

# Navigating Ethics & Compliance Online System (ECOS) User Guide

## Compliance Module: Principal Investigator Self-Assessment Form – Study Closure Checklist (PISAF-SCC)

*[ECOS User Guide – Compliance (PISAF)\_SCC Ver 1, 26 Sep 2024]*

# Contents

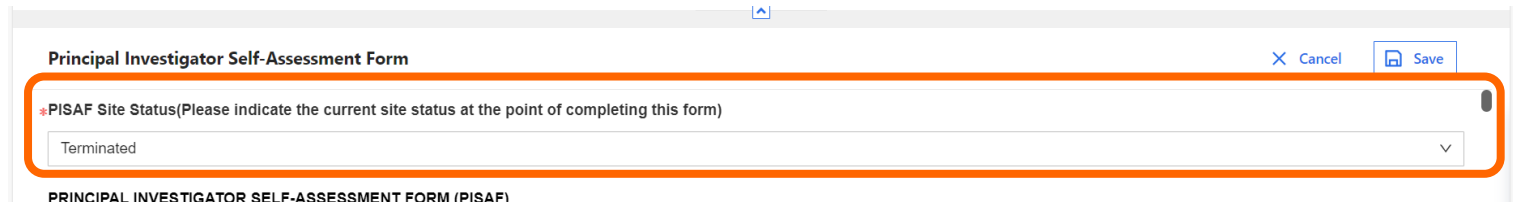
## **Principal Investigator Self-Assessment Form (PISAF) - Study Closure Checklist (SCC) User Guide for:**

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

1. When does the SCC Task occur
2. PISAF-SCC Module General Interface
3. How to Locate the SCC task
4. How to View/ Edit/ Submit the SCC
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6. How to Export the SCC

# 1) When does the SCC Task occur

- The Study Closure Checklist (SCC) provides guidance to the PI/ Site PI, Co-I and study team during study completion.
- Completion of SCC is **required** for NHG researchers with studies monitored under the **NHG Monitoring Programme for HBR studies**.
- The SCC task will be triggered on ECOS when:
  - 1) The PI submits **Study Status Report (SSR)** in the **IRB module** to notify study completion/ termination.
  - 2) The PI reports Study Site Status as **Completed/ Terminated** during the completion of the PISAF.



The screenshot displays a web form titled "Principal Investigator Self-Assessment Form". At the top right, there are "Cancel" and "Save" buttons. The main content area contains a dropdown menu labeled "\*PISAF Site Status(Please indicate the current site status at the point of completing this form)". The dropdown is currently set to "Terminated". Below the dropdown, the text "PRINCIPAL INVESTIGATOR SELF-ASSESSMENT FORM (PISAF)" is visible. An orange rectangular box highlights the dropdown menu and its label.

# 1) PISAF-SCC Module General Interface - Columns

The screenshot shows the ECOS 'Site Task List' interface. On the left is a navigation menu with items like Homepage, IRB, CRMS, Compliance, FCOI, SDB, and Report. The 'Site Task List' item is highlighted. The main area has tabs for 'Deviation/Non Compliance', 'Serious Adverse Event', 'Principal Investigator Self-Assessment Form', and 'Study Closure Checklist'. The 'Study Closure Checklist' tab is active. Below the tabs is a table with columns: Category, ECOS Ref, Study Site, PI/Site PI, Task Status, and Action. The table contains three rows of data. A 'Columns' modal is open, showing a list of columns with checkboxes and drag handles. The 'Clear' button is highlighted with a red box, and the 'Save' button is highlighted with a red box. A green box labeled '1' is around the 'Columns' button in the top right. A green box labeled '2' is around the 'Save' button. A green box labeled '3' is around the 'Clear' button.

Category	ECOS Ref	Study Site	PI/Site PI	Task Status	Action
UAT_3B_unlimited scc auto	2024-3514	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Pending	
UAT_QA_unlimited_scc	2024-3511	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Pending	
UAT_3B_adhocx1_scc auto	2024-3504	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Pending	

**Column Selection Modal:**

- ☒ ECOS Ref
- ☒ Study Site
- ☒ PI/Site PI
- ☒ Department
- ☒ Task Status
- ☒ Date Sent to PI
- ☒ Task Due Date
- ☒ Initial Submission Date
- ☒ Outcome Date
- ☒ PISAF Site Status
- ☒ Form Ref

Buttons: Clear, Cancel, Save

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** and click on “Save”.
3. To reset the columns to its default view, click on “Clear”

# 1) PISAF-SCC Module General Interface – Export Listing

The screenshot shows the ECOS 'Site Task List' interface. The left sidebar has 'Site Task List' highlighted. The main area displays a table of tasks. An 'Export' button is highlighted with a red box and labeled '1'. A dropdown menu is shown below the table, with 'Download Original' and 'Safe Download (PDF)' options highlighted with a red box and labeled '2'.

