

Introduction to Ethics & Compliance Online System (ECOS)

Webinar
22 Apr 2024



Today's sharing includes

What is ECOS?

- What are the modules and when will they be available?



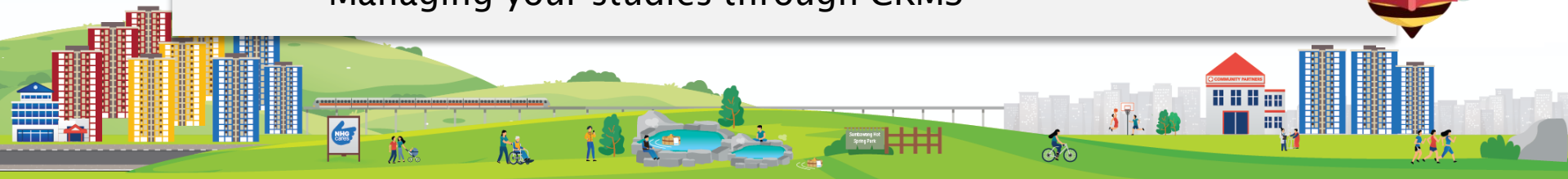
User Accounts

- How to login
- How to create an account (for new users)
- What to do on your 1st login



Navigating the System

- Managing your IRB submissions
- Managing your studies through CRMS



Why do we need to move to ECOS?

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

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



iPhone 5 in Slate

iPhone 5 (2012)
ROAM (2012)

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



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

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

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



ECOS – Ethics & Compliance Online System

- 1 Common IRB Form
- [New & Optional] Research Office Checker for institutions' pre-endorsement checks
- Minimum training validation
- No need to upload CVs

Institutional Review Board (IRB) & Minimum Training

Clinical Research Management System (CRMS)

**Phase 1
Launching May 2024**

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

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

Compliance & Reporting

Financial Conflict of Interest (FCOI)

FCOI declarations synced for DSRB applications

**Phase 2
Launching in Q3 2024**

Submit SDB applications

Standing Database (SDB)
(NHG & NUHS Only)

Quality Management

- Audit
- Monitoring

- ECOS is web-based! You may access it from your personal computers
- It is accessible to Public Healthcare Institutions (PHI) and non-PHIs users (e.g., Pharma Sponsors, Academic Institutions (i.e., NUS))



ECOS – Key Actions for Users

Soft Launch (Early-Mid May)

- Check & update migrated User Profiles
- Submit new studies, FCOI Declaration* and Min Training records
- Update CRMS
- Create new account (for users who are not migrated)

Launch (End May)

- Check studies that are migrated in Wave 1 (i.e., studies that have achieved an outcome as of 01 April 2024)
→ Submit all other forms

From July onwards

- Check studies that are migrated in Wave 2 (i.e., remaining studies that have achieved an outcome as of 01 June 2024)

*More information on the next declaration cycle will be provided at a later date



User profiles – Who will be migrated?

The following accounts* will be migrated from ROAM to ECOS

1. **PI, Site-PI or Co-I in an Active Study**
2. **ROAM Key Appointment Holder** (e.g., DR, IR, DSRB Chairpersons/ Members)

[Reference: ECOS Launch Frequently Asked Questions (FAQ) 1st published: FAQ #1, 27 Nov 23, Refreshed: FAQ #4, 19 Jan 24, FAQ #6, 28 Feb 24]

All other accounts will not be migrated to ECOS

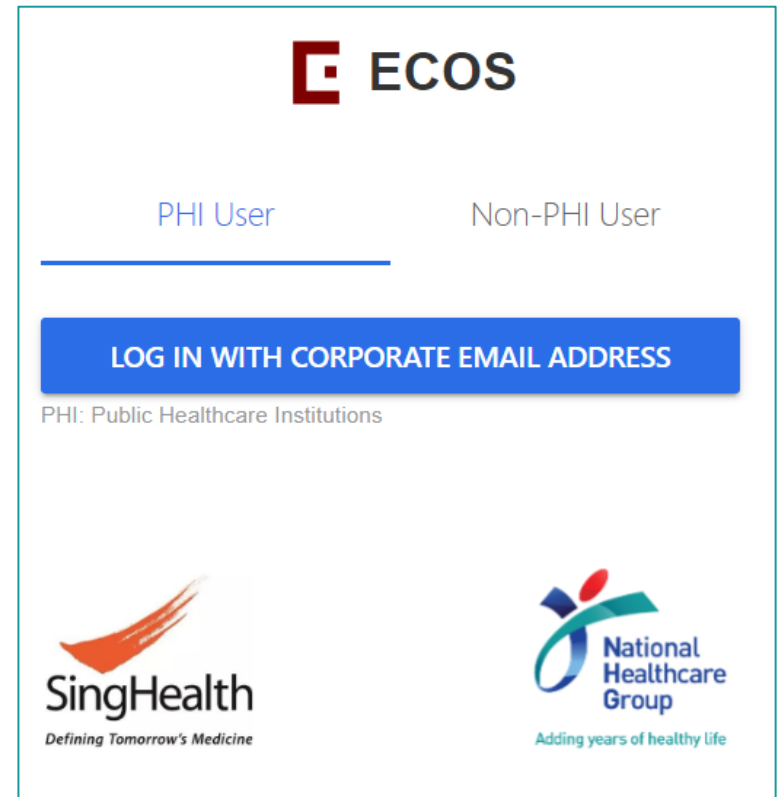
- You will need to create your profile in ECOS when it is launched

**This only applied to profiles that are valid and complete.*

- *Minimum Training Completion Records (i.e. CITI, FCOI, GCP) uploaded before 01 March 2024 will be migrated together with the profiles.*

Public Healthcare Institutions (PHI) Users – Logging In

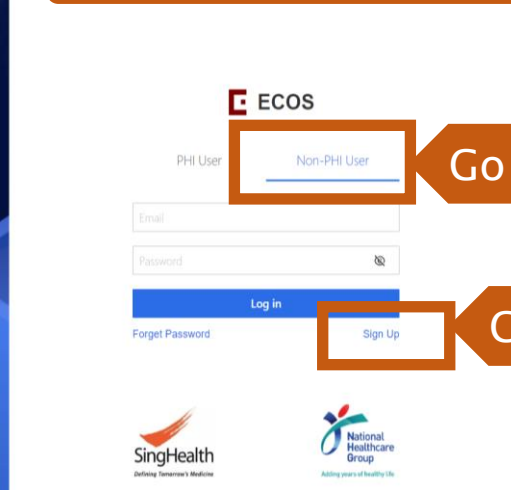
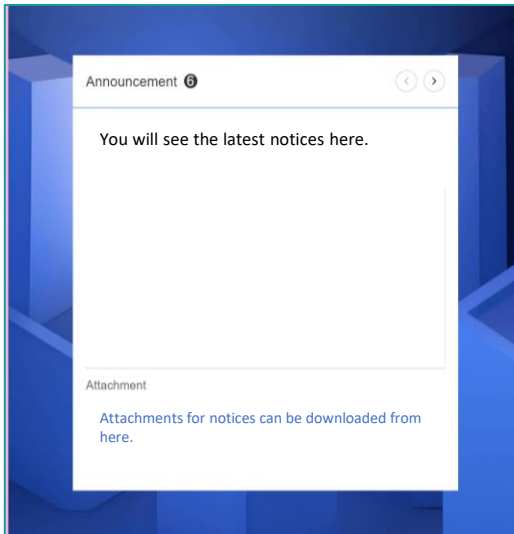
- Login via your corporate email address (M365) & Password
 - ECOS account will be automatically generated for users with corporate email accounts (M365)
 - Two factor authentication (2FA) via Microsoft Authenticator will be required



- These include users from NHG, SingHealth, NUHS, MOH, MOHH, AIC
- All other users should log in using the “Non-PHI Users” tab

Non-PHI Users – Creating a new account (1)

Non-PHIs users (e.g., Pharma Sponsors, Academic Institutions (i.e., NUS))



ECOS

PHI User Non-PHI User

Email

Password

Log in

Forget Password Sign Up

SingHealth
Delivering Tomorrow's Medicine

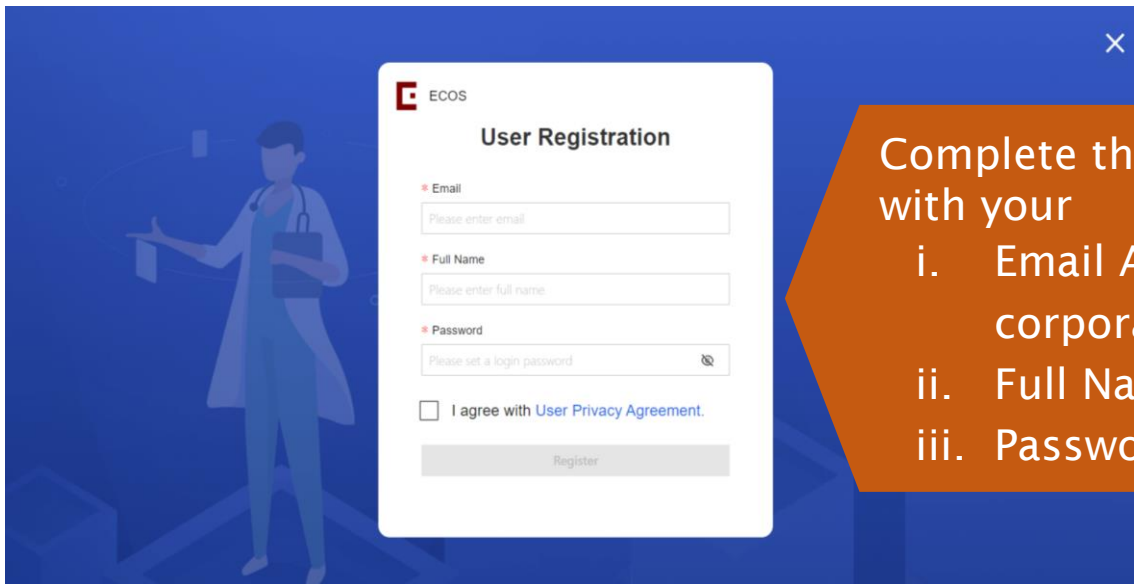
National Healthcare Group
Adding years of healthy life

Go to the “Non-PHI User” tab

1

Click on “Sign Up”

2



ECOS

User Registration

* Email

* Full Name

* Password

I agree with [User Privacy Agreement](#).

Register

Complete the registration form with your

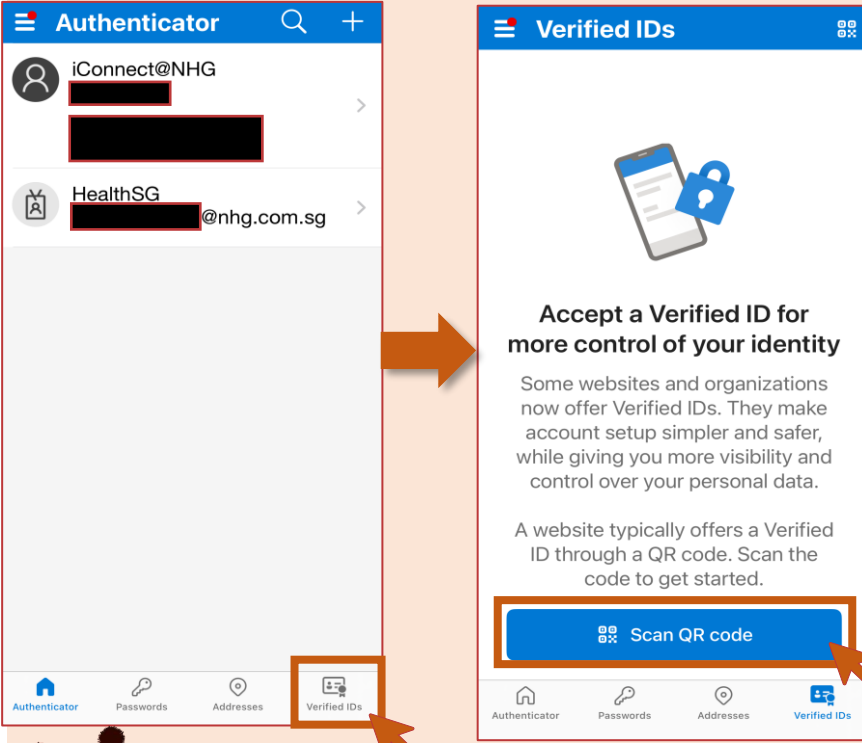
- i. Email Address (preferably corporate)
- ii. Full Name
- iii. Password

3

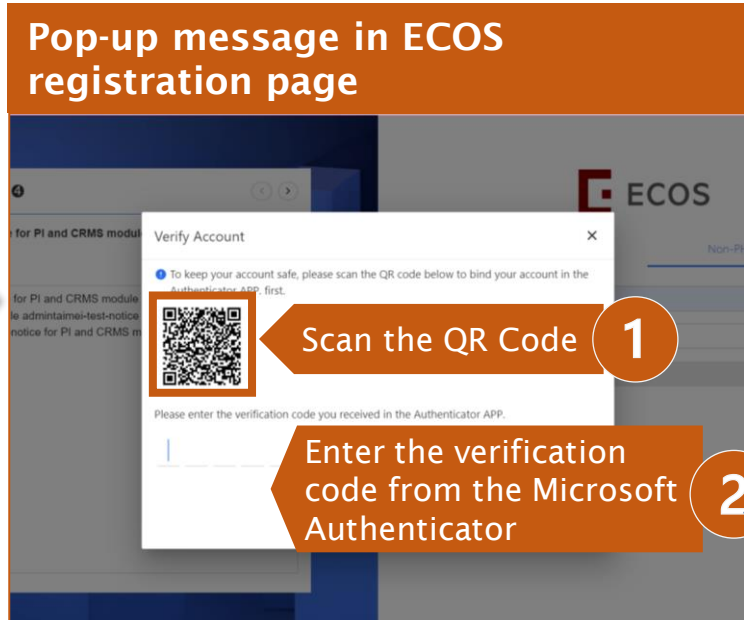
First-Time ECOS Users – Pairing of Microsoft Authenticator

If you already have the Microsoft Authenticator, you will need to pair it to this account for the first time.

