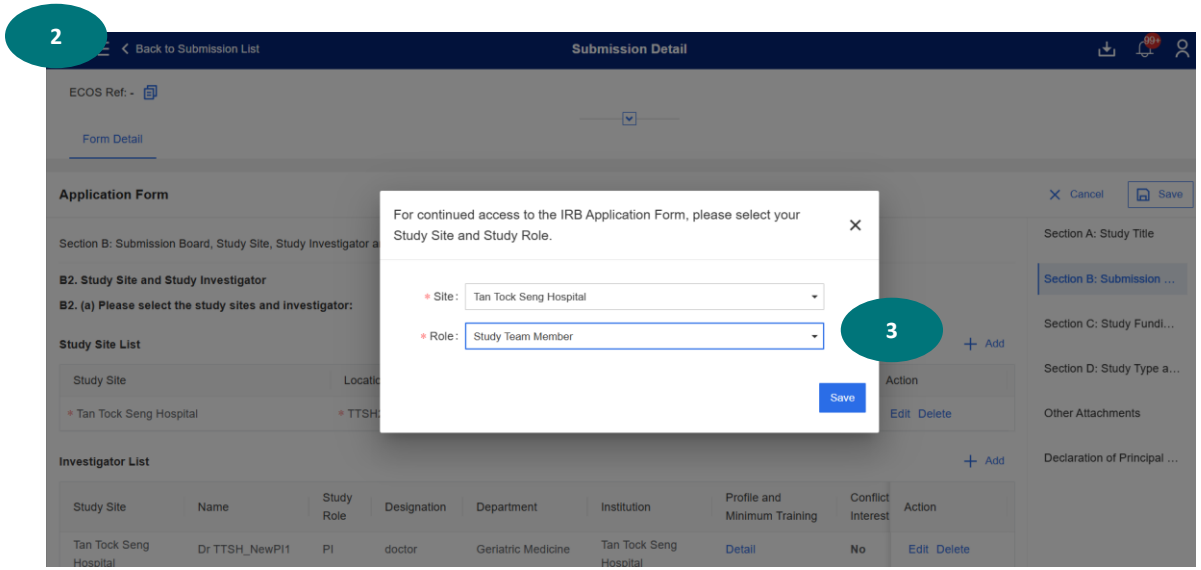
Note:
Complete **Sections A (Study Title)** and **B (Submission IRB and Board)** and save to generate a new ECOS reference number for your study

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)





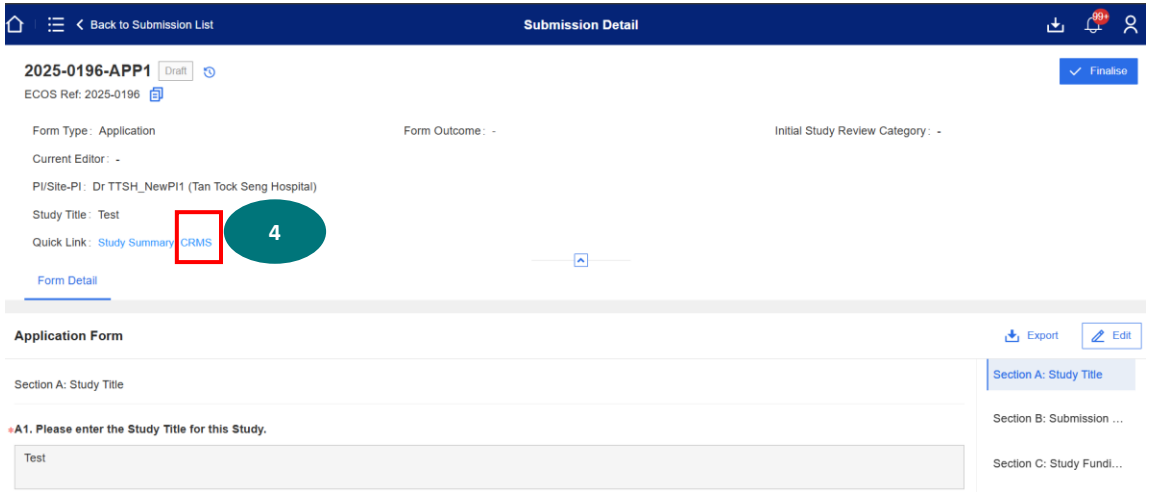
1) At the first save of the IRB APP Form, the system will recognise that (TTSH_STM1) is not part of the Investigator List in Section B2 (a).
2) This will trigger a prompt (next slide).