Category	ECOS Ref	Study Site	PI/Site PI	Department	Task Status	Action
UAT_3B_unlimited scc auto	2024-3514	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	🔍
UAT_QA_unlimited_scc	2024-3511	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	🔍
UAT_3B_adhocx1_scc auto	2024-3504	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	🔍

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.

## Sheet1

### Compliance Site Task - PISAF List

Downloaded By: Dr TTSH\_NewPI1

Downloaded Date and Time: 25-Sep-2024 01:15:26

Category	ECOS Ref	Study Site	PI/Site PI	Department	Task Status	Date Sent to PI
UAT Test reminders	2024-3493	Tan Tock Seng Hospital	Dr TTSH_NewPI1	Geriatric Medicine	Closed with Satisfaction	23-Sep-2024
UAT QA unlimited scc	2024-3503	Tan Tock Seng Hospital	Dr TTSH_NewPI1	Geriatric Medicine	Pending	23-Sep-2024
UAT 3B unlimited scc	2024-3490	Tan Tock Seng Hospital	Dr TTSH_NewPI1	Geriatric Medicine	Closed with Satisfaction	23-Sep-2024

# 1) PISAF Module General Interface – Filter

The screenshot displays the ECOS PISAF Module General Interface. The top navigation bar includes the ECOS logo, a 'Site Task List' tab, and notification icons. The left sidebar contains a menu with options: Homepage, IRB, CRMS, Compliance, Site Task List (highlighted), FCOI, SDB, and Report. The main content area shows a table with columns: Category, ECOS Ref, Study Site, PI/Site PI, Department, Task Status, and Action. The table lists three tasks, all with a status of 'Pending'. A 'Filter(1)' button is visible above the table. A 'Filter' dialog box is open, showing fields for Category, ECOS Ref, Study Site, PI/Site PI, Department, Task Status (with 'Pending' selected), Date Sent to PI, and Task Due Date. The 'Reset' and 'Search' buttons at the bottom of the dialog are highlighted. Numbered callouts 1, 2, and 3 indicate the steps: 1. Click on 'Filter', 2. The default settings for the filter show only pending tasks, and 3. Click on 'Search'.

Category	ECOS Ref	Study Site	PI/Site PI	Department	Task Status	Action
UAT_3B_unlimited scc auto	2024-3514	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	
UAT_QA_unlimited_scc	2024-3511	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	
UAT_3B_adhocx1_scc auto	2024-3504	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	

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/ Queried**). 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.

### 3) Locate your SCC task – via Homepage

ECOS Dashboard

1

2

Compliance 4

- Deviation/Non Compliance - Site 0
- Serious Adverse Event - Site 0
- PI Self-Assessment Form - Site 2
- Study Closure Checklist - Site 2

ECOS My Tasks

3

4

Compliance 4

Study Closure Checklist - Site (2)

Latest Submission Date	Task Status	Form Type	Form Status	Form Ref/Task ID	Study Title	PI/Site-PI	Action
26-Sep-2024	Pending	SCC	Pending	2024-3511-Khoo Teck Puat Hospital-SCC-001	012	Dr KTPH_NewPI1	
25-Sep-2024	Pending	SCC	Pending	2024-3504-Khoo Teck Puat Hospital-SCC-002	005	Dr KTPH_NewPI1	

#### Via Homepage > Dashboard


1. You can locate your outstanding SCC task via “Homepage” > “Dashboard” on the left navigation panel.
2. Locate the “Compliance” tile and click on **Study Closure Checklist - Site**. It will lead you to “My Tasks”.
3. You can also access “Homepage” > “My Task” via the left navigation panel.
4. Click on the “Compliance” tile and locate the sub-tab “Study Closure Checklist - Site”.
5. To view the SCC task, click on “” under the “Action” column.

### 3) Locate your SCC task – via Compliance module

PISAF and Study Closure Checklist (SCC) share the same navigation panel with **Compliance > Deviation/Non Compliance & Serious Adverse Event**.