In Microsoft Authenticator



The image shows two screenshots from the Microsoft Authenticator app. The left screenshot shows the main interface with two accounts: 'iConnect@NHG' and 'HealthSG @nhg.com.sg'. The right screenshot shows the 'Verified IDs' screen with the heading 'Accept a Verified ID for more control of your identity'. Below the heading is explanatory text and a 'Scan QR code' button. A red box highlights the 'Verified IDs' icon in the bottom navigation bar of the first screenshot and the 'Scan QR code' button in the second screenshot. Arrows indicate the flow from the account list to the Verified IDs screen.



The image shows a screenshot of the ECOS registration page with a 'Verify Account' pop-up message. The pop-up contains a QR code and a text input field for a verification code. Two numbered callouts are present: '1 Scan the QR Code' pointing to the QR code, and '2 Enter the verification code from the Microsoft Authenticator' pointing to the text input field.



If you do not already have the Microsoft Authenticator, you will be prompted to download it from Apple Store or Playstore and create an account.

What to do on your 1st login (New Users) (1)

TTSH_STM2 Salutation: Mr Indicate your salutation **1**

Profile and Minimum Training Information Study Information

Current Appointment Details Provide 'Primary Appointment' **2** + Add

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

Academic Qualifications Provide at least 1 'Academic Qualification' **3** + Add

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

Employment History + Add

Institution/Organisation	Department	Designation	From	To	Action
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Registration Type + Add
For medical practitioners / dental practitioners / pharmacists, please provide your registration information

Registration Council	Type of Current Registration	Date of Registration	Action
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Users with migrated profiles should verify the information and update (if necessary).

What to do on your 1st login (New Users) (2)

Profile and Minimum Training Information







Upload your Minimum Training Certificates

4

Minimum Training Certificates ⓘ

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

PI/ Site PI and Co-I must submit their training completion report (CITI, FCOI) and certificates (GCP &/or HBR – refer to your cluster’s minimum training requirements)

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		D  
SingH...	HBRA Essentials	HBR CERTIFI...	01-Dec-2022	-	Permanent	● Completed		 
SingH...	CITI Biomed	CITI CERTIFI...	01-Nov-2021	-	Permanent	● Completed		  E

- A Display the type of studies that you can conduct.
- B Click to add new training certification achieved.
- C Check Document Review Status for latest update.
Type of Document Review Status: Draft, Pending Review, Completed and Rejected
- D Click to edit and update the training certification.
- E View the history of the submission of the training certification.



- You will not be allowed to submit new applications and study amendments until your relevant training reports and certificates have been uploaded and verified.
- Users with migrated profiles should verify the information and update (if necessary).

NHG Minimum Training Requirement

The Minimum Training Secretariat will review your training certification and update the type of studies that you can conduct based on the following criteria:



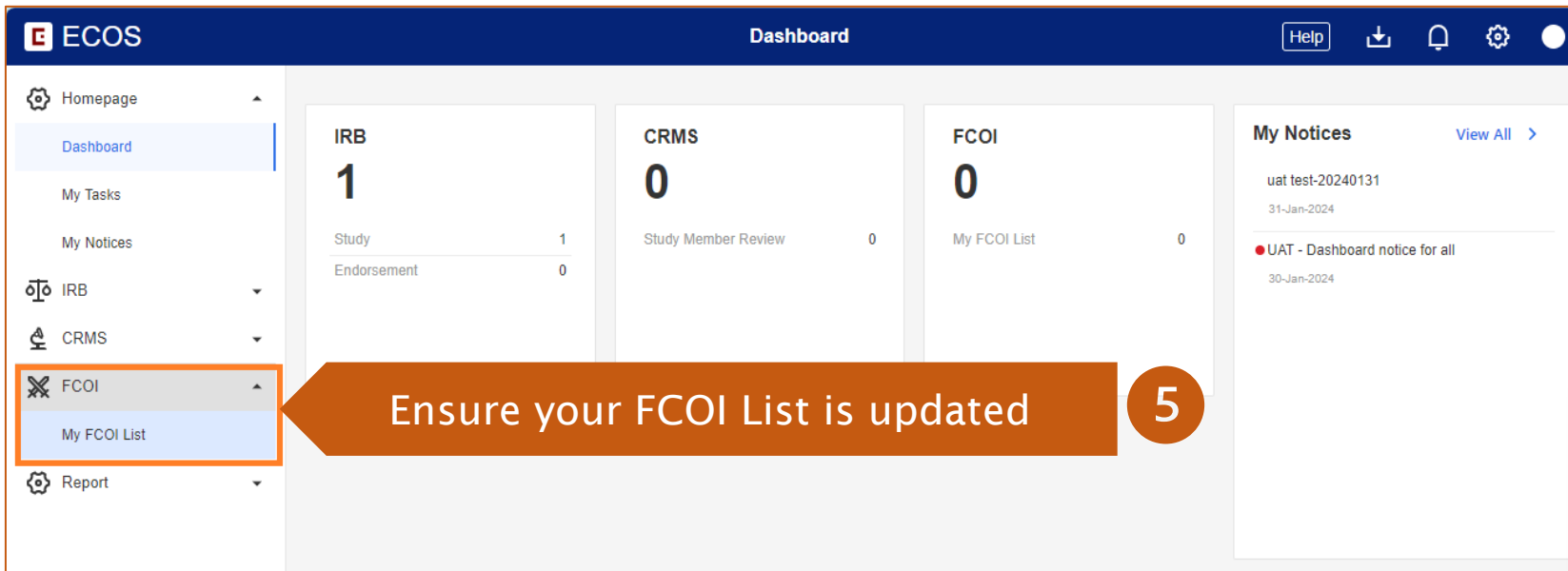
		Training Certification			
		<i>Please refer to NHG Research website for details of the minimum training requirements.</i>			
		NHG Collaborative Institutional Training Initiative (CITI)*	NHG CITI Financial Conflict of Interest (FCOI)	Human Biomedical Research (HBR) Minimum Training	Good Clinical Practice (GCP)
Type of Studies That You can Conduct	Non-HBR*	✓	✓		
	HBR	✓	✓	✓	
	Clinical Trials		✓		✓

* For population health research, CITI should contain Social, Behavioural and Educational (SBE) modules.



What to do on your 1st login (New Users) (3)

On your Dashboard



ECOS Dashboard

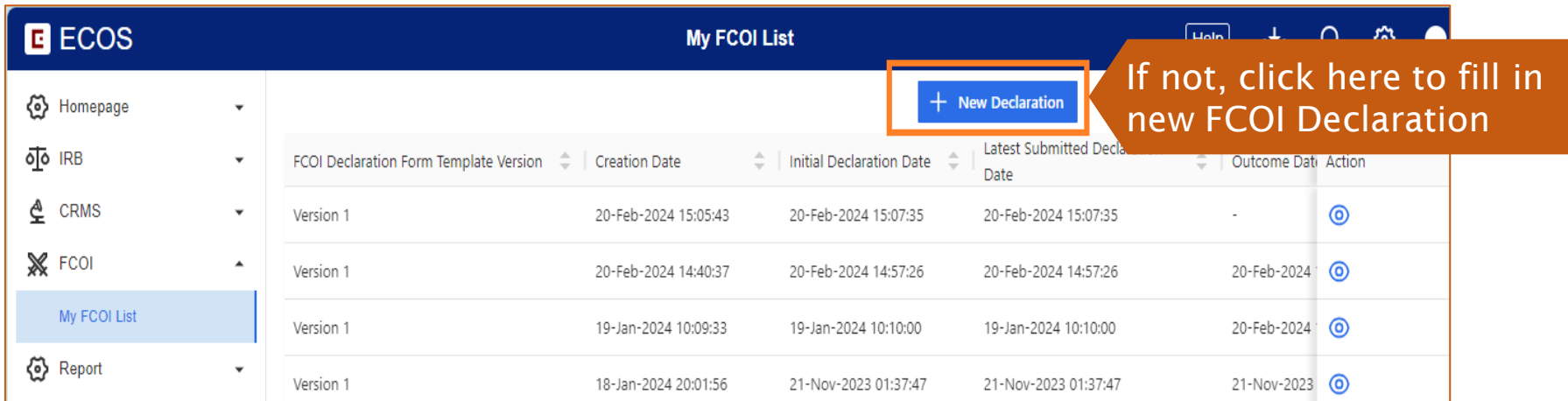
IRB: 1 Study, 0 Endorsement

CRMS: 0 Study Member Review

FCOI: 0 My FCOI List

My Notices: uat test-20240131 (31-Jan-2024), UAT - Dashboard notice for all (30-Jan-2024)

Ensure your FCOI List is updated 5



ECOS My FCOI List

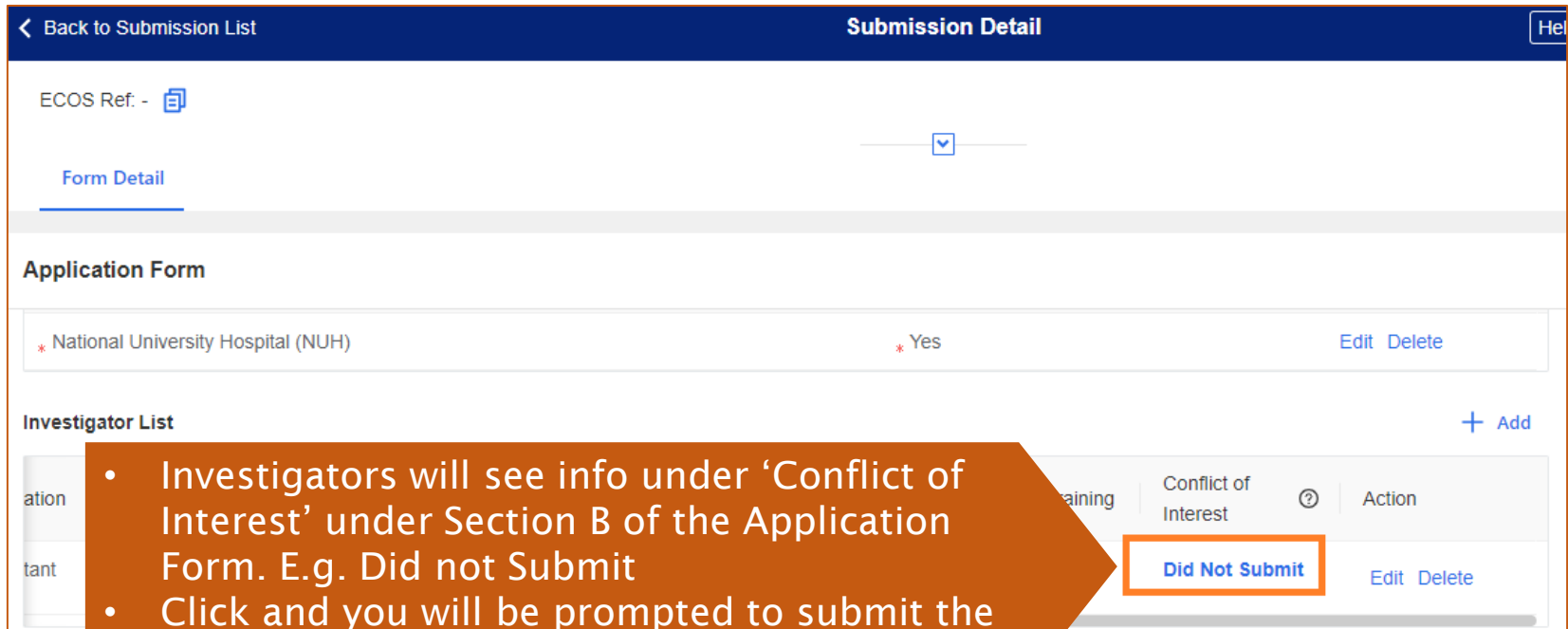
+ New Declaration

FCOI Declaration Form Template Version	Creation Date	Initial Declaration Date	Latest Submitted Declaration Date	Outcome Date	Action
Version 1	20-Feb-2024 15:05:43	20-Feb-2024 15:07:35	20-Feb-2024 15:07:35	-	🕒
Version 1	20-Feb-2024 14:40:37	20-Feb-2024 14:57:26	20-Feb-2024 14:57:26	20-Feb-2024	🕒
Version 1	19-Jan-2024 10:09:33	19-Jan-2024 10:10:00	19-Jan-2024 10:10:00	20-Feb-2024	🕒
Version 1	18-Jan-2024 20:01:56	21-Nov-2023 01:37:47	21-Nov-2023 01:37:47	21-Nov-2023	🕒


If not, click here to fill in new FCOI Declaration

What to do on your 1st login (New Users) (4)

On the IRB Application Form



Submission Detail

ECOS Ref: - 

Form Detail

Application Form

* National University Hospital (NUH)	* Yes	Edit Delete
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Investigator List + Add

