

Navigating Ethics & Compliance Online System (ECOS) User Guide

Audit Module

[ECOS User Guide – Audit Module Ver 1, 20 Dec 2024]

Contents

Audit Module User Guide for:

Principal Investigator (PI) / Site Principal Investigator (Site PI)/ Co-Investigator (Co-I) and Study Team Member (STM)

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4. How to Draft Corrective Action and Preventive Action (CAPA) for Audit Findings
5. How to View/ Reply to CAPA Query

1) Audit Module General Interface - Columns

The screenshot displays the ECOS 'My Tasks' interface. The top navigation bar includes 'ECOS', 'My Tasks', and user profile icons. A left sidebar contains navigation options: 'Homepage', 'Dashboard', 'My Tasks' (highlighted), 'My Notices', and a list of modules: 'IRB', 'CRMS', 'Compliance', 'Audit', and 'Monitoring'. The main dashboard area shows six task count cards: IRB (1), CRMS (0), FCOI (0), Monitoring (0), Compliance (0), and Audit (0). Below these is a 'PI (0)' card. A table of tasks is visible, with columns for 'Form Type', 'ECOS Ref', 'Study Site', 'Auditor Name', and 'Date Sent to PI'. A 'Columns' dialog box is open, titled 'Column Selected 8'. It contains a search bar, a 'Select All' checkbox, and a list of columns with checkboxes and drag handles: 'Form Type', 'ECOS Ref', 'Study Site', 'Audit Status', 'Task Due Date', 'Auditor Name', 'Date Sent to PI', and 'Task Status'. At the bottom of the dialog are 'Clear', 'Cancel', and 'Save' buttons. Numbered callouts (1-3) point to the 'Columns' button, the dialog box, and the 'Clear' button respectively.

1. Click on “**Columns**” to **change the layout** of information presented.
2. You can adjust the **columns display order** by pulling the display information **up and down** using  and click on “**Save**”.
3. To reset the columns to its default view, click on “**Clear**” and “**Save**”.
4. Study tasks are listed according to the **user’s assigned role**. Tab/ tasks shown here may vary across the users.

1) Audit Module General Interface – Export Listing

The screenshot shows the ECOS 'My Tasks' interface. The 'Audit' module is highlighted in the top navigation bar. Below it, the 'PI (0)' button is also highlighted. The main table displays two audit tasks. The 'Export' button in the top right of the table is highlighted with a red box and labeled '1'. A dropdown menu is open from the 'Export' button, showing two options: 'Download Original' and 'Safe Download (PDF)'. The 'Safe Download (PDF)' option is highlighted with a red box and labeled '2'.

Form Type	ECOS Ref	Study Site	Audit Status	Task Due Date	Auditor Name	Date Sent to PI	Action
Site CAPA	2024-3708	Khoo Teck Puat Hospital	Closed	08-Dec-2024	A/Prof NHG_A3	06-Dec-2024	
Site CAPA	2024-3699	Khoo Teck Puat Hospital	CAPA Pending Completion	30-Nov-2024	A/Prof NHG_A2, A/Prof 何庆青	29-Nov-2024	

1. You can export the listing you are viewing by clicking on “Export”.
2. Select “Download Original” as an Excel file or “Safe Download” as PDF file.

Audit Study Information							
Downloaded By: Ms KTPH_PISP1							
Downloaded Date and Time: 12-Dec-2024 14:52:04							
Form Type	ECOS Ref	Study Site	Audit Status	Task Due Date	Auditor Name	Date Sent to PI	Task Status
Site CAPA	2024-3708	Khoo Teck Puat Hospital	Closed	08-Dec-2024	A/Prof NHG_A3	06-Dec-2024	Completed
Site CAPA	2024-3699	Khoo Teck Puat Hospital	CAPA Pending Completion	30-Nov-2024	A/Prof NHG_A2, A/Prof 何庆青	29-Nov-2024	Terminated