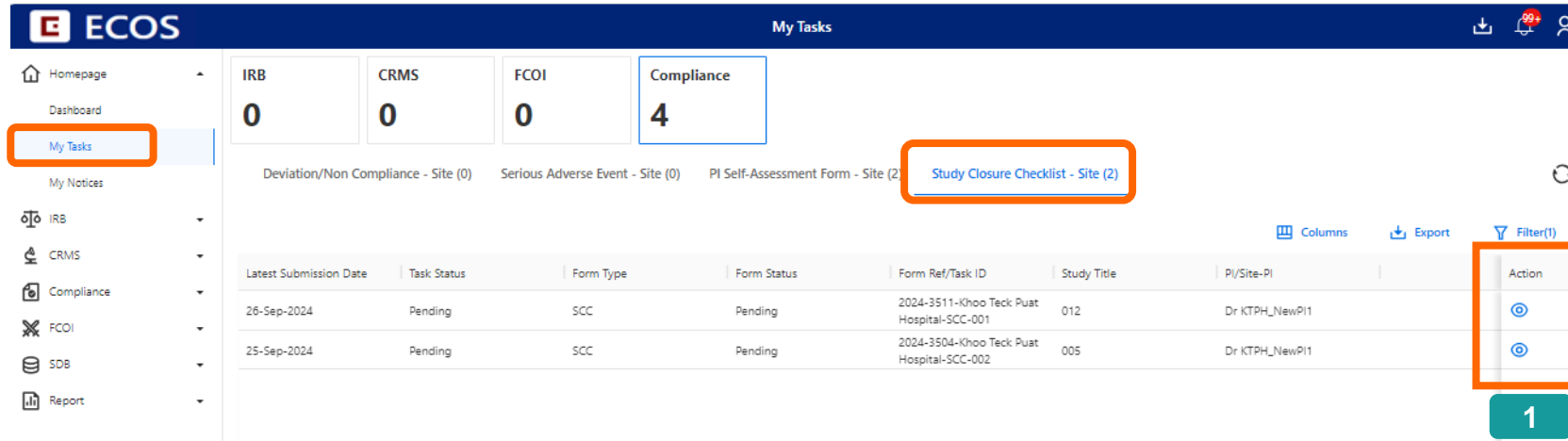


#### Via Compliance > Site Task List

1. You can also locate **all assigned SCC tasks** via “**Compliance > Site Task List**”.
2. Click “**Study Closure Checklist**” sub-header.
3. By default, you will see tasks which are pending your action (**Task Status = Pending/ Queried**).
4. Click on “” view button under the “**Action**” column to view the SCC form.



## 4) How to View/ Edit/ Submit SCC



The screenshot shows the ECOS 'My Tasks' dashboard. The left sidebar has 'My Tasks' highlighted. The top navigation bar shows counts for IRB (0), CRMS (0), FCOI (0), and Compliance (4). Below this, there are tabs for 'Deviation/Non Compliance - Site (0)', 'Serious Adverse Event - Site (0)', 'PI Self-Assessment Form - Site (2)', and 'Study Closure Checklist - Site (2)'. The 'Study Closure Checklist - Site (2)' tab is selected. A table lists tasks with columns: Latest Submission Date, Task Status, Form Type, Form Status, Form Ref/Task ID, Study Title, and PI/Site-PI. Two rows are visible, both with 'Pending' status and 'SCC' form type. The 'Action' column for each row contains a 'View' icon (an eye). A red box highlights the 'View' icon in the first row, and a red circle with the number '1' is placed below it.


Latest Submission Date	Task Status	Form Type	Form Status	Form Ref/Task ID	Study Title	PI/Site-PI	Action
26-Sep-2024	Pending	SCC	Pending	2024-3511-Khoo Teck Puat Hospital-SCC-001	012	Dr KTPH_NewPI1	
25-Sep-2024	Pending	SCC	Pending	2024-3504-Khoo Teck Puat Hospital-SCC-002	005	Dr KTPH_NewPI1	

**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 edit the SCC.

By default, only the PI can submit the form.



Locate the SCC task through the methods described in Section 3.

1. Click on the  **View** button under “**Action**” column to edit the SCC Form.

You will arrive at **Site Task Detail** page.

## 4) How to View/ Edit/ Submit SCC

The screenshot shows the 'Site Task Detail' page for SCC form 2024-3511-Khoo Teck Puat Hospital-SCC-001. The interface includes a top navigation bar, a main content area with a 'Form History' table, and a 'Study Closure Checklist' section. Numbered callouts highlight key features: 1. The SCC Form reference number in the top bar. 2. The 'Pending' status label and its icon. 3. The 'Quick Link: Study Summary, CRMS' text. 4. The 'Edit' button in the top right corner.

**1** Back to Site Task List

**2024-3511-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital** **Pending** **2** **Submit**

ECOS Ref: 2024-3511

PI/Site PI: Dr KTPH\_NewPI1 Last Updated By: - Initial Submission Date: -

Current Editor: -

Study Title: 012

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

**4** **Edit**

**Form History**

SCC sent to PI.	System	26-Sep-2024 09:58:41
SCC task created.	A/Prof NHG_PISAF_2	26-Sep-2024 09:40:53

**Study Closure Checklist**

**STUDY CLOSURE CHECKLIST (SCC)**

**1.DATA**

\*1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.

☐ Yes

☐ NA

**1.1 Comments:**

1. This is the SCC Form reference no.
2. The label indicates the task status of the SCC. Next to label is the “**Form History**” icon. You can click on the icon to view form history.
3. These quick links will bring you to **IRB Module - Study Summary** and **Clinical Research Management System (CRMS)** information.
4. Click on “**Edit**” to start completing the form.