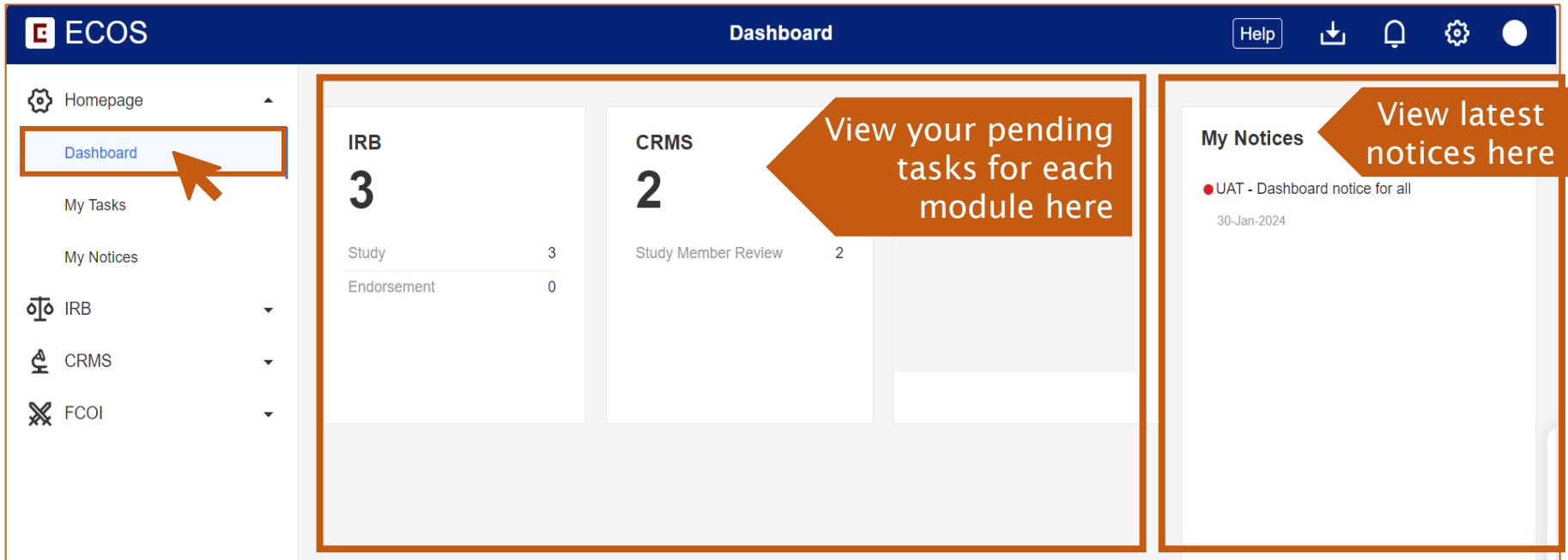
Investigator	Training	Conflict of Interest	Action
Investigator		Conflict of Interest	Did Not Submit Edit Delete

- Investigators will see info under 'Conflict of Interest' under Section B of the Application Form. E.g. Did not Submit
- Click and you will be prompted to submit the FCOI declaration in the FCOI module.

You will not be allowed to submit new applications and study amendments until your FCOI Declaration has been completed.



Navigating the system – Dashboard



The screenshot shows the ECOS Dashboard interface. The top navigation bar includes the ECOS logo, the word "Dashboard", and utility icons for Help, download, notifications, settings, and a user profile. A left-hand navigation menu lists "Homepage", "Dashboard" (highlighted with a blue bar and an orange arrow), "My Tasks", "My Notices", "IRB", "CRMS", and "FCOI". The main content area is divided into three sections: "IRB" with a large number "3" and a table showing "Study" (3) and "Endorsement" (0); "CRMS" with a large number "2" and a table showing "Study Member Review" (2); and "My Notices" with a large number "1" and a list item "UAT - Dashboard notice for all" dated "30-Jan-2024". Two orange callout boxes with arrows point to the IRB and CRMS sections, containing the text "View your pending tasks for each module here". Another orange callout box with an arrow points to the "My Notices" section, containing the text "View latest notices here".

Module	Count
IRB	3
CRMS	2

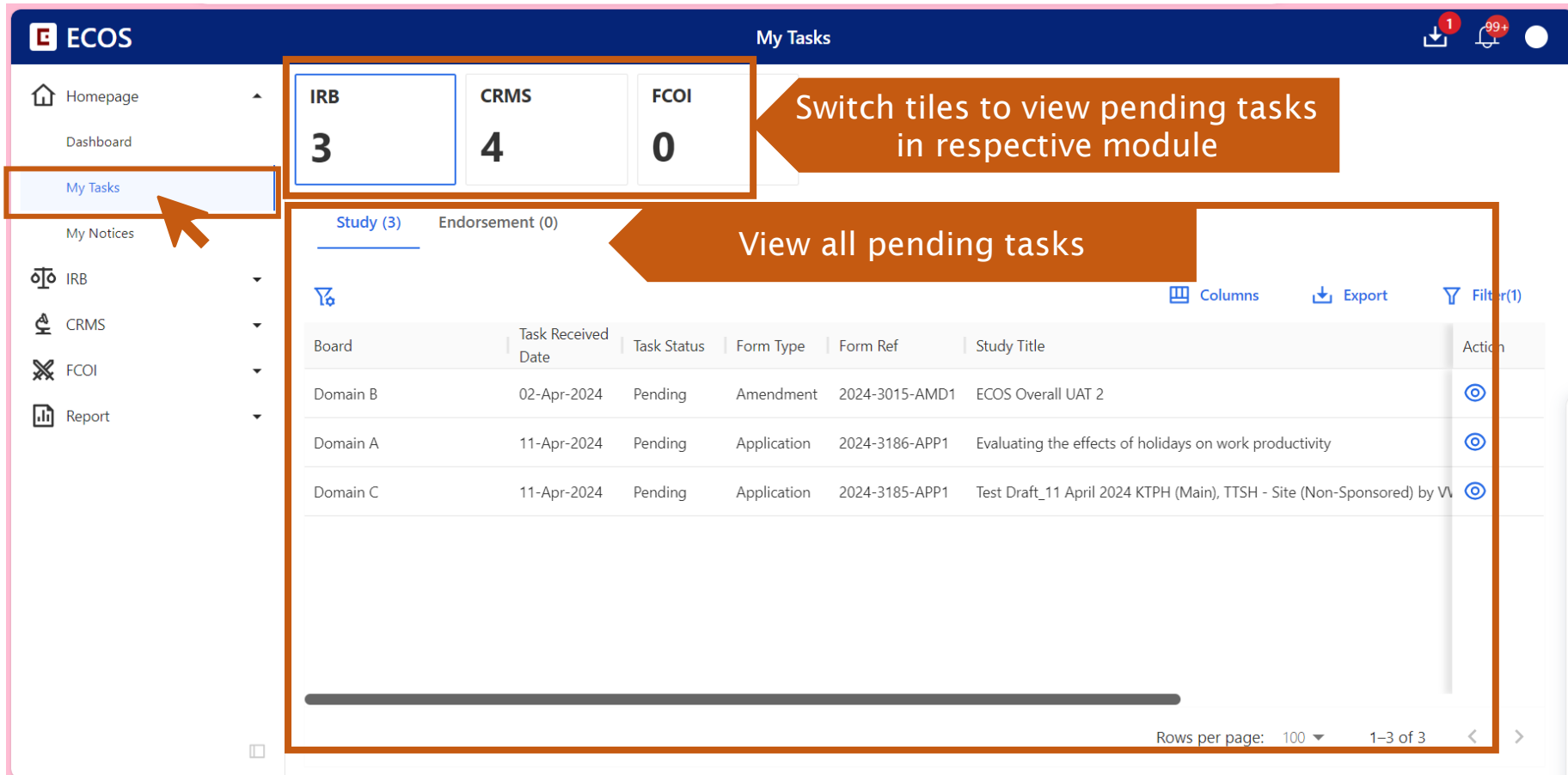
Task	Count
Study	3
Endorsement	0

Notice	Date
UAT - Dashboard notice for all	30-Jan-2024



The timeout for ECOS is 30 minutes.
(Editing the form does not count as being active)

Navigating the system – My Tasks



ECOS My Tasks

IRB 3 CRMS 4 FCOI 0

Switch tiles to view pending tasks in respective module

My Tasks

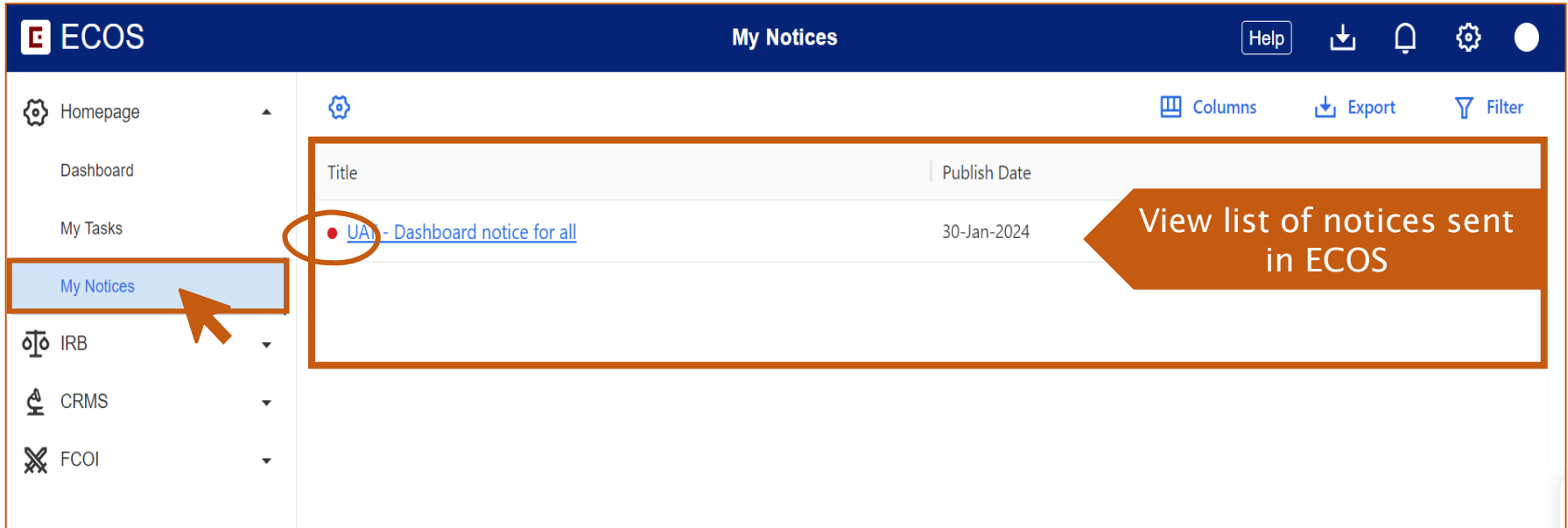
Study (3) Endorsement (0)

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 W	

Rows per page: 100 1-3 of 3

Navigating the system – My Notices



Title	Publish Date
• UA - Dashboard notice for all	30-Jan-2024



The '●' indicates that the notice has not been read.

Navigating the system – System notifications

ECOS Study List

Click to view System Notifications

ECOS Ref	IRB	PI/Site-PI	Department	Number of Sites	Study Title
2024-3189	NHG DSRB Domain B	Dr TTSH_P1 (Tan Tock Seng Hospital)	Medical Oncology(Tan Tock Seng Hospital)	1	Test study - TTSH single site sponsored for approval
2024-3186	NHG DSRB Domain A	Dr TTSH_P1 (Tan Tock Seng Hospital)	Medical Oncology(Tan Tock Seng Hospital)	1	Evaluating the effects of holidays on work productivity
2024-3185	NHG DSRB Domain C	A/Prof KTPH_SP1 (Khoo Teck Puat Hospital), Dr TTSH_P1 (Tan Tock Seng Hospital)	General Surgery(Khoo Teck Puat Hospital), Medical Oncology(Tan Tock Seng Hospital)	2	Test Draft_11 April 2024 KTPH (Main), TTSH (Non-Sponsored) by VW
2024-3083	NHG DSRB Domain B	Dr TTSH_P1 (Tan Tock Seng Hospital)	Department of Medical Oncology(Tan Tock Seng Hospital)	1	Please enter the Study Title for this Study
2024-3015	NHG DSRB Domain B	A/Prof KTPH_SP1 (Khoo Teck Puat Hospital), Dr TTSH_P1 (Tan Tock Seng Hospital)	Department of General Surgery(Khoo Teck Puat Hospital),Medical Oncology(Tan Tock Seng Hospital)	2	ECOS Overall UAT 2