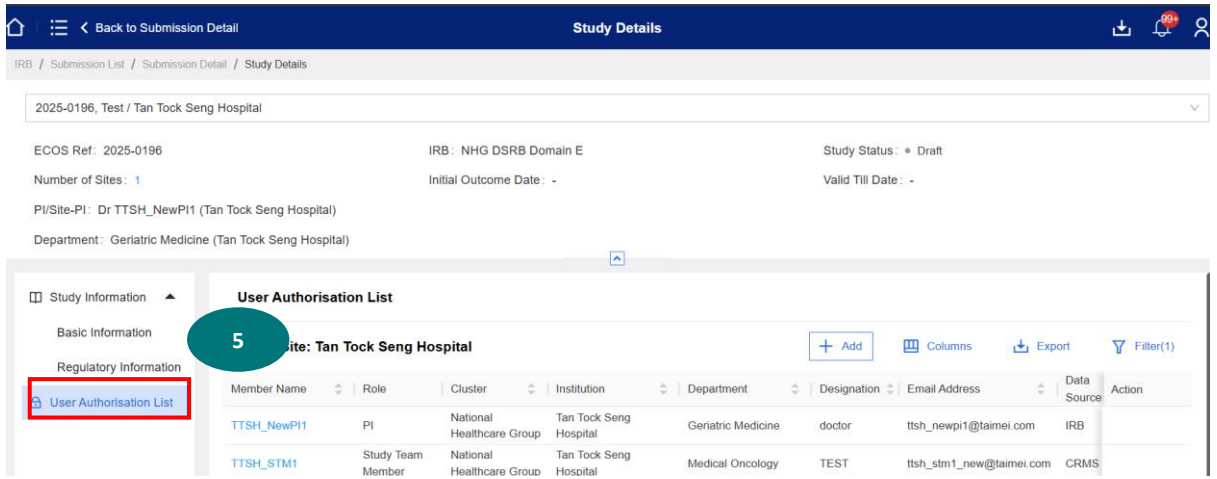
3) Only 3 options for Role available for user to select: Study Administrator, Study Sponsor or Study Team Member.
4) Select the correct Site and Role, then click Save.
5) The system will register this and add (TTSH_STM1) to the CRMS User Authorisation List (next slide).

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 (TTSH_STM1)