1) Audit Module General Interface – Filter

The screenshot displays the ECOS 'My Tasks' interface. The top navigation bar includes the ECOS logo, 'My Tasks', and user icons. The left sidebar contains navigation options: Homepage, Dashboard, My Tasks (highlighted), My Notices, IRB, CRMS, Compliance, Audit, and Monitoring. The main content area shows task counts for various categories: IRB (1), CRMS (0), FCOI (0), Monitoring (0), Compliance (0), and Audit (0). A 'PI (0)' link is also present. A table lists tasks with columns for Form Type, ECOS Ref, Study Site, Audit Status, and Task Due Date. A 'Filter' dialog box is open, allowing users to refine their search. The dialog includes fields for Form Type, ECOS Ref, Study Site, Task Due Date (with Start and End date pickers), Auditor Name, Date Sent to PI (with Start and End date pickers), and Task Status (set to Pending). The 'Filter' button is labeled '1', the 'Search' button is labeled '2', and the 'Reset' button is labeled '3'.

1. Click on “Filter” to tailor the listing you wish to view.

2. The default settings for the filter show only **pending** tasks for your action (**Task Status = Pending**). To reset to default filter settings, click on “Reset”.

3. After selecting the parameters to filter, click on “Search”.

Note: To view all assigned tasks (including completed tasks), ensure all filters are cleared.

2) Locate your CAPA task (method 1)– via Homepage

ECOS Dashboard

Navigation Panel:

- Homepage
- Dashboard** (1)
- My Tasks
- My Notices
- IRB
- CRMS
- Compliance
- Audit
- Monitoring
- FCOI
- SDB
- Report

Summary Tiles:

- IRB** (0)
 - Study: 0
 - Endorsement: 0
- CRMS** (0)
 - Study Member Review: 0
- FCOI** (0)
 - My FCOI List: 0
- Monitoring** (0)
 - PI/Site-PI: 0
 - Plan Reviewer: 0
 - Responsible Person: 0
- Compliance** (0)
 - Deviation/Non Compliance - Site: 0
 - Serious Adverse Event - Site: 0
 - PI Self Assessment Form: 0
- Audit** (0)
 - PI: 0

Via Homepage > Dashboard

1. You can locate your outstanding audit task via “Homepage” > “Dashboard” on the left navigation panel.
2. Locate the “Audit” tile and click on “Audit”. It will lead you to “My Tasks”.
3. You can also access “Homepage” > “My Task” via the left navigation panel.
4. Click on the “Audit” tile.
5. To view the audit task, click on  “View” under the “Action” column. The page will be directed to the study audit details (audit report/audit observation list).

ECOS My Tasks

Navigation Panel:

- Homepage
- Dashboard
- My Tasks** (3)
- My Notices
- IRB
- CRMS
- Compliance
- Audit
- Monitoring

Summary Row:

- IRB** (0)
- CRMS** (0)
- FCOI** (0)
- Monitoring** (0)
- Compliance** (0)
- Audit** (1) (4)

Table:

Form Type	ECOS Ref	Study Site	Audit Status	Task Due Date	Auditor Name	Action
Site CAPA	2024-3709	Institute of Mental Health	CAPA Pending Completion	02-Jan-2025	A/Prof NHG_A4	 (5)

2) Locate your CAPA task (method 2)- via Audit menu

ECOS Study Audit Information

Columns Export Filter

ECOS Reference	Audit Number	Study Title	Study Site	No. of Findings	No. of Comments	CAPA Due Date	Audit Status	Actual Start Date	Action
2024-3713	2024-3713-Khoo Teck Puat Hospital-AUD01	Audit UAT test 18 (Routine audit-COI)	Khoo Teck Puat Hospital	0	1	-	Audit Closed	06-Dec-2024	 2
2024-3699	2024-3699-Khoo Teck Puat Hospital-01	Audit UAT test 4 (Routine audit-COI)	Khoo Teck Puat Hospital	6	2	30-Nov-2024	Audit Closed	29-Nov-2024	
2024-3708	2024-3708-Khoo Teck Puat Hospital-AUD01	Audit UAT test 11 (Routine audit-COI)	Khoo Teck Puat Hospital	6	4	08-Dec-2024	Audit Closed	04-Dec-2024	

Via Audit> Study Audit Information

1. PI/Site PI, Co-I and Study Team Member can:

- Locate the **audit report** sent by auditor
- **View the findings, comments and recommendations** that arise from the audit
- **Complete the corrective action and corrective action (CAPA)** if needed in findings.