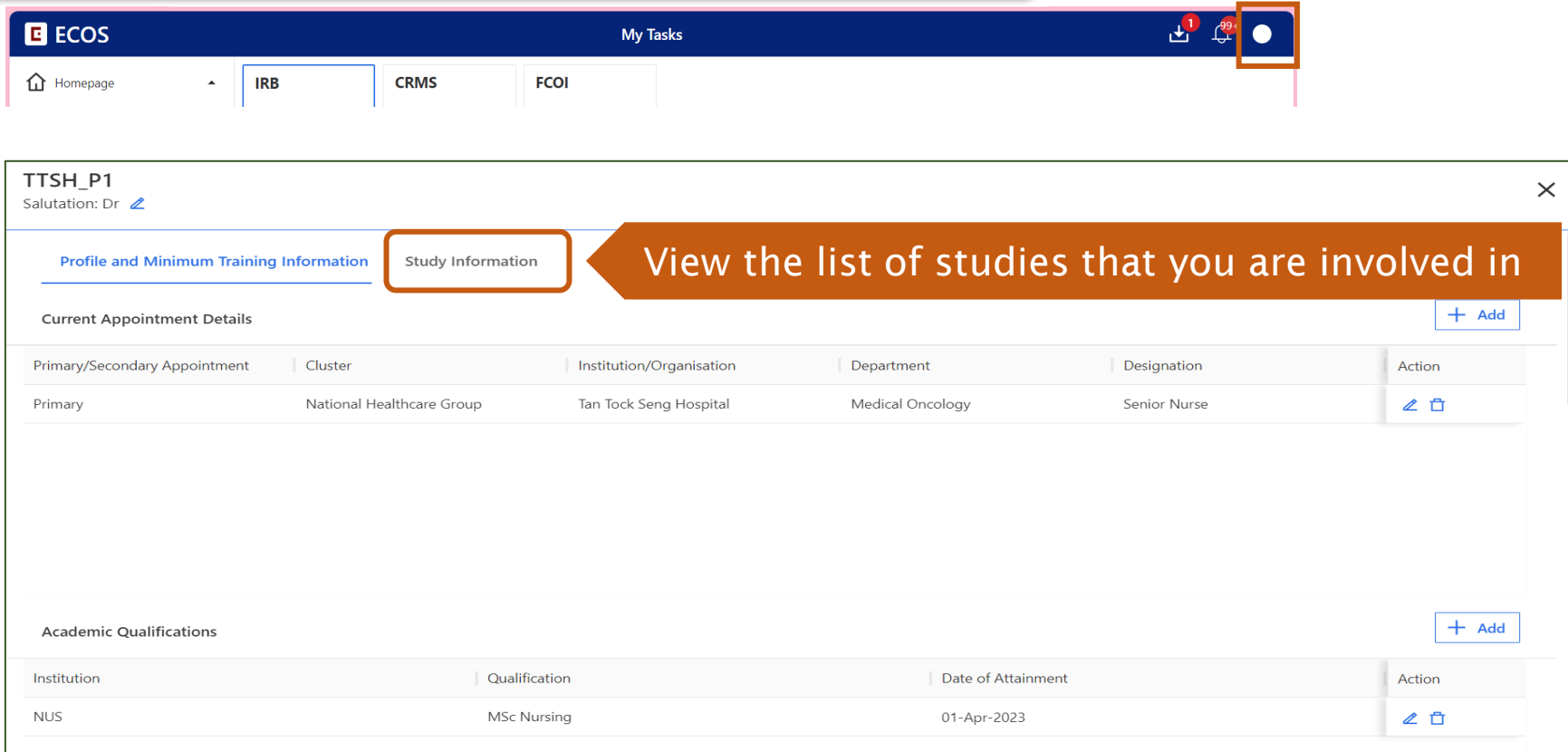
Pending Review Tasks Unfinished Tasks Unfinished Quality Co



A pop-up window will appear when the “🔔” is clicked

Where to find your studies? (1)

Under your “User Profile” page



The screenshot shows the ECOS user interface. At the top, there is a navigation bar with 'ECOS' and 'My Tasks'. Below this is a menu with 'Homepage', 'IRB', 'CRMS', and 'FCOI'. The 'IRB' tab is selected. On the right side of the navigation bar, there are notification icons and a profile picture icon, which is highlighted with a red box. Below the navigation bar, the user profile page for 'TTSH_P1' is displayed. The profile includes a salutation 'Dr' and two tabs: 'Profile and Minimum Training Information' and 'Study Information'. The 'Study Information' tab is highlighted with a red box. A red arrow points from this tab to a red callout box containing the text 'View the list of studies that you are involved in'. Below the tabs, there are sections for 'Current Appointment Details' and 'Academic Qualifications', each with an '+ Add' button. The 'Current Appointment Details' section contains a table with the following data:

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

The 'Academic Qualifications' section contains a table with the following data:

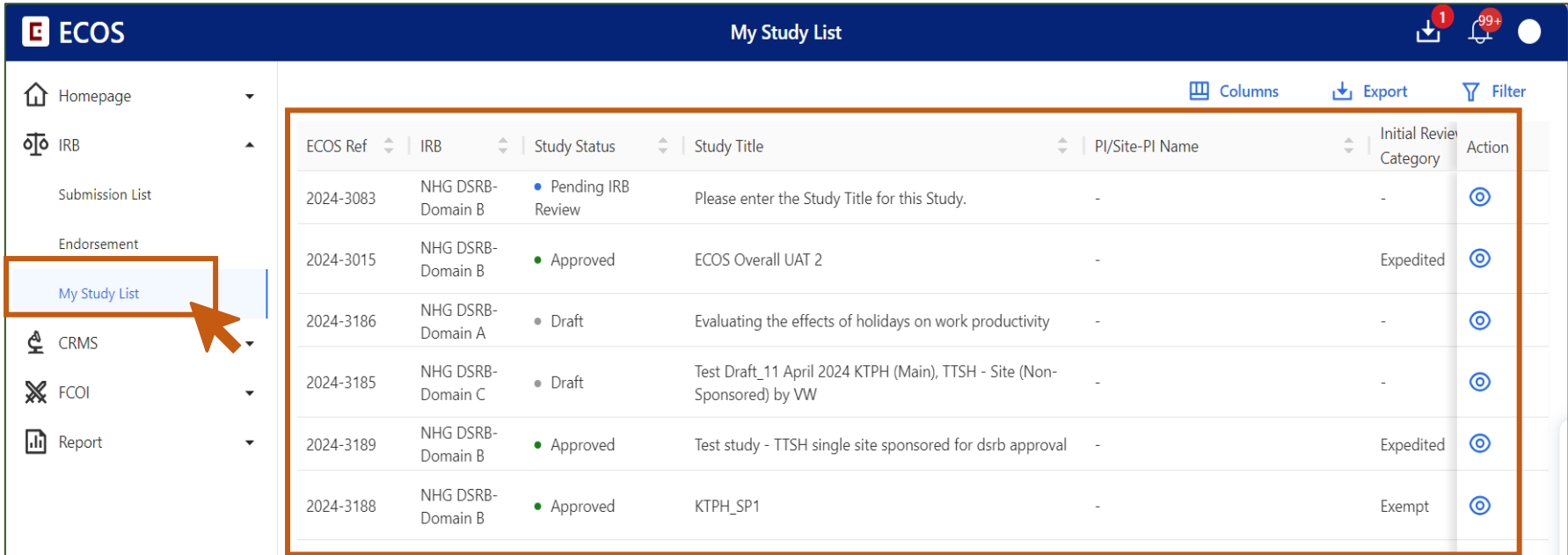
Institution	Qualification	Date of Attainment	Action
NUS	MSc Nursing	01-Apr-2023	Edit Delete

Your list of studies will only be available after the launch (end May 2024).



Where to find your studies? (2)

Under IRB Dashboard



ECOS My Study List

Columns Export Filter

ECOS Ref	IRB	Study Status	Study Title	PI/Site-PI Name	Initial Review Category	Action
2024-3083	NHG DSRB-Domain B	Pending IRB Review	Please enter the Study Title for this Study.	-	-	🔍
2024-3015	NHG DSRB-Domain B	Approved	ECOS Overall UAT 2	-	Expedited	🔍
2024-3186	NHG DSRB-Domain A	Draft	Evaluating the effects of holidays on work productivity	-	-	🔍
2024-3185	NHG DSRB-Domain C	Draft	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	-	Expedited	🔍
2024-3188	NHG DSRB-Domain B	Approved	KTPH_SP1	-	Exempt	🔍



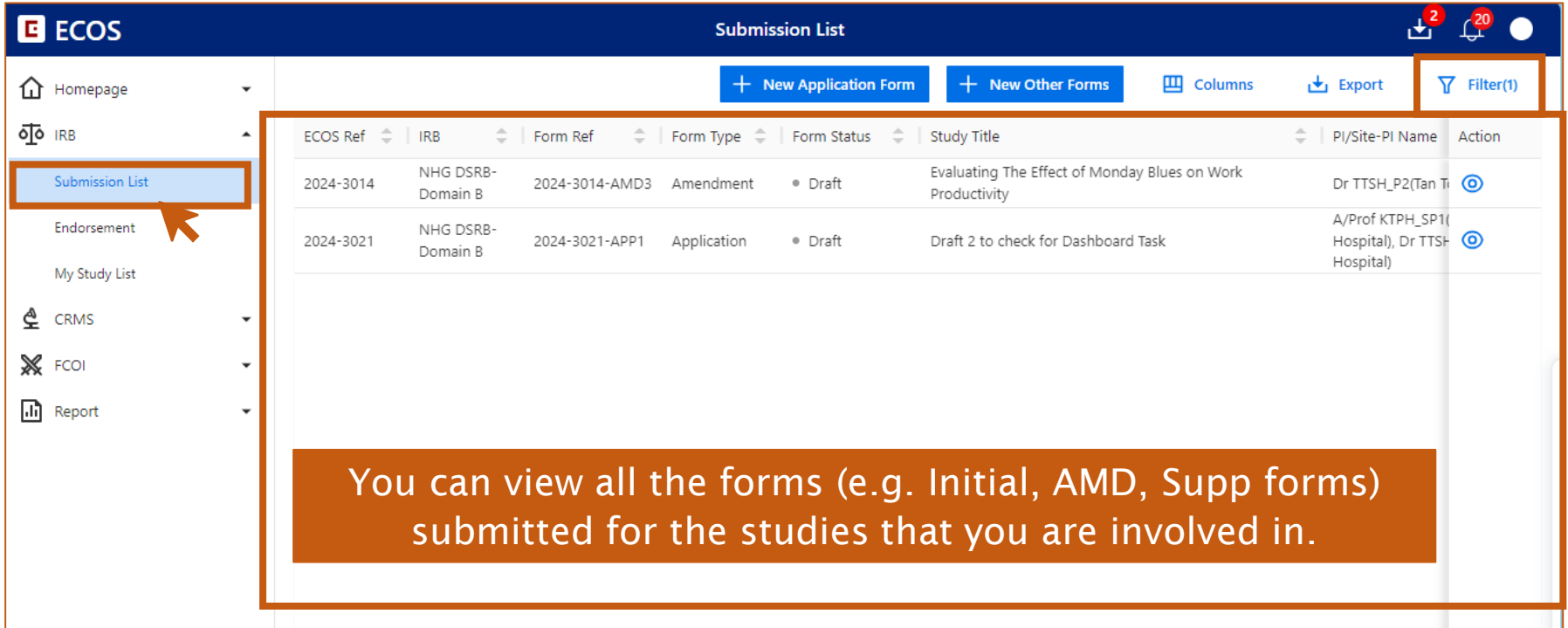
Your list of studies will only be available after the launch (end May 2024).

Managing your IRB Submissions

- Where to find your submissions and studies
- How to submit a new application/ other forms
- Where to find your study summary



IRB Dashboard – Submission List



ECOS Submission List

+ New Application Form + New Other Forms Columns Export Filter(1)

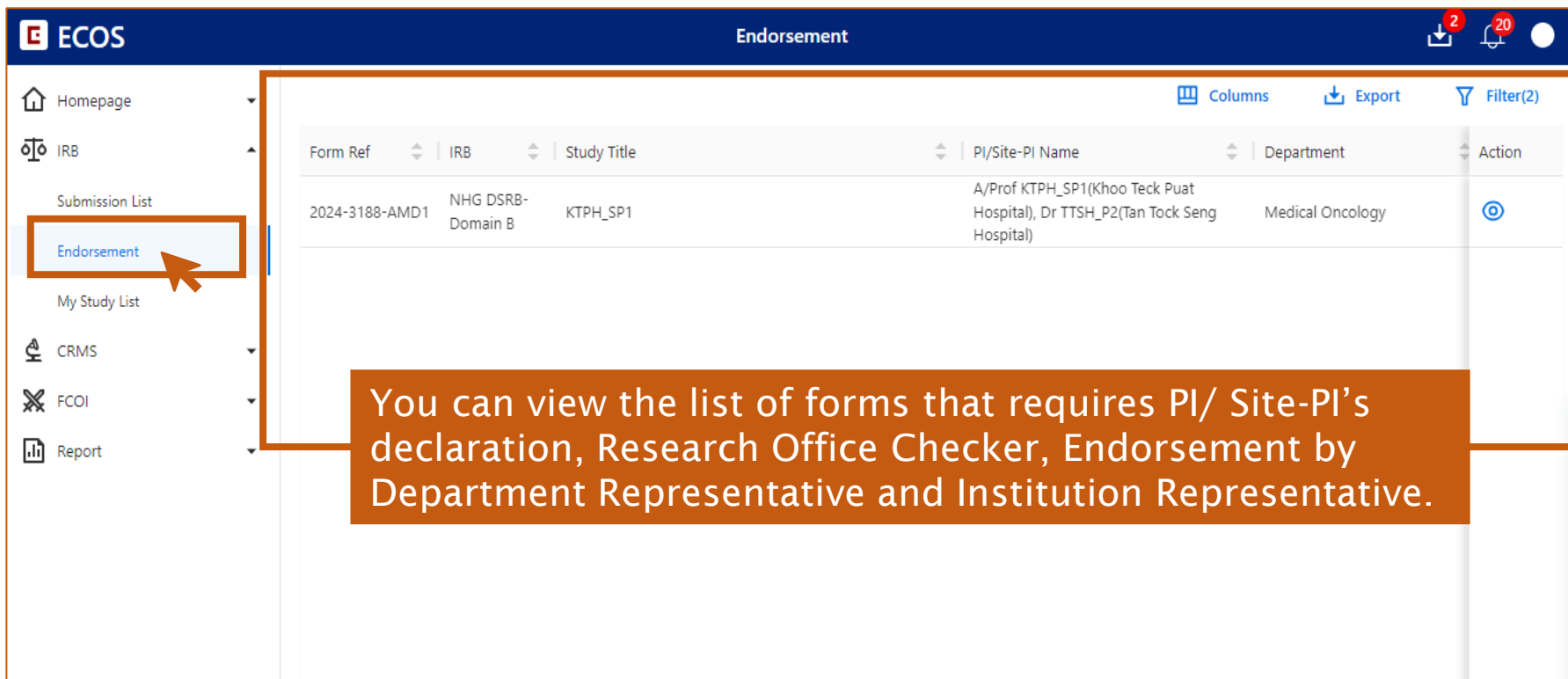
ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title	PI/Site-PI Name	Action
2024-3014	NHG DSRB-Domain B	2024-3014-AMD3	Amendment	Draft	Evaluating The Effect of Monday Blues on Work Productivity	Dr TTSH_P2(Tan T...	
2024-3021	NHG DSRB-Domain B	2024-3021-APP1	Application	Draft	Draft 2 to check for Dashboard Task	A/Prof KTPH_SP1(Hospital), Dr TTSH-Hospital)	

You can view all the forms (e.g. Initial, AMD, Supp forms) submitted for the studies that you are involved in.