4) Click on CRMS

5) (TTSH_STM1)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

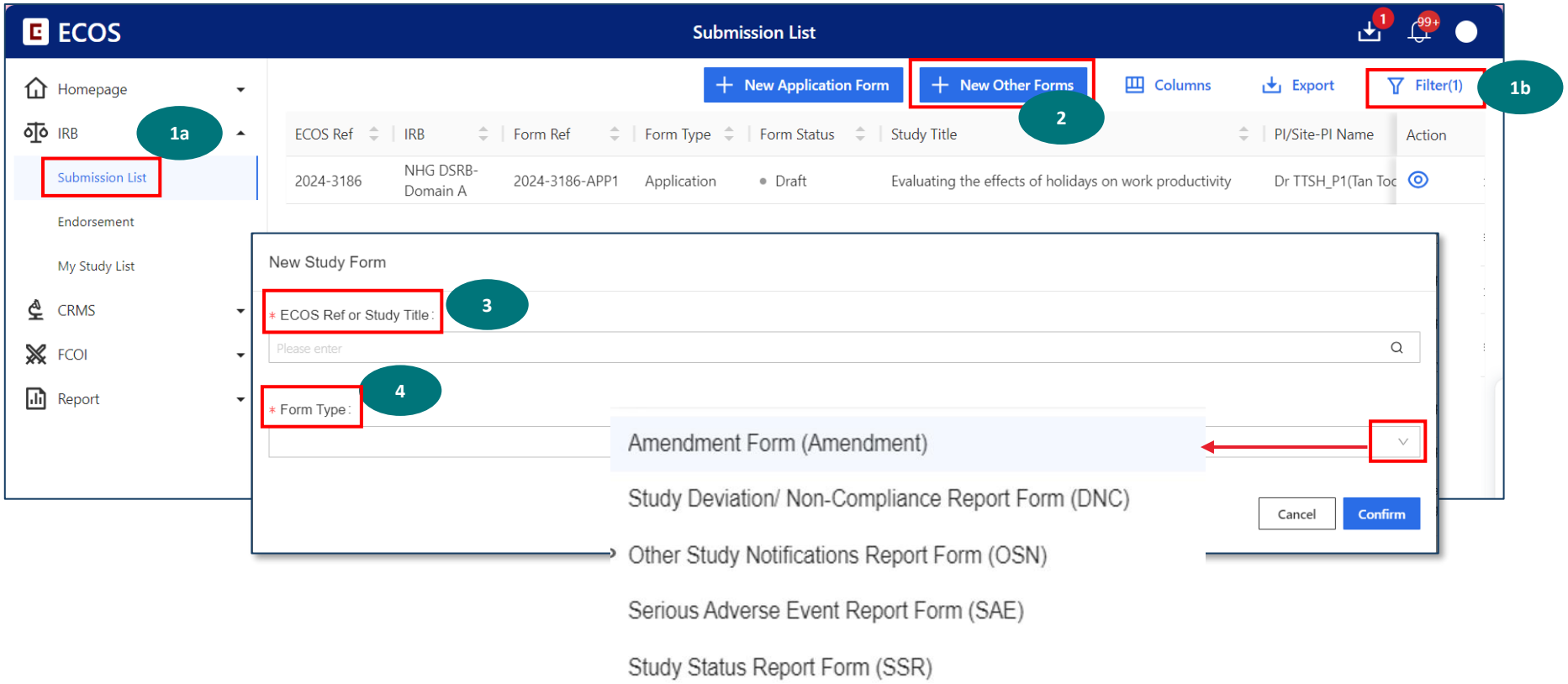
1(a) Click IRB > **"Submission List"**

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

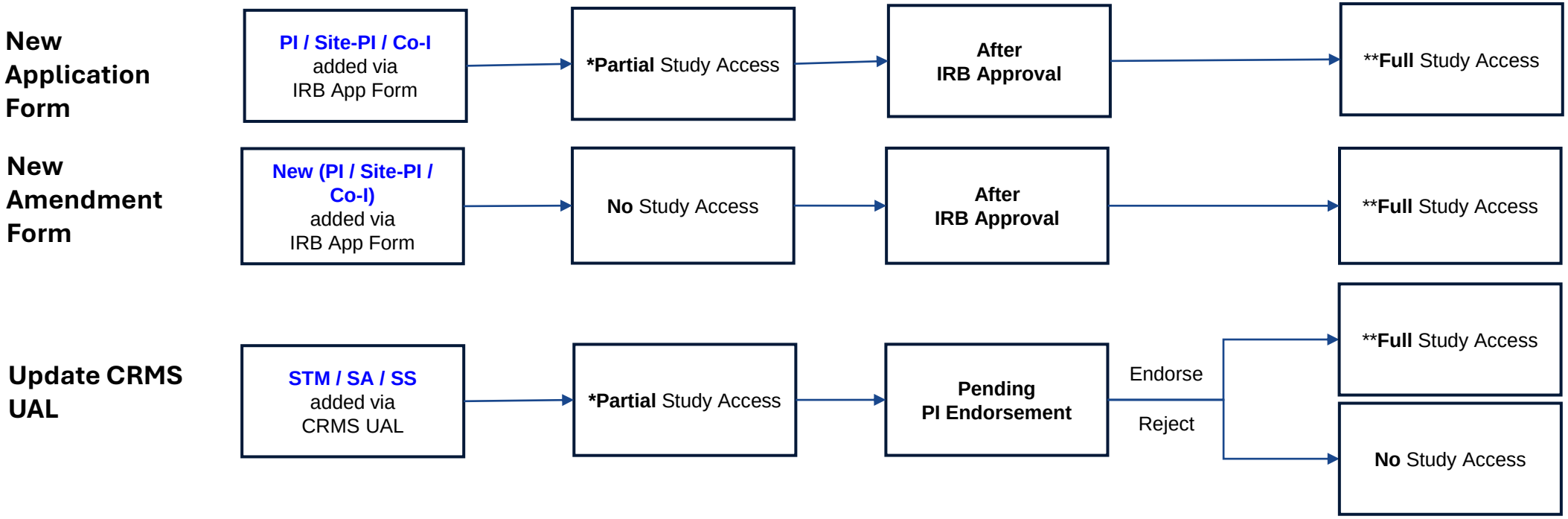


5 Clinical Research Management System (CRMS)