2. To view the audit task, click on  under the “Action” column.

Note: The PI, Co-I and active Study Team Member (STM) listed in Clinical Research Management System User Authorization List (CRMS UAL) can view and reply to CAPA.

By default, only the PI can submit the CAPA form.

3) View and Access Your Study Audit Information

Home | Back to Study Audit Information | Study Audit Information Detail

2024-3713-Khoo Teck Puat Hospital-AUD01 | Khoo Teck Puat Hospital Audit Closed
ECOS Ref: 2024-3713

Plan Audit 1 Saved at 06-Dec-2024 10:41

Planned Start Date: 09-Dec-2024 Planned Start Time: 07:00
Planned End Date: 29-Dec-2024 Planned End Time: 07:00

Venue: KTPH
Audit Agenda: xx
Attachment: No file uploaded.
Remarks: yy

Via Audit > Study Audit Information

1. Click on “**Plan Audit**” to view **Planned Audit Schedule Detail and Audit Notification**.

Audit Notification Saved at 06-Dec-2024 10:42

Subject: NHG RQM Study Review (2024-3713) - Notice of Study Review Visit

To: KTPH_PISP1<ktp_hisp1@taimei.com>

Cc: NHG_A3<nhg_a3@taimei.com>, KTPH_ROA1<ktp_hoa1@taimei.com>, baob9<nhg-site3-tester222@taimei.com>, BVH_MTSec<shs-site16-tester6@taimei.com>, baob9<baob9@taimei.com>

Dear Ms KTPH_PISP1,

ECOS Reference: 2024-3713
Study Title: Audit UAT test 18 (Routine audit-COI)
Principal Investigator: Ms KTPH_PISP1

3) View and Access Your Study Audit Information

2024-3713-Khoo Teck Puat Hospital-AUD01 | Khoo Teck Puat Hospital Audit Closed

ECOS Ref: 2024-3713

Plan Audit

Site Audit

Audit Report

Audit Report Observation

Site Audit Closed

NHG RQM STUDY REVIEW REPORT

Default Section

Export Attachment

Download List Delete All

NHG RQM STUDY REVIEW REPORT 2024-3713.pdf 230.23 KB Delete Download To Local

Default Section

SECTION A - STUDY TEA...

SECTION B - IRB DOCU...

SECTION C - REGULATO...

SECTION D - SUBJECT R...

SECTION E- INFORMED ...

SECTION F - INVESTIGA...

SECTION G - SAFETY RE...

Audit-COI)

NHG RQM For-Cause Study Review Report

Note: As the study review report is a restricted document, please do not retain a copy in the Investigator File.

Date of Study Review: 13-Dec-2024

Date of Report: 13-Dec-2024

CAPA Due Date: 12-Jan-2025

Mode of Audit: Physical Audit

1. Executive Summary

Study Title	Audit UAT test 32 (For-cause audit)
ECOS Reference	2024-3835
Principal Investigator (PI)	Mr TISHI_PISP1
Contact Details of PI	Business Address: Business Email: tsh_pisp1@tatmci.com
Study Site	Tan Teck Seng Hospital
RQM Auditor(s)	A/Prof NHG_A1
Audit Report Reviewer	Dr NHS_ARR2
Observers (if any)	2
List of site staff present	S AA BB CC DD EE
Number of findings/comments	Critical Finding: 0 Major Finding: 2 Minor Finding: 1 Comment: 2

Version 3.1 dated 11 Dec 2024
RESTRICTED SENSITIVE NORMAL
[Document classification should be revised in accordance to the sensitivity of data collected] Page 1 of 6

Via Audit > Study Audit Information

1. PI/Site PI/Co-I/STM may view their respective study's Audit Report.
2. To export a copy of the audit report, click on "Export".
3. The "Download List" will appear at the bottom of the browser.
4. When the export is complete, click "Download To Local". The PDF copy of the form will be displayed, and you may save it to your computer local drive.

3) View and Access Your Study Audit Information

The screenshot shows the 'Study Audit Information Detail' page for '2024-3833-Khoo Teck Puat Hospital-AUD02'. The interface includes a sidebar with 'Audit Report Observation' highlighted (1), a table of audit observations with 'Export CAPA' and 'Download To Local' buttons (2), and a preview of the CAPA plan document (3).