- You should not see any forms on this page on your first login
- Use the filter function to search for forms with outstanding tasks

IRB Dashboard – Endorsement



The screenshot shows the ECOS Endorsement dashboard. The left sidebar contains navigation options: Homepage, IRB, Submission List, Endorsement (highlighted with a red box and an arrow), My Study List, CRMS, FCOI, and Report. The main content area displays a table of IRB forms with the following columns: Form Ref, IRB, Study Title, PI/Site-PI Name, Department, and Action. A red box highlights the 'Endorsement' menu item in the sidebar. A text box explains the purpose of the table.

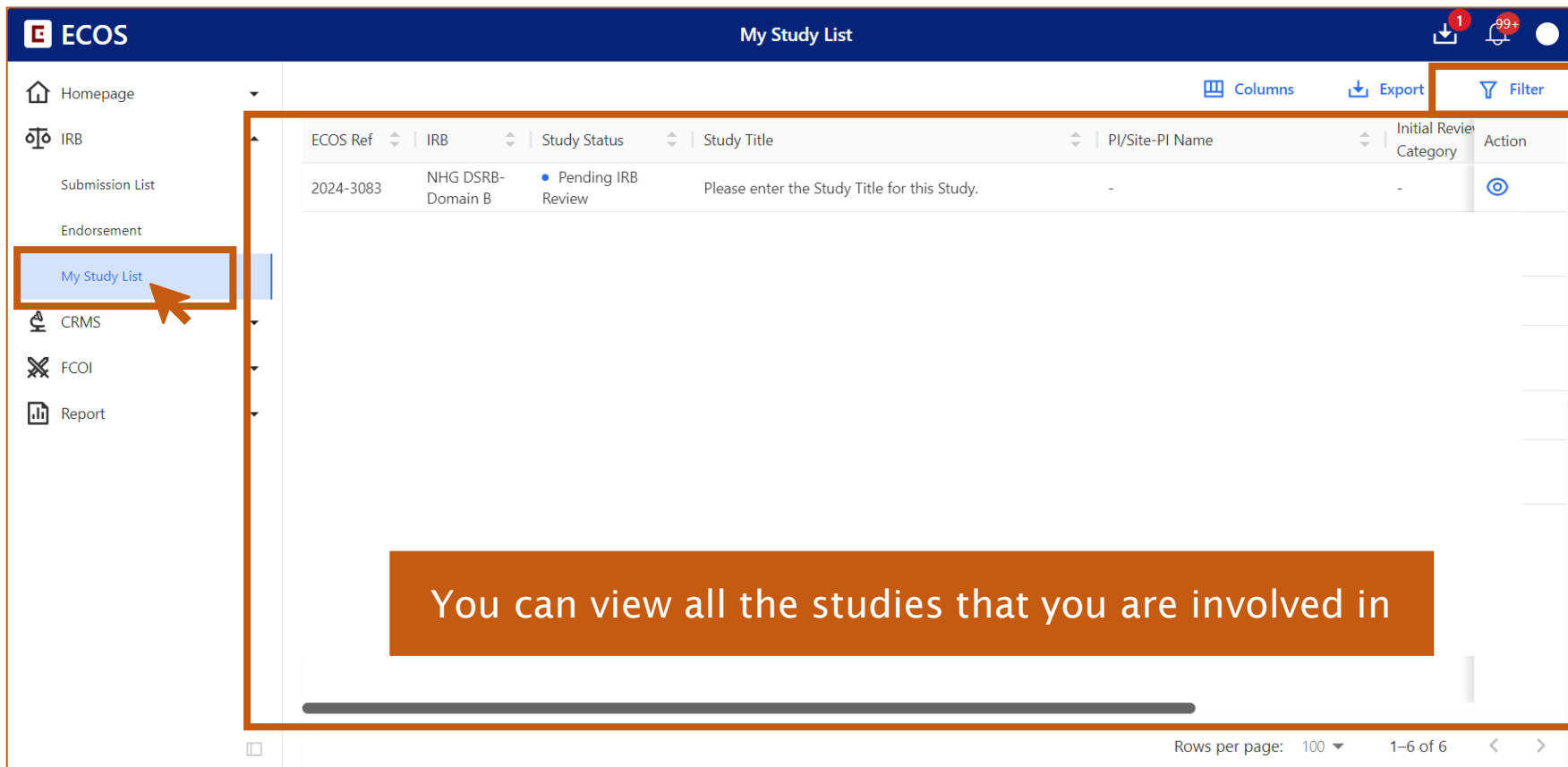
Form Ref	IRB	Study Title	PI/Site-PI Name	Department	Action
2024-3188-AMD1	NHG DSRB-Domain B	KTPH_SP1	A/Prof KTPH_SP1(Khoo Teck Puat Hospital), Dr TTSH_P2(Tan Tock Seng Hospital)	Medical Oncology	

You can view the list of forms that requires PI/ Site-PI's declaration, Research Office Checker, Endorsement by Department Representative and Institution Representative.



- Only applicable to users with specific roles
- Research Office Checker is an optional role that institutions may choose to adopt

IRB Dashboard – My study list



ECOS My Study List

ECOS Ref	IRB	Study Status	Study Title	PI/Site-PI Name	Initial Review Category	Action
2024-3083	NHG DSRB-Domain B	Pending IRB Review	Please enter the Study Title for this Study.	-	-	

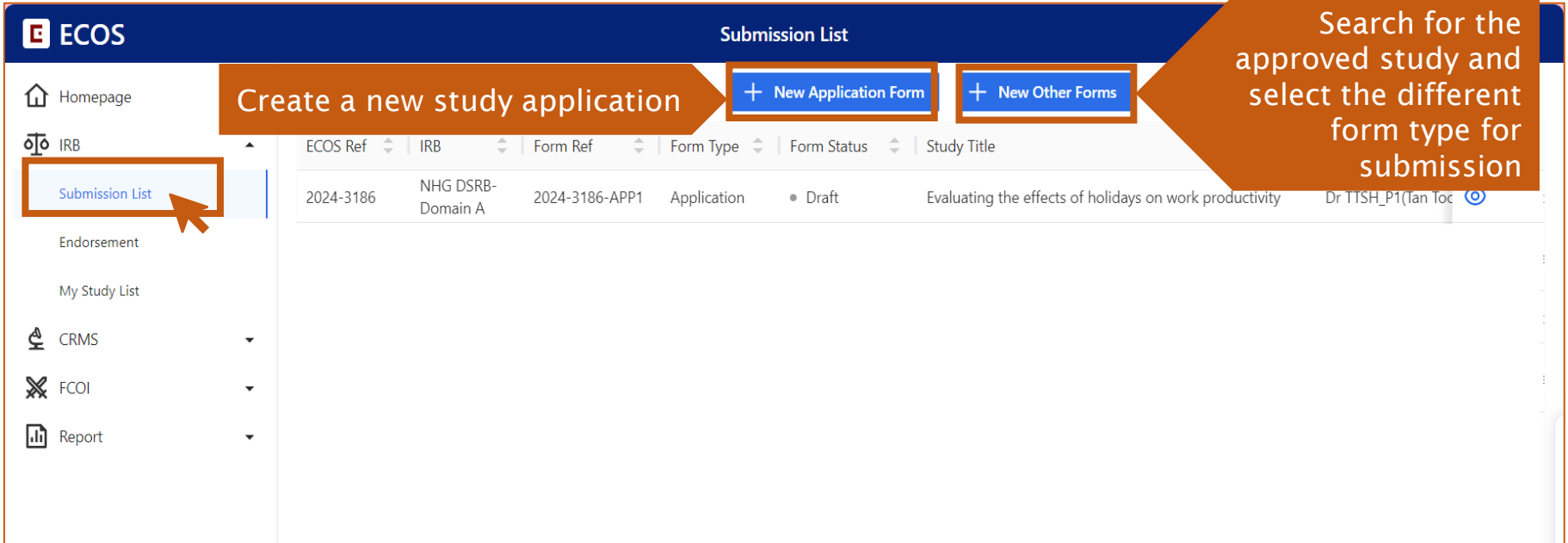
You can view all the studies that you are involved in

Rows per page: 100 1-6 of 6



- You should not see any studies on this page on your first login
- Use the filter function to search for studies with outstanding tasks

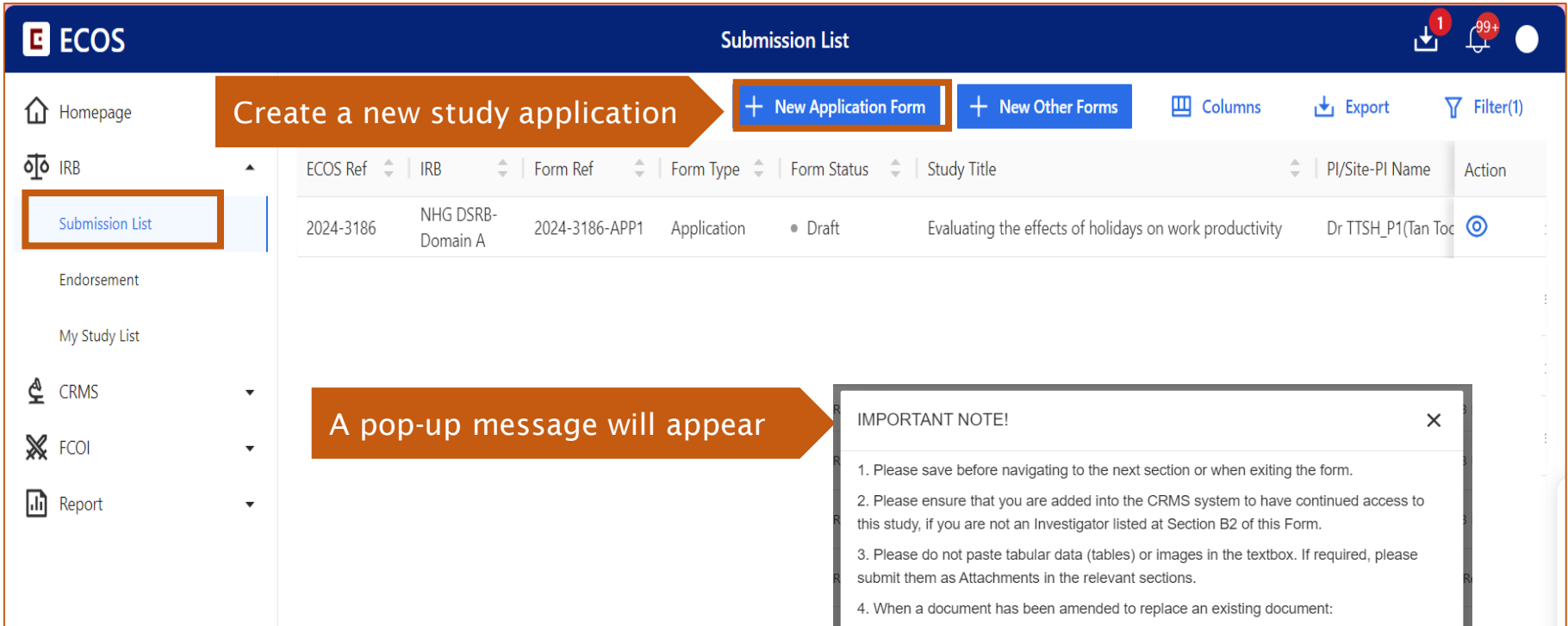
How to submit a new application/other forms



The screenshot shows the ECOS Submission List interface. The left sidebar contains navigation options: Homepage, IRB, Submission List (highlighted with a blue box and an orange arrow), Endorsement, My Study List, CRMS, FCOI, and Report. The main content area is titled 'Submission List' and features two buttons: '+ New Application Form' and '+ New Other Forms', both highlighted with orange boxes. An orange arrow points from the text 'Create a new study application' to the '+ New Application Form' button. Another orange arrow points from the text 'Search for the approved study and select the different form type for submission' to the '+ New Other Forms' button. Below the buttons is a table with the following data:

ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title
2024-3186	NHG DSRB-Domain A	2024-3186-APP1	Application	• Draft	Evaluating the effects of holidays on work productivity

How to submit a new application



ECOS Submission List

Create a new study application

+ New Application Form + New Other Forms

Columns Export Filter(1)

ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title	PI/Site-PI Name	Action
2024-3186	NHG DSRB-Domain A	2024-3186-APP1	Application	Draft	Evaluating the effects of holidays on work productivity	Dr TTSH_P1(Tan Toc	

A pop-up message will appear

IMPORTANT NOTE!