- How to Add Study Team Members
- Managing My Studies

Overview

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.“**

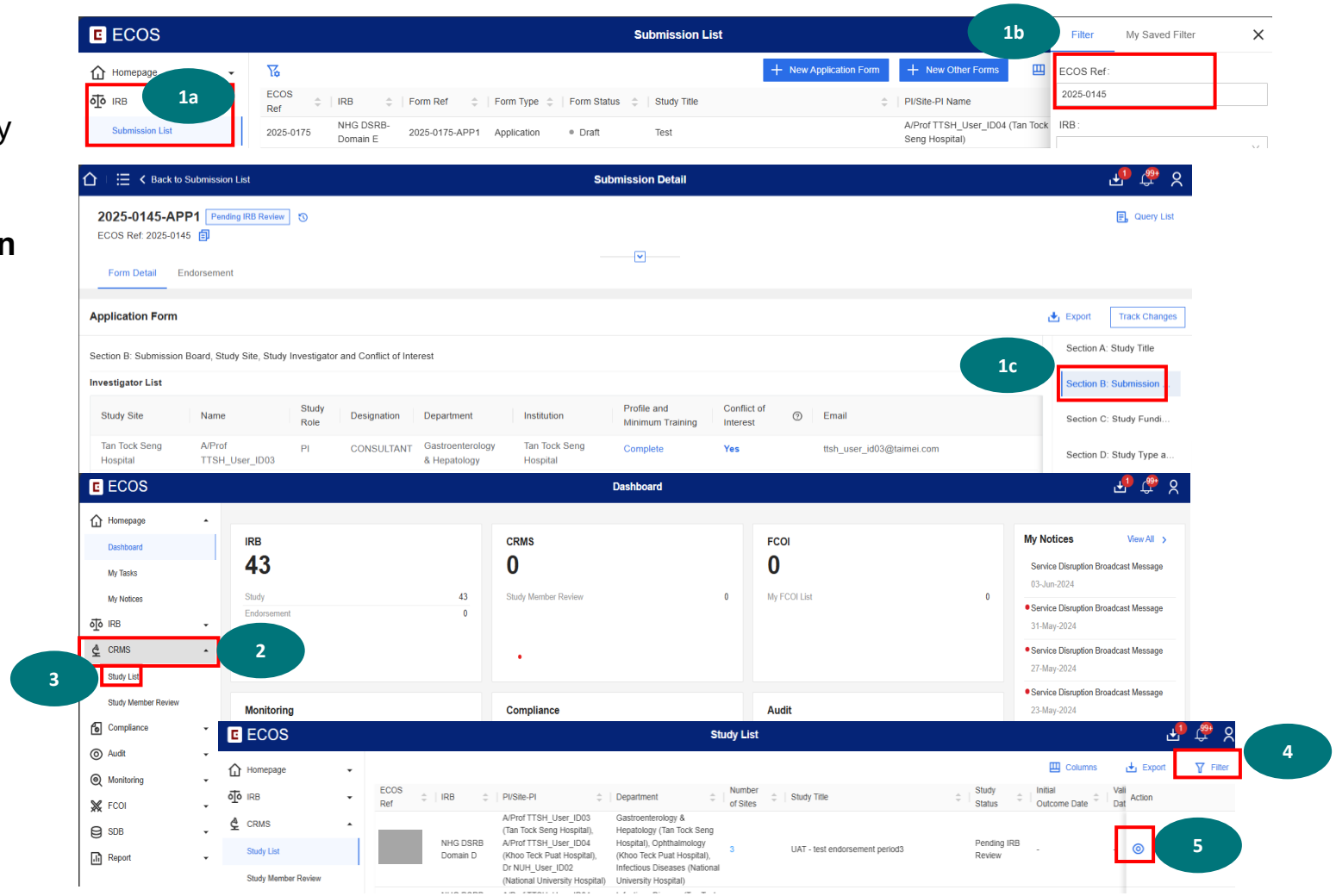
1(c) In the **“Application Form”** > **“Section B: Submission Board, Study Site, Study Investigator and Conflict of Interest”,** is updated in the “Dashboard” page