Comment Number	Comment Item	Category of Comment	Comment Summary	Comment Description	Reference
AUD-C02	General	Biological Materials	materials not stored properly	materials not stored properly	-
AUD-C01	General	Investigator File / Essential Documents	-	CV not filed	-

Finding No.	Grading of Finding	Category of Finding	Finding Summary	Finding Description	Recommendation	Root Cause	Corrective Action	Preventive Action	CAPA Implementation Date
AUD-F03	Major	Informed Consent Process and Documentation	No informed consent process documentation.	No informed consent process documentation for all the recruited BB subjects.	To submit NCR.				

Via Audit > Study Audit Information

1. PI/Site PI/Co-I/STM may view their respective study's Audit Findings/Comments and Corrective Action Preventive Action (CAPA) Report (if CAPA is already submitted to auditor).
2. To export a copy of the audit CAPA report, click on "Export CAPA".
3. When the export is complete, click "Download To Local". The PDF copy of the form will be displayed, you may save it to your computer local drive.

4) How to Draft CAPA

The screenshot shows the ECOS Dashboard with the following data:

Category	Count
IRB	0
CRMS	0
FCOI	0
Monitoring	0
Compliance	0
Audit	1

The Audit tile is expanded to show:

Category	Count
PI	1

The My Tasks page shows a table with the following data:

Form Type	ECOS Ref	Study Site	Audit Status	Task Due Date	Auditor Name
Site CAPA	2024-3831	Khoo Teck Puat Hospital	CAPA Pending Completion	18-Jan-2025	A/Prof NHG_A1

Via Dashboard > My Tasks

1. The PI/Co-I and STM can locate the task via **“Dashboard”**
2. Locate the **“Audit”** tile, click on **“PI”** and you will enter **“My Tasks” > “PI”** page.
3. By default, you will see tasks which are pending your action (CAPA Pending Completion/ Query Pending Reply).
4. Click on **“View”** button under the **“Action”** column which will direct the user to the study audit details page.

4) How to Draft CAPA

Study Audit Information Detail

2024-3833-Khoo Teck Puat Hospital-AUD02 | Khoo Teck Puat Hospital Visit Completed Submit Reply Query

ECOS Ref: 2024-3833

Site Audit CAPA Pending Closure The status will reflect the site audit report status.

Audit Report Observation CAPA Due Date: 15-Jan-2025 Export CAPA

Finding Comment

Comment Number	Comment Item	Category of Comment	Comment Summary	Comment Description	Reference	View
AUD-C02	General	Biological Materials	materials not stored properly	materials not stored properly	-	3
AUD-C01	General	Investigator File / Essential Documents	-	CV not filed	-	

Rows per page: 100 1-2 of 2

Via Audit > Study Audit Information Detail

1. Click “Audit Report Observation”, you will be able to see the “Finding” and “Comment” tabs.
2. In this page, you can see the detail breakdown of the **comments** which **do not require** Corrective Action and Preventive Action (CAPA). The comment number labelled as **AUD-Cxx**.
3. Click on view to see the detail comments.

4) How to Draft CAPA

2024-3831-Khoo Teck Puat Hospital-AUD01 | Khoo Teck Puat Hospital Visit Completed Submit Reply Query

ECOS Ref: 2024-3831

IRB: NHG DSRB-Domain A PI/Site-PI: A/Prof KTPH_SP2 Auditor: A/Prof NHG_A1

Current Study Site Status: Approved Audit Category: Routine Audit

Study Title: Audit UAT test 27 (System audit)

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

Site Audit CAPA Pending Closure **The status will reflect the site audit report status.**