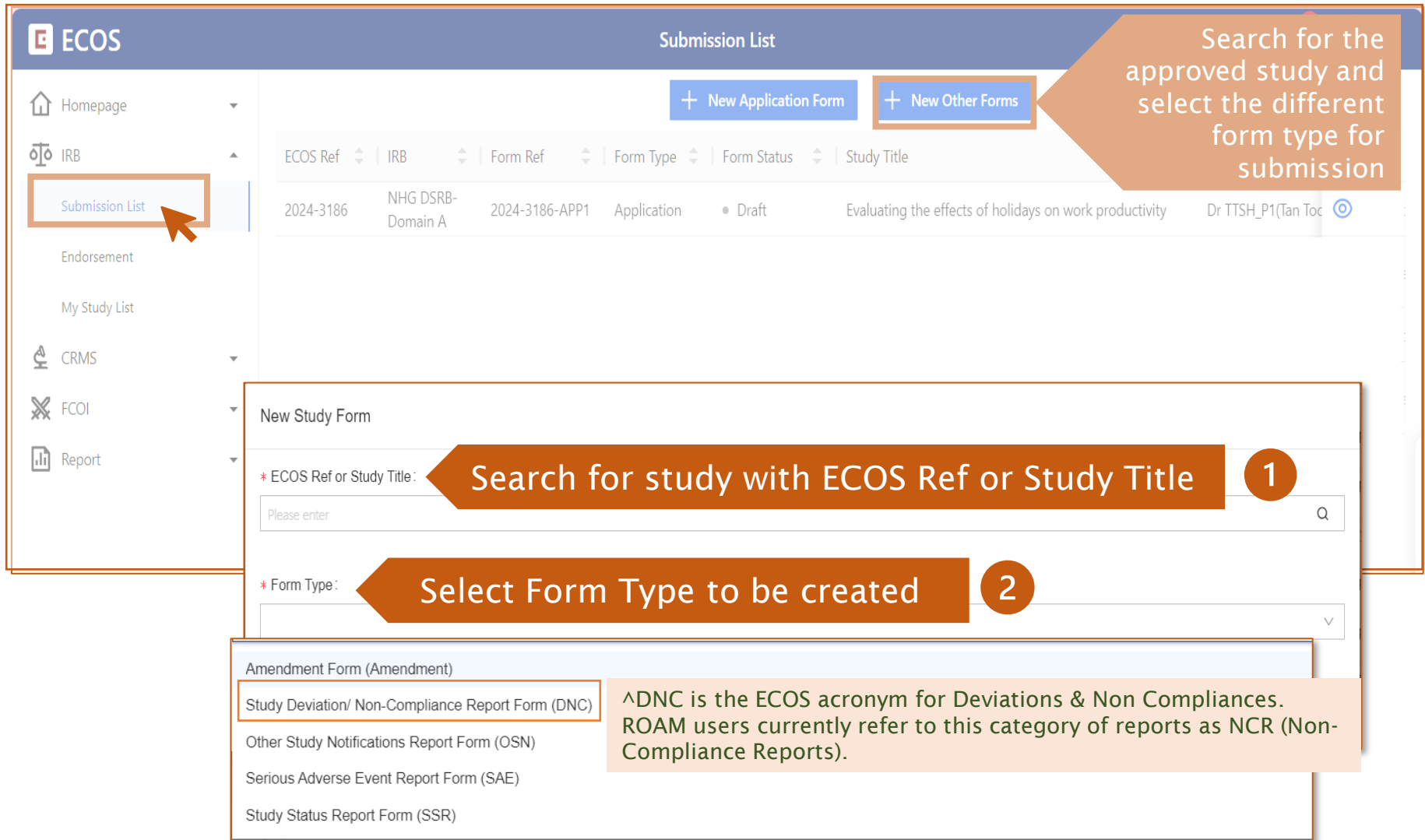
1. Please save before navigating to the next section or when exiting the form.
2. Please ensure that you are added into the CRMS system to have continued access to this study, if you are not an Investigator listed at Section B2 of this Form.
3. Please do not paste tabular data (tables) or images in the textbox. If required, please submit them as Attachments in the relevant sections.
4. When a document has been amended to replace an existing document:
 - a. Please ensure that both the clean and tracked copies are uploaded.
 - b. 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.
 - c. Please remove the obsolete copies as only the latest version is required.

1 Click on 'Close' button to proceed with the creation of form

Close

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

How to submit other forms



The screenshot shows the ECOS Submission List interface. The left sidebar contains navigation options: Homepage, IRB, Submission List (highlighted with a red box and arrow), Endorsement, My Study List, CRMS, FCOI, and Report. The main content area is titled 'Submission List' and features two buttons: '+ New Application Form' and '+ New Other Forms' (highlighted with a red box). A callout box points to the '+ New Other Forms' button with the text: 'Search for the approved study and select the different form type for submission'. Below the buttons is a table with columns: ECOS Ref, IRB, Form Ref, Form Type, Form Status, and Study Title. A row is visible with values: 2024-3186, NHG DSRB-Domain A, 2024-3186-APP1, Application, Draft, and Evaluating the effects of holidays on work productivity. Below the table is a 'New Study Form' section with two input fields: 1. '* ECOS Ref or Study Title:' with a search icon and a callout box: 'Search for study with ECOS Ref or Study Title'. 2. '* Form Type:' with a dropdown menu and a callout box: 'Select Form Type to be created'. The dropdown menu is open, showing options: Amendment Form (Amendment), Study Deviation/ Non-Compliance Report Form (DNC) (highlighted with a red box), Other Study Notifications Report Form (OSN), Serious Adverse Event Report Form (SAE), and Study Status Report Form (SSR). A callout box explains: '^DNC is the ECOS acronym for Deviations & Non Compliances. ROAM users currently refer to this category of reports as NCR (Non-Compliance Reports)'.

ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title
2024-3186	NHG DSRB-Domain A	2024-3186-APP1	Application	Draft	Evaluating the effects of holidays on work productivity

1 Search for study with ECOS Ref or Study Title

2 Select Form Type to be created

Amendment Form (Amendment)

Study Deviation/ Non-Compliance Report Form (DNC)

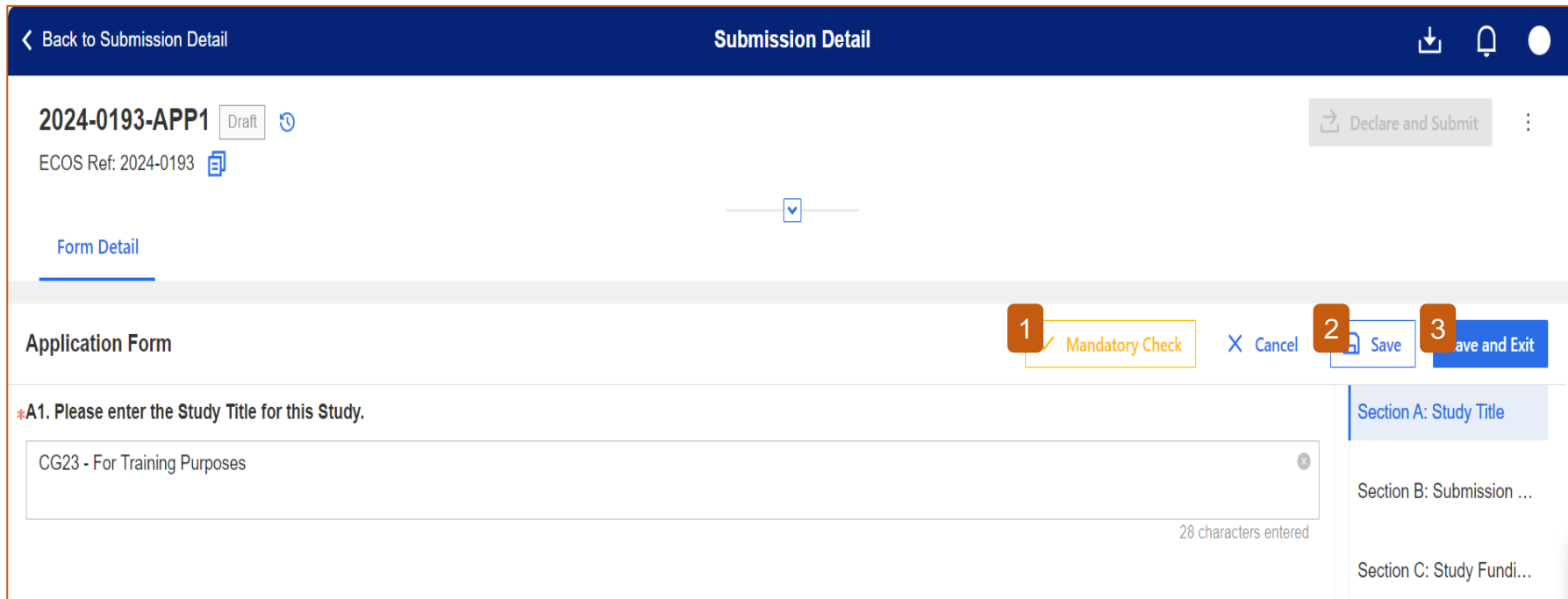
Other Study Notifications Report Form (OSN)

Serious Adverse Event Report Form (SAE)

Study Status Report Form (SSR)

^DNC is the ECOS acronym for Deviations & Non Compliances. ROAM users currently refer to this category of reports as NCR (Non-Compliance Reports).

Key features of Application Form (1)



Submission Detail

2024-0193-APP1 Draft 🔄

ECOS Ref: 2024-0193 📄

📄 Declare and Submit ⋮

Form Detail

Application Form 1 Mandatory Check ✕ Cancel 2 Save 3 Save and Exit

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

CG23 - For Training Purposes ✕

28 characters entered

Section A: Study Title

Section B: Submission ...

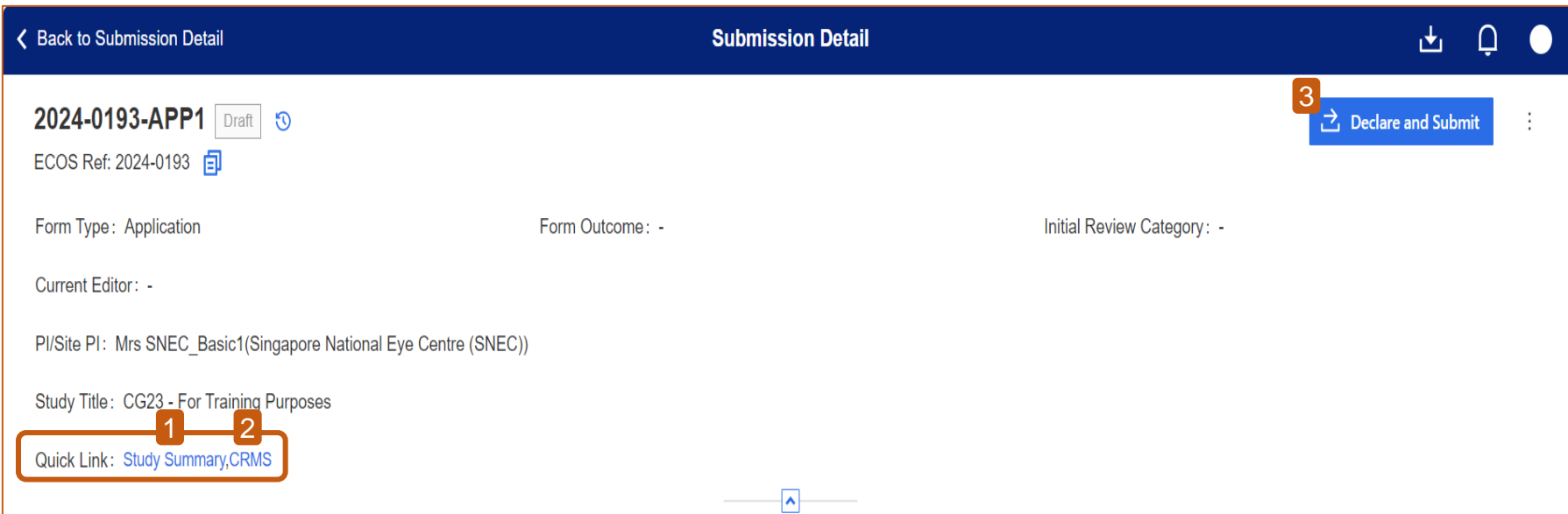
Section C: Study Fundi...

- 1 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.