2) Go to CRMS , click **dropdown menu**

3) Click to view **“Study List”** available

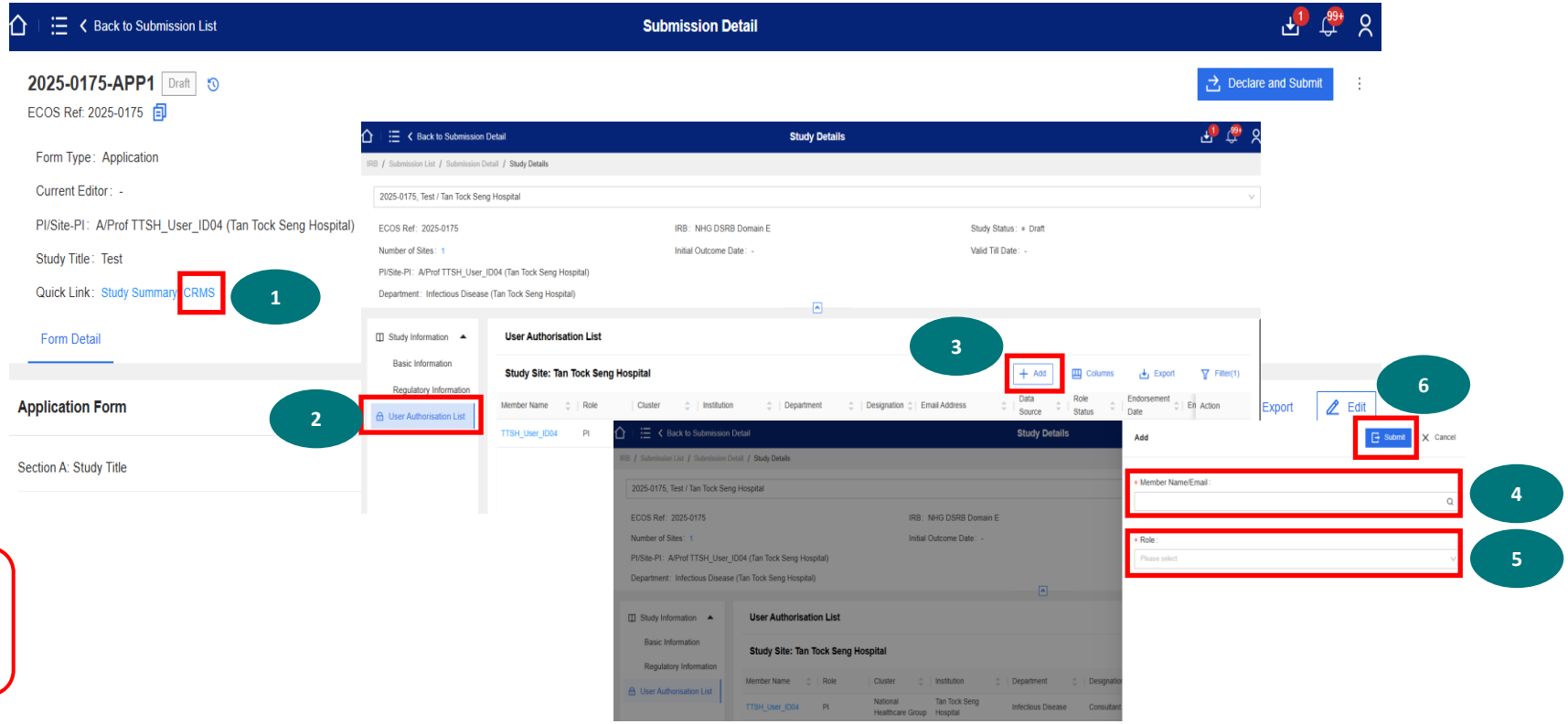
4) Click “**Filter”** for your study

5) Click **eye icon** to view your study



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

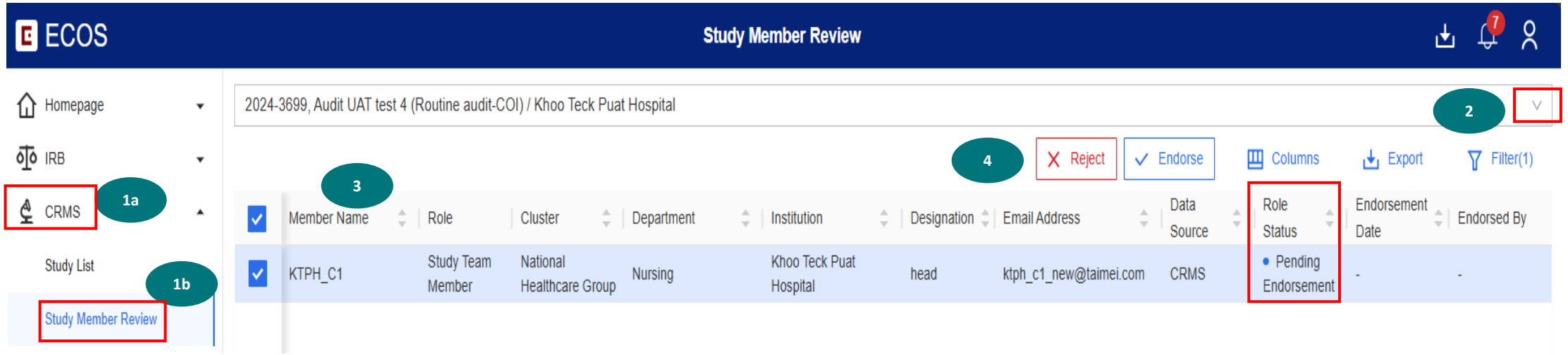
1) Click **“CRMS”**, on the **“Submission Detail”** page
2) Click **“User Authorization List”**
3) Click **“Add”**
4) Enter **“Member name/ email”** to search for correct user. (User must have a valid ECOS Account)
5) Select the relevant role: Study Administrator/Study Member/ Study Sponsor.
6) Click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