Audit Report Observation CAPA Due Date: 18-Jan-2025 Export CAPA

1 Audit Report Observation

Finding Number	Finding Item	Grading of Finding	Category of Finding	Finding Summary	Finding Description	Recommendation	Action
2 AUD-F01	A1. List of study team members and responsibilities (in accordance to study delegation log and discussion with the PI/designated staff)	Minor	Study Team	Responsibility log is not available.	What Is an Audit Scope? Defining an audit scope sets boundaries for the assessment by requiring organizations to outline anything that could otherwise impact the security of the protected information. Understanding the scope is crucial for both the auditors and the entity being audited, as it sets clear expectations and	What Is an Audit Scope? Defining an audit scope sets boundaries for the assessment by requiring organizations to outline anything that could otherwise impact the security of the protected information. Understanding the scope is crucial for both the auditors and the entity being audited, as it sets clear expectations and	3 Edit

Rows per page: 100 1-2 of 2

4

Via Audit > Study Audit Information Detail

1. Click “Audit Report Observation”, you will be able to see the “Finding” and “Comment” tabs.
2. In this page, you can see the detail breakdown of the audit findings which require Corrective Action and Preventive Action (CAPA). The finding number is labelled as AUD-Fxx.
3. Click the pen icon  to view and edit the details of each finding.
4. After responded to the CAPA, the green tick will appear.

4) How to Draft CAPA

The screenshot shows the 'Finding Detail' page for finding AUD-F01. It includes a description of the finding, a 'Corrective Action Preventive Action' section, and a modal form for entering CAPA details. The modal form has fields for Root Cause, Corrective Action, Preventive Action, and CAPA Implementation Date. A 'Submit' button is visible in the modal. Below the modal, there is an 'Attachment' button and a notification area showing a 'Task Completed' message and an email notification from NHG RQM Study Review (2024-3668) – Overall Audit Closed. The site audit status is shown as 'Closed'.

5. Click “Edit” to start completing the form.

6. Fields marked with*are mandatory for completion.

7. The “Save” button will appear after you click the edit button. Click on “Save” intermittently to ensure the edits have been saved successfully.

8. Site staff can upload supporting document for CAPA. There will be a reminder not to attach document containing personal identifiers.

9. After the CAPA form has been saved for one finding, the user can navigate to next finding to continue drafting CAPA. After CAPA is completed for all findings, the PI can click the “Submit” button to send the CAPA to auditor.

10. The PI will receive an email notification if CAPA is acceptable and when auditor closes the audit.

11. The site audit status changed to “Site Audit Closed”.

5. Click “Edit” to start completing the form.
6. Fields marked with*are mandatory for completion.
7. The “Save” button will appear after you click the edit button. Click on “Save” intermittently to ensure the edits have been saved successfully.
8. Site staff can upload supporting document for CAPA. There will be a reminder not to attach document containing personal identifiers.
9. After the CAPA form has been saved for one finding, the user can navigate to next finding to continue drafting CAPA. After CAPA is completed for all findings, the PI can click the “Submit” button to send the CAPA to auditor.
10. The PI will receive an email notification if CAPA is acceptable and when auditor closes the audit.
11. The site audit status changed to “Site Audit Closed”.

5) How to View and Reply CAPA Query

The screenshot illustrates the process of viewing and replying to a CAPA query. It is divided into six numbered steps:

1. On the main finding detail page, the 'Query List' button is highlighted.
2. The 'Query List' modal window is shown, with the 'Pending Query' tab selected.
3. A specific query item is shown, with the 'Reply Query' input field highlighted.
4. A close-up of the 'Reply Query' input field is shown.
5. The 'Reply Query' button is highlighted.
6. The 'Reply Query' dialog box is shown, with the 'Confirm' button highlighted.

1. If the CAPA is queried by auditor, a **red dot** will appear beside the ‘**Query list**’ button to indicate that there is an action pending (i.e. to address the query).
 2. To **view query(ies)**, click on the “**Query List**” button. A sliding window will appear, where you can view and respond to the query(ies).
 3. Query(ies) are **organised according to the respective sections of the findings**. To address each query that is currently pending response, you will need to **enter your reply under “Pending Query” tab > “Reply Query”**.
 4. You can view all queries under “**All Query**” tab.
 5. Remember to revise the CAPA before clicking “**Reply Query**” to auditor.
 6. Click “**Confirm**” to proceed with reply query.
- Note:** The study team can view the track changes after the CAPA is submitted.

Thank You

Please contact Research Quality (NHGHQ)
researchquality@nhg.com.sg if you have any question
about ECOS Audit module.