The timeout for ECOS is **30 minutes**.
(Editing the form does **not** count as being active)




Key features of Application Form (2)



Submission Detail

2024-0193-APP1 Draft 

ECOS Ref: 2024-0193 

Form Type: Application Form Outcome: - Initial Review Category: -

Current Editor: -

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

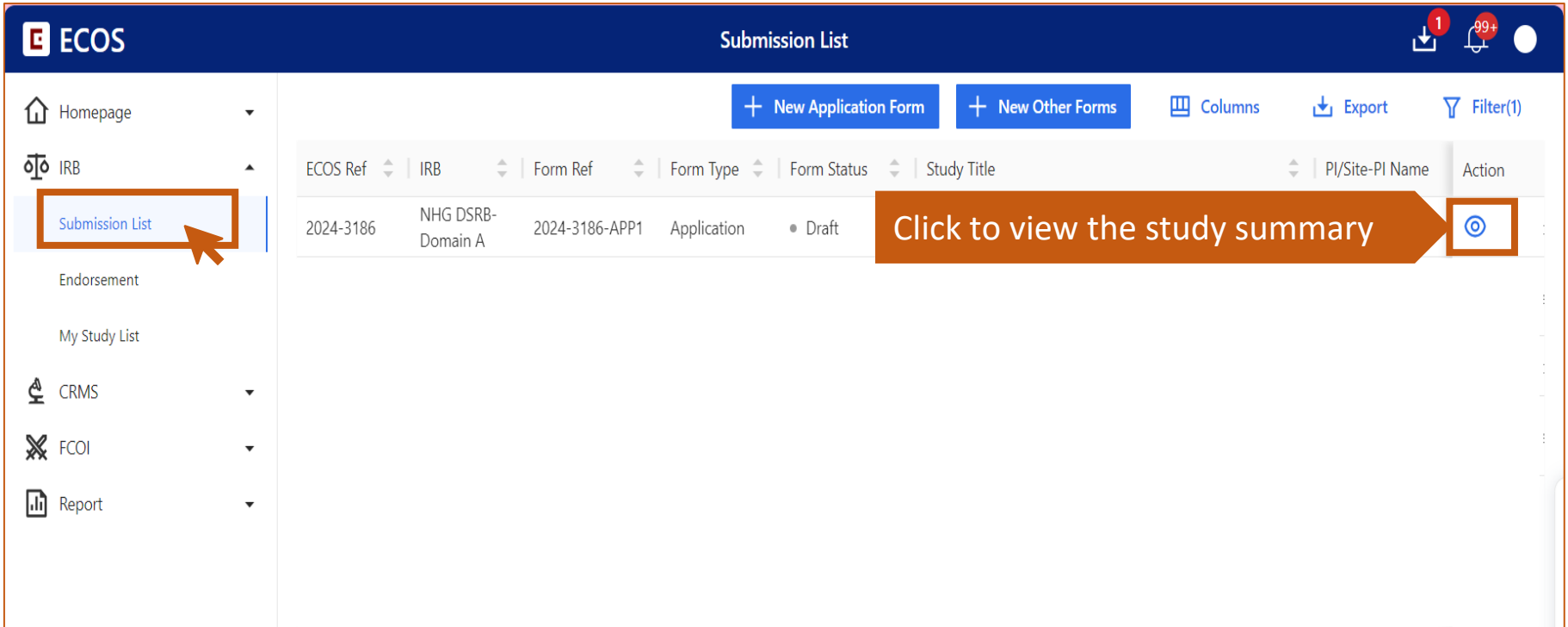
Study Title: CG23 - For Training Purposes

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


3 ➔ Declare and Submit ⋮

- 1 View the 'Study Summary' such as Forms, Forms Attachments and Study Letter submitted for the study.
- 2 Refer to the training guide for CRMS module for more information.
- 3 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.

Where to find your study summary



The screenshot shows the ECOS Submission List interface. The left sidebar contains navigation options: Homepage, IRB, Submission List (highlighted with a blue box and an arrow), Endorsement, My Study List, CRMS, FCOI, and Report. The main content area displays a table of submissions. The table has columns for ECOS Ref, IRB, Form Ref, Form Type, Form Status, Study Title, PI/Site-PI Name, and Action. A single row is visible with the following data: ECOS Ref: 2024-3186, IRB: NHG DSRB-Domain A, Form Ref: 2024-3186-APP1, Form Type: Application, Form Status: Draft. An orange callout box with the text "Click to view the study summary" points to the Action column, which contains a magnifying glass icon. The top navigation bar includes buttons for "New Application Form" and "New Other Forms", and utility icons for Columns, Export, and Filter(1). The top right corner shows notification icons for 1 message and 99+ alerts.

ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title	PI/Site-PI Name	Action
2024-3186	NHG DSRB-Domain A	2024-3186-APP1	Application	Draft			



Study summary can be accessed from Submission List and My Study List

Managing your studies through the Clinical Research Management System (CRMS)

- Where to find your studies
- Managing IRB Submission for Sponsored Study
- Managing your study team
- Managing your study activities

The use of this module is optional for non-sponsored studies



CRMS – Overview

You can capture information such as:

- Primary & backup site coordinators
- Funding/ Grant details
- Study agreement information
- Sponsor/CRO contract
- Publications and presentations

Project managers/Study coordinators can create & track Study Milestones (e.g. IRB approval, Study Initiation, First participant screened)

- Track recruitment numbers (by month and in total)
- Capture participants' information (e.g. Basic information, Signed ICF tracking, Visit plan)

Study Information

Site Information

User Authorisation List

Milestones

Participants

You can capture information such as:

- Sponsor, CRO contact details
- IRB review fees billing contact details
- Regulation information (e.g. submission details)

- Study team members/ Sponsors added can draft IRB form
- 3 types of roles can be assigned (each affecting their access in CRMS):
 - Study Sponsor
 - Study Administrator
 - Study Team Member
- PI, Site-PI and Co-I will be auto-synced from IRB App Form

Participant List

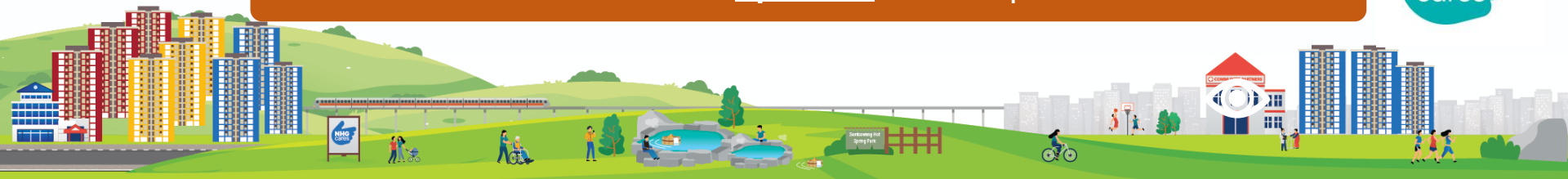
Visit Plan

Study Configuration

Group

ICF Version

The use of this module is optional for non-sponsored studies

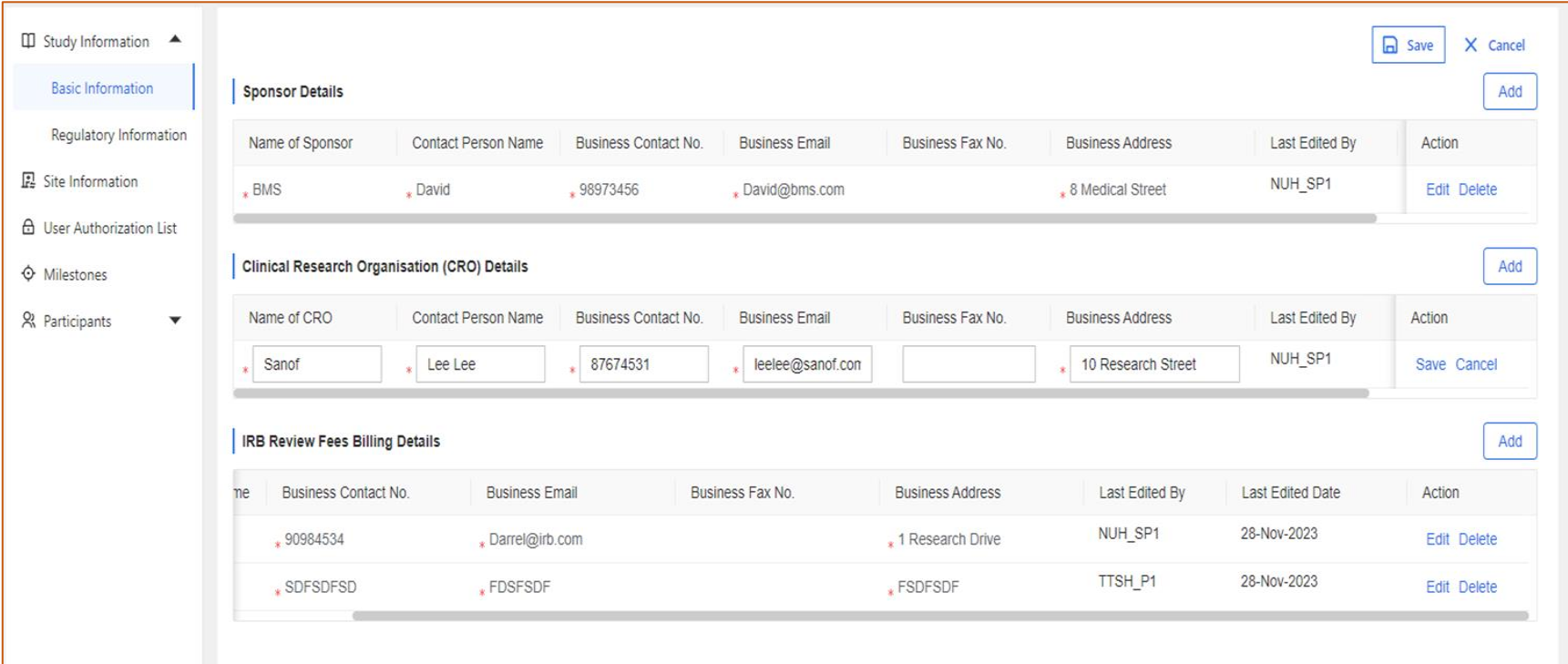


CRMS – Managing IRB Submission for Sponsored Study

CRMS role in IRB submission

If Pharmaceutical/Industry Sponsored was selected in Section C1 (funding information) in the IRB application form, following CRMS sections need to be completed to support the IRB submission:

- Study Information → Sponsor/ CRO and IRB billing details



The screenshot displays the 'Study Information' section of the CRMS interface. It features a sidebar with navigation options: Basic Information, Regulatory Information, Site Information, User Authorization List, Milestones, and Participants. The main content area is divided into three sections, each with an 'Add' button:

- Sponsor Details:** A table with columns: Name of Sponsor, Contact Person Name, Business Contact No., Business Email, Business Fax No., Business Address, Last Edited By, and Action. One entry is shown for 'BMS' with contact 'David' at '8 Medical Street'.
- Clinical Research Organisation (CRO) Details:** A table with columns: Name of CRO, Contact Person Name, Business Contact No., Business Email, Business Fax No., Business Address, Last Edited By, and Action. One entry is shown for 'Sanof' with contact 'Lee Lee' at '10 Research Street'.
- IRB Review Fees Billing Details:** A table with columns: Name, Business Contact No., Business Email, Business Fax No., Business Address, Last Edited By, Last Edited Date, and Action. Two entries are shown for different billing details.

CRMS – Managing your study team

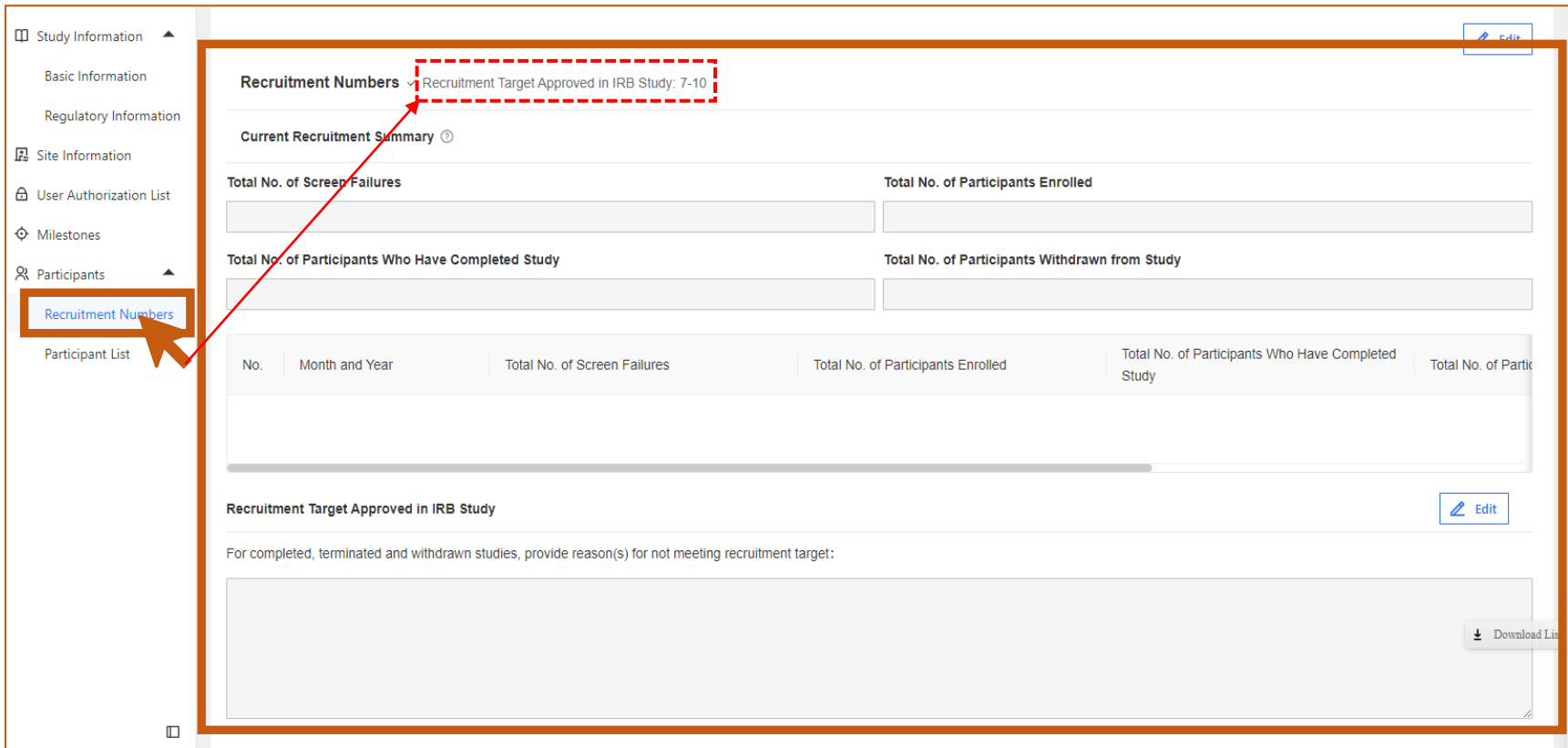
User Authorisation List – the Gateway to ECOS