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?



1(a) Click CRMS

1(b) Go to **"Study Member Review"**

2) Click **dropdown arrow** 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.).

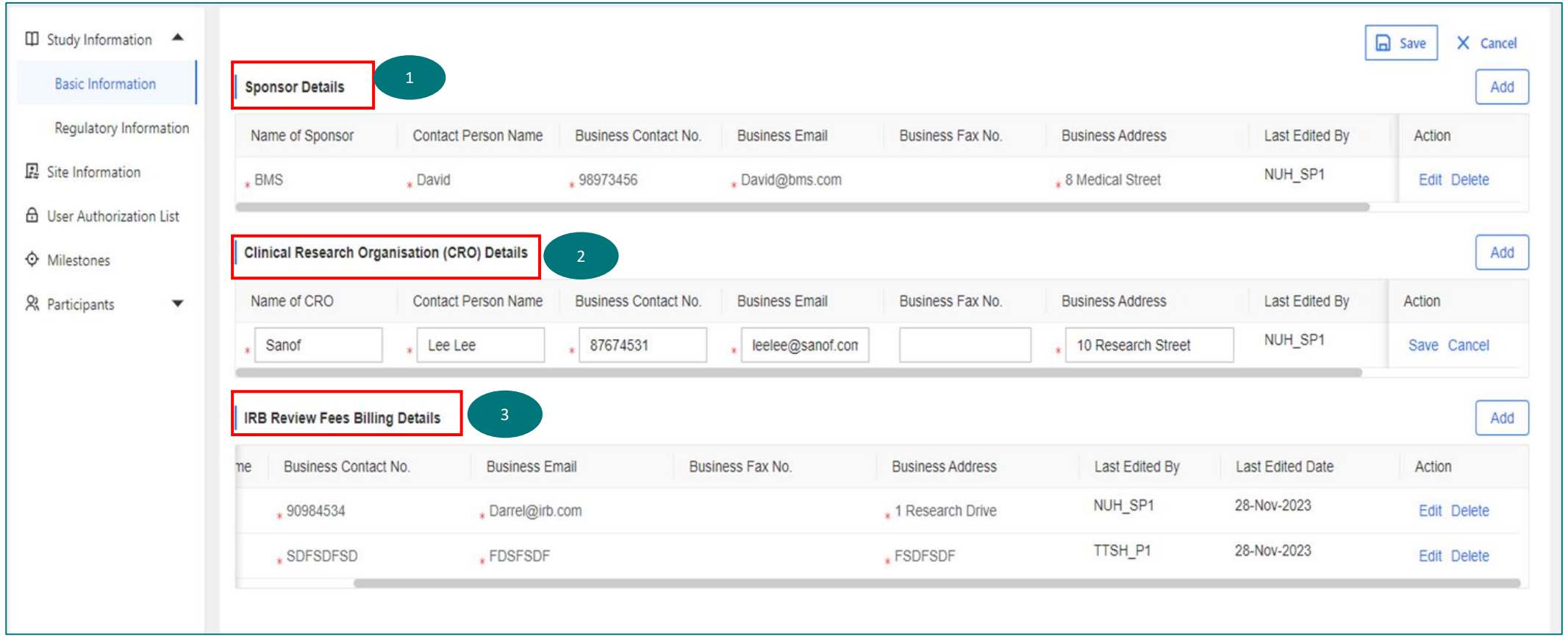
PI to **Deactivate**, if access was not appropriately given.