## 4) How to View/ Edit/ Submit SCC

**Site Task Detail**

2024-3511-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital Pending 🔍 Submit

ECOS Ref: 2024-3511 🔍

PI/Site PI: Dr KTPH\_NewPI1 Last Updated By: - Initial Submission Date: -

Current Editor: -

Study Title: 012

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

**Study Closure Checklist** Cancel Save

**STUDY CLOSURE CHECKLIST (SCC)** 1

1.DATA

\*1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.

☐ Yes

☐ NA

1.1 Comments:

0 characters entered

**Site Task Detail**

2024-3511-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital Pending 🔍 Submit

ECOS Ref: 2024-3511 🔍

PI/Site PI: Dr KTPH\_NewPI1 Last Updated By: Dr KTPH\_NewPI1 Initial Submission Date: -

Current Editor: -

Study Title: 012

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

**Study Closure Checklist** Export Edit Track Changes

**STUDY CLOSURE CHECKLIST (SCC)**

1.DATA

\*1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.

☒ Yes

☐ NA

1.1 Comments:

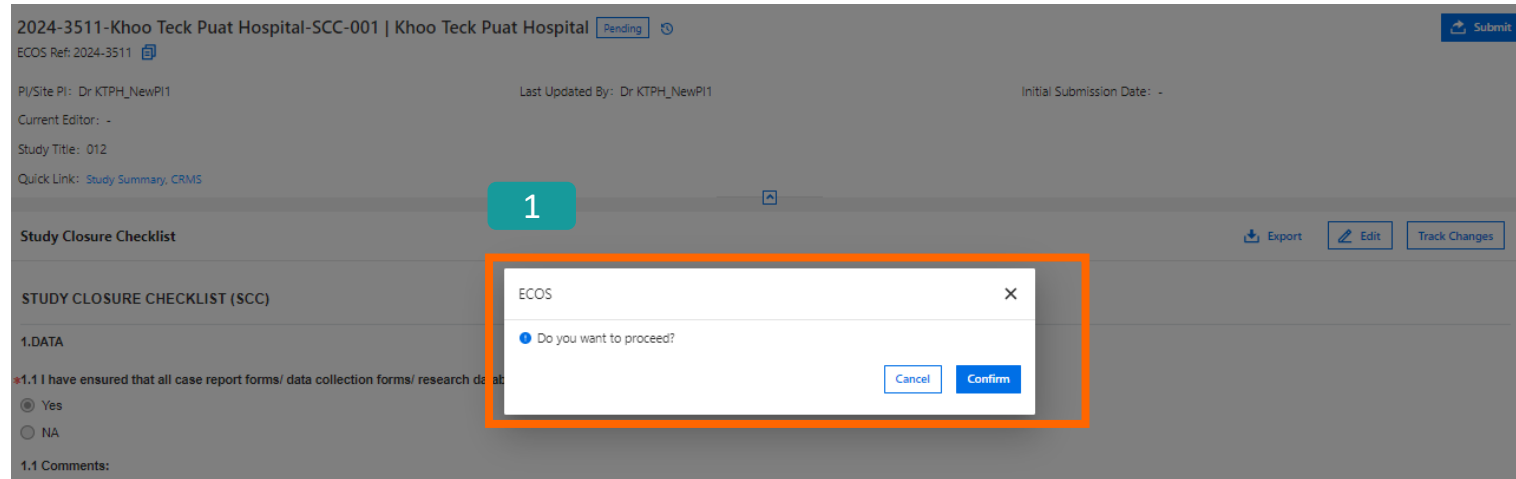
1. Scroll down to complete the rest of the SCC form. Fields marked with \* are mandatory for completion.

2. Click on “**Save**” to ensure the edits have been saved successfully.

3. After the form has been saved, the “**Submit**” button will be enabled (color change from grey to blue).

4. By default, **only the PI** can be able to see and click on the “**Submit**” button. Co-I and active STM listed in CRMS UAL can **only view and edit** the SCC.

## 4) How to View/ Edit/ Submit SCC



The screenshot shows the 'Site Task Detail' page for '2024-3511-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital'. The status is 'Pending'. A blue 'Submit' button is in the top right. A teal box with the number '1' highlights a white pop-up window titled 'ECOS' with the question 'Do you want to proceed?' and 'Cancel' and 'Confirm' buttons.

2024-3511-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital Pending Submit

ECOS Ref: 2024-3511

PI/Site PI: Dr KTPH\_NewPI1 Last Updated By: Dr KTPH\_NewPI1 Initial Submission Date: -

Current Editor: -

Study Title: 012

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

Study Closure Checklist

STUDY CLOSURE CHECKLIST (SCC)

1.DATA