- User Authorization List controls user access to ECOS modules for Study Team Member, Study Administrators and Study Sponsor roles.
- Addition of the users above require PI authorisation

User Authorisation List											
Member Name	Role	Cluster	Institution	Department	Designation	Email Address	Data Source	Role Status	Endorsement Date	Endorsed	Action
TTSH_P2	PI	National Healthcare Group	Tan Tock Seng Hospital	Medical Oncology	Doctor	shs-site1-tester8@taimei.com	IRB	● Active	02-Apr-2024	-	
TTSH_User_ID04	Col	National Healthcare Group	Tan Tock Seng Hospital	Infectious Disease	medical office	nhg-site1-tester1@taimei.com	IRB	● Active	02-Apr-2024	-	
SS2	Study Sponsor	External	Novartis Pharma	-	Sponsor	5923d5b6-9a87-42fa-80be-dcadd37999f8@taimei.com	CRMS	● Active	02-Apr-2024	TTSH_P2	Deactivate
TTSH_SA2	Study Administrator	National Healthcare Group	Tan Tock Seng Hospital	Medical Oncology	CRC	ef246c8e-d575-4863-bd4b-be7b8d3d0e8e@taimei.com	CRMS	● Active	02-Apr-2024	TTSH_P2	Deactivate
TTSH_STM2	Study Team Member	National Healthcare Group	Tan Tock Seng Hospital	Medical Oncology	CRC	shs-site1-tester4@taimei.com	CRMS	● Active	02-Apr-2024	TTSH_P2	Deactivate

CRMS – Managing your study activities (1)

You can now track and enter recruitment number



Recruitment Numbers Recruitment Target Approved in IRB Study: 7-10

Current Recruitment Summary ⓘ

Total No. of Screen Failures

Total No. of Participants Enrolled

Total No. of Participants Who Have Completed Study

Total No. of Participants Withdrawn from Study

No.	Month and Year	Total No. of Screen Failures	Total No. of Participants Enrolled	Total No. of Participants Who Have Completed Study	Total No. of Participants Withdrawn from Study

Recruitment Target Approved in IRB Study [Edit](#)

For completed, terminated and withdrawn studies, provide reason(s) for not meeting recruitment target:

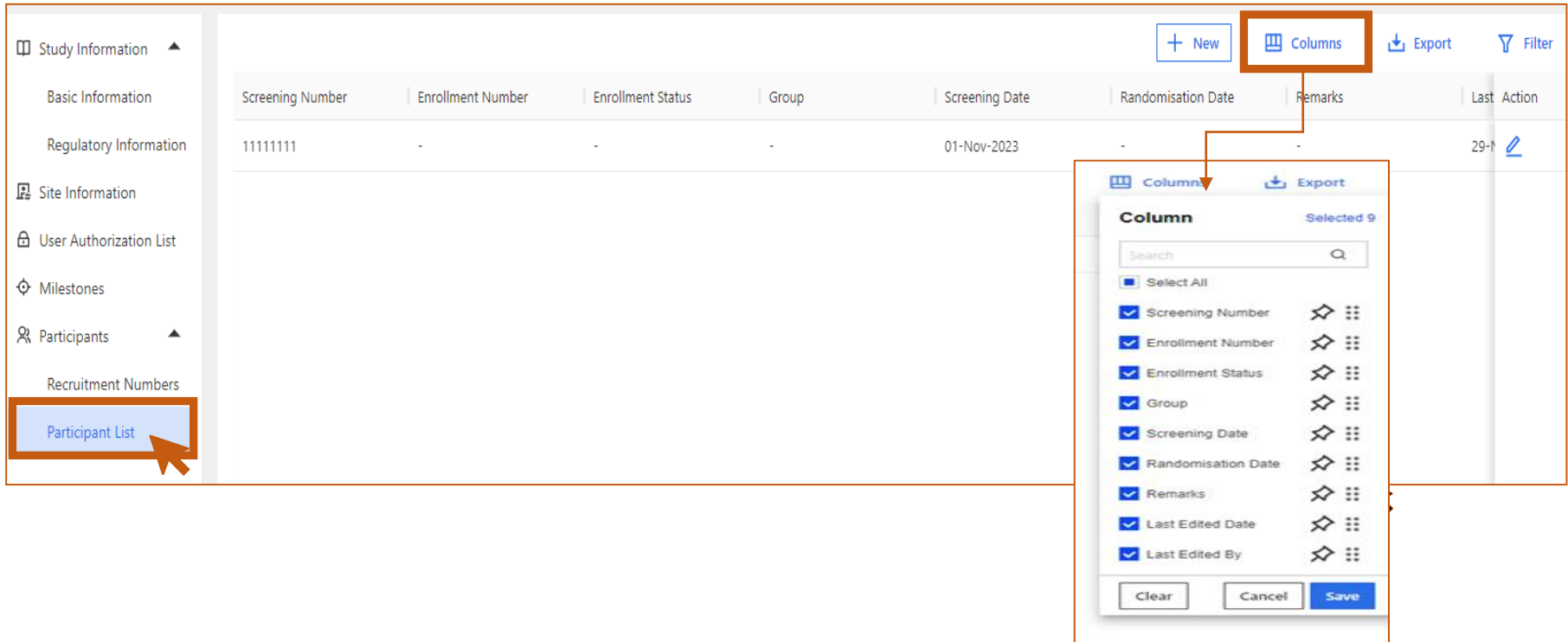
[Download List](#)




Step-by-step training on the navigation of the CRMS will be made available in ECOS Launch Website. Stay tuned for details.

CRMS – Managing your study activities (2)

You can have an overview of the list of participants screened, enrolled and/or randomized.



The screenshot displays the CRMS interface. On the left, a navigation menu includes 'Study Information', 'Site Information', 'User Authorization List', 'Milestones', and 'Participants'. Under 'Participants', 'Participant List' is highlighted. The main area shows a table with columns: Screening Number, Enrollment Number, Enrollment Status, Group, Screening Date, Randomisation Date, Remarks, and Last Action. A 'Columns' dialog box is open, showing a list of columns with checkboxes and drag handles. The columns listed are: Screening Number, Enrollment Number, Enrollment Status, Group, Screening Date, Randomisation Date, Remarks, Last Edited Date, and Last Edited By. All are checked. The dialog also has 'Clear', 'Cancel', and 'Save' buttons.

Screening Number	Enrollment Number	Enrollment Status	Group	Screening Date	Randomisation Date	Remarks	Last Action
11111111	-	-	-	01-Nov-2023	-	-	29-N 

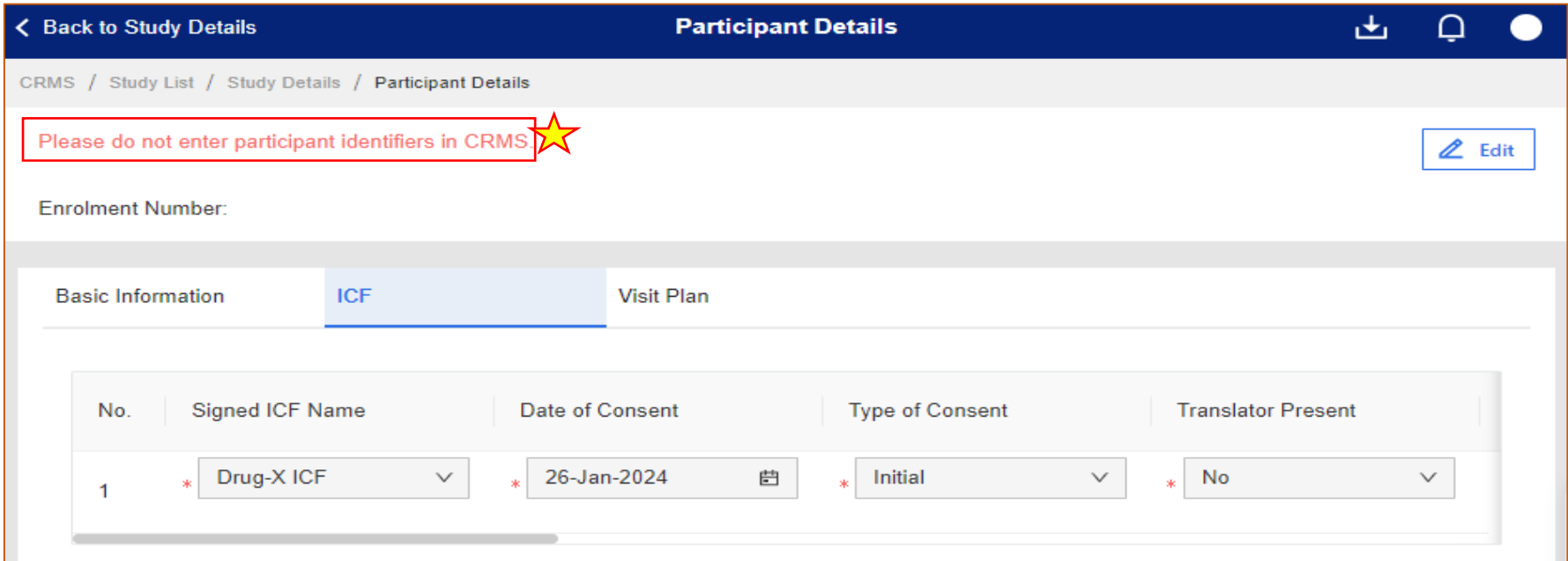





IMPORTANT – Participant identifiers should not be entered into CRMS.

CRMS – Managing your study activities (3)



Consists of 3 sub-pages to allow subject related data entry:

- Basic Information
- ICF Details
- Visit Plan



< Back to Study Details Participant Details   

CRMS / Study List / Study Details / Participant Details

Please do not enter participant identifiers in CRMS   Edit

Enrolment Number:

Basic Information **ICF** Visit Plan

No.	Signed ICF Name	Date of Consent	Type of Consent	Translator Present
1	* Drug-X ICF	* 26-Jan-2024	* Initial	* No



IMPORTANT – Participant identifiers should not be entered into CRMS.

Module-specific Training Materials & Recording

- ✓ IRB Guidebook is available on '[ECOS Launch Support Portal > User Guides](#)'.
 - Slides for this Webinar will be uploaded on '[ECOS Launch Support Portal > Training](#)'
 - For NHG staff only, the recording of this Webinar will be uploaded on eLEARN (<https://elearn.sg/>)
 - Module-specific training materials will be made available soon.
 - Stay tuned to the NHG Research Website (www.research.nhg.com.sg)
OR look out for emails from OHRPP@nhg.com.sg!



The screenshot shows the NHG Research Website navigation menu with the following items: Home, Ethics & Quality, Research Grants, Training & Education, Talent Development, Conducting Research, and Resources. The breadcrumb trail is: Home > Research Ethics Framework > ECOS Launch Support for NHG. The main heading is "ETHICS & QUALITY". Below it is a photo of a doctor attending to a patient in a hospital bed. A sidebar menu lists: Introduction to Ethics, Apply for Ethics Approval, DSRB Announcements, DSRB FAQ, Standing Databases & Tissue Banks, Research Quality, Quality Improvement, and ECOS Launch Support. The main content area is titled "ECOS Launch Support for NHG" and has a sub-menu: Home, Announcements, FAQs, Migration Prep, User Guides, and Training. The "User Guides" item is highlighted. Below this is the heading "ECOS USER GUIDES" and a star icon next to the link "IRB Guidebook: Application Form (Ver 1, dated 1 Mar 2024)". A descriptive paragraph follows: "This guidebook will assist researchers in drafting their IRB Application Form in the ECOS system and provides a listing of all the Sections and Questions in the IRB Application Form for reference." A cartoon bee holding a pencil is in the bottom right corner.

www.research.nhg.com.sg

For more information on ECOS

Home » Research Ethics Framework » ECOS Launch Support for NHG

www.research.nhg.com.sg

ETHICS & QUALITY



- Introduction to Ethics ▶
- Apply for Ethics Approval ▶
- DSRB Announcements
- DSRB FAQ
- Standing Databases & Tissue Banks ▶
- Research Quality ▶
- Quality Improvement
- ECOS Launch Support** ▶

ECOS Launch Support for NHG

[ECOS Home](#) | [ECOS Announcements](#) | **[ECOS FAQs](#)** | [ECOS Migration Prep](#) | [ECOS User Guides](#)

What is ECOS?

The **Ethics and Compliance Online System (ECOS)** is the new ethics review infrastructure that is co-developed by NHG and SingHealth. The ECOS system will replace the current NHG ROAM system in mid 2024.

The ECOS system is intended to support research enterprise functions across the research lifecycle from Study Initiation to Completion, allowing IRBs, institutions, and researchers to have a one stop oversight of research related activities.

As part of NHG's preparations to ensure a smooth transition from the current ROAM System over to the succeeding ECOS system, we have created a new information website to act as a central reference and information portal.

All posted announcements, news and guides related to the ECOS system and the decommissioning of the NHG ROAM System will be made available here on this portal.

ECOS Launch Support Site for NHG: <https://for.sg/ecos> (Both NHG-Intranet & Internet accessible)

For More Information



Any Questions?



Mailing List Subscription





THANK YOU