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

Managing IRB Submission for Sponsored Study

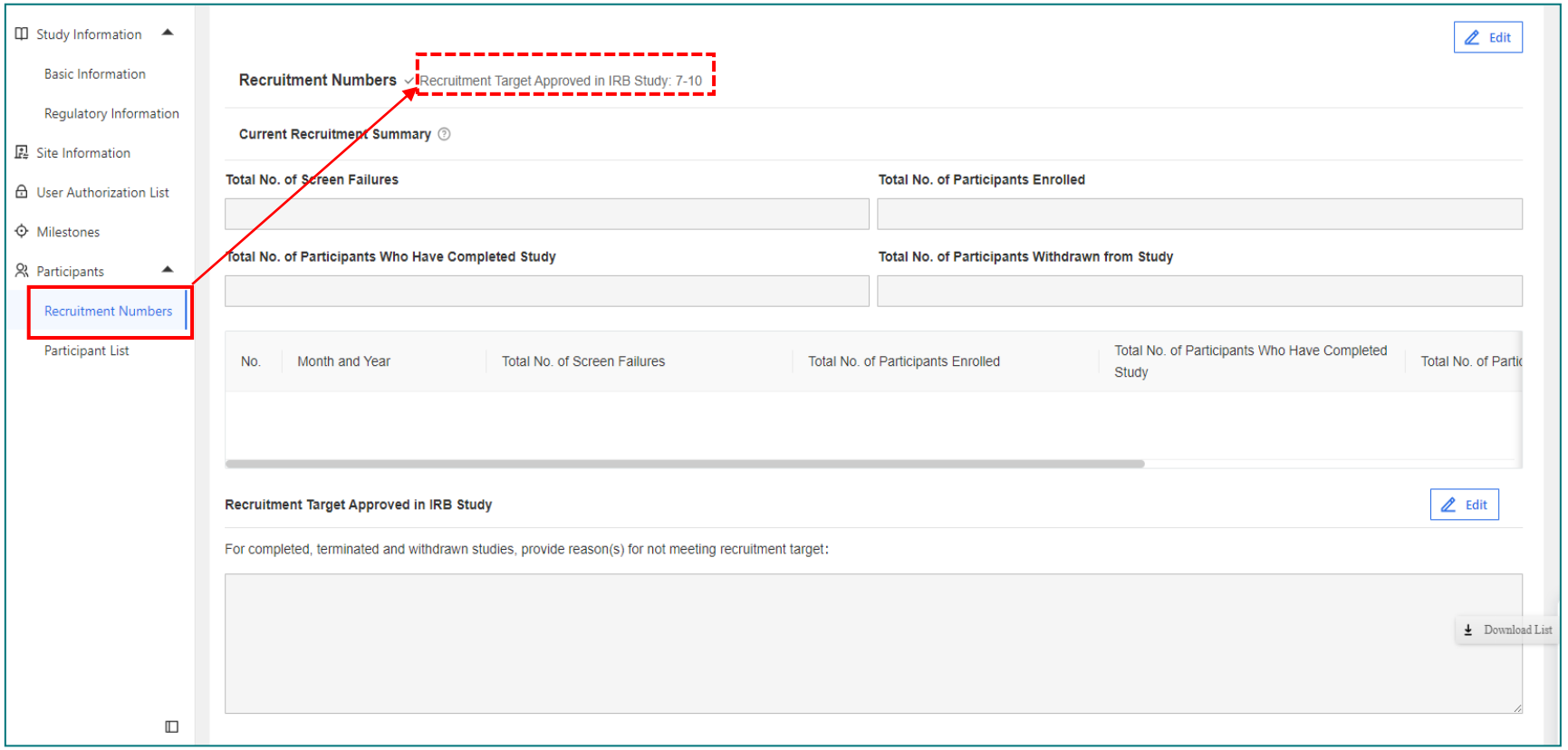
The following CRMS sections in **"Study Information > Basic Information"** will need to be completed to support the IRB application, if Section C1 (funding information) "Pharmaceutical / Industry Sponsored" was selected:

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



Managing Your Study Activities

You can now track and enter recruitment number

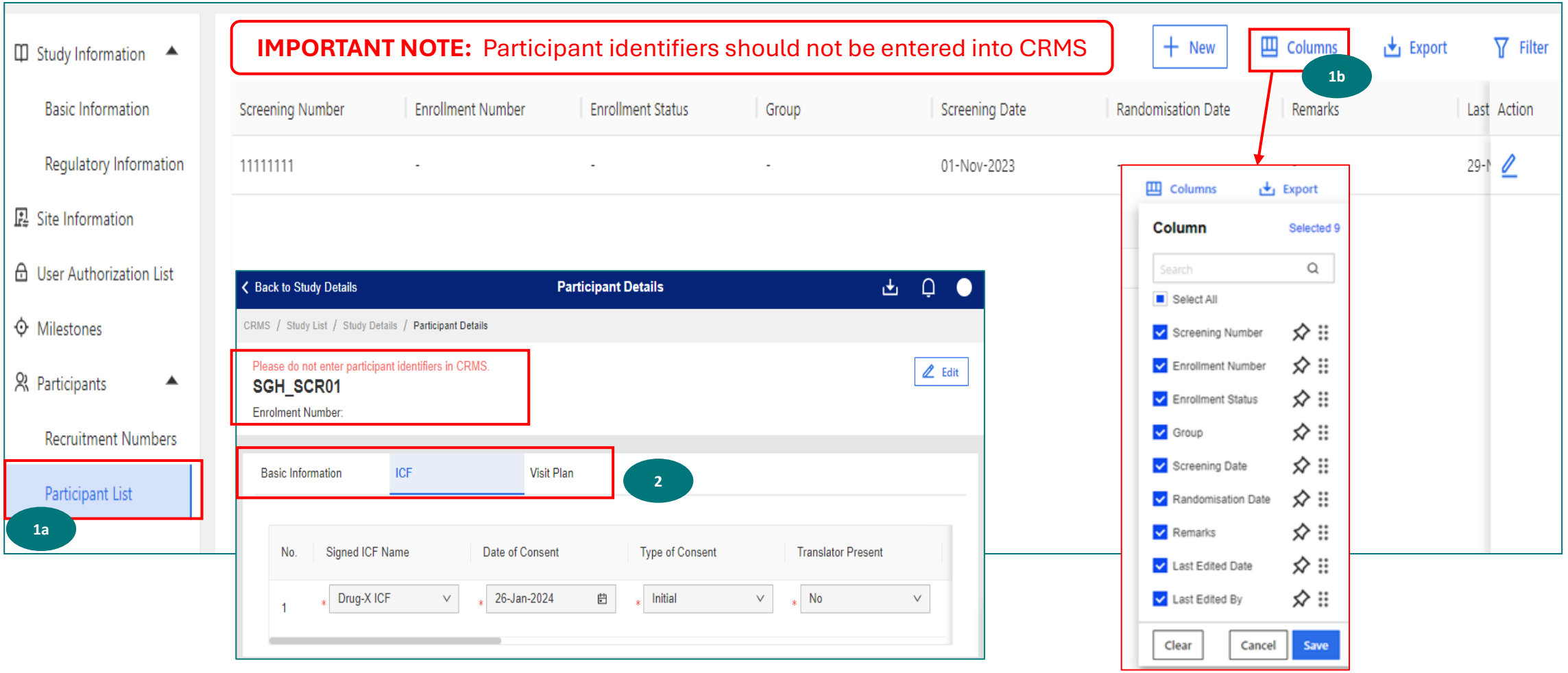


For step-by-step training on the navigation of Managing Your Research Activity, please refer to CRMS module guide in [ECOS User Guides]

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.



Resources

- ECOS Modules User Guides
- Useful Contacts

ECOS Modules User Guides

View the User Guides here.	
1. General ECOS Functionality & Overview	• Creating New User Accounts & General Overview • Minimum Training Certification submission • Financial Conflict of Interest (FCOI) submission
2. IRB Ethics Submissions	• Overview of IRB Ethics Submissions • IRB Ethics Application Form - List of Sections & Questions • Mastering IRB Submissions - Key points to note for effective response
3. Managing Your Research Activity	• Using the Clinical Research Management System (CRMS) to manage research projects and activities
4. Responding to the NHG Health Research Institution for Deviation/ Non-Compliance & Serious Adverse Events from HBR Studies	• How to manage DNC & SAE from HBR Studies
5. Standing Database (SDB) Submissions	• SDB User Module Guide - For Users - For Endorsers (RDOC/DR/IR) • SDB Forms Guidebook
6. For ECOS Institution & Department Representatives	For ECOS Users, who are appointed as Institution or Department Representatives (IR & DR), to locate and complete their Endorsement Tasks
7. Research Quality Programmes	• How to complete the Principal Investigator Self-Assessment Form (PISAF) & Study Closure Checklist (SCC) • ECOS Monitoring Module • 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.ITDHELP@nhghealth.com.sg
(1800-483-4357)

NUHS users
ITDHELP@nuhs.edu.sg
(1800-483-4357)

SingHealth users
it.helpdesk@singhealth.com.sg
(1800-666-7777)

For Non-PHI Users

https://for.sg/ecos-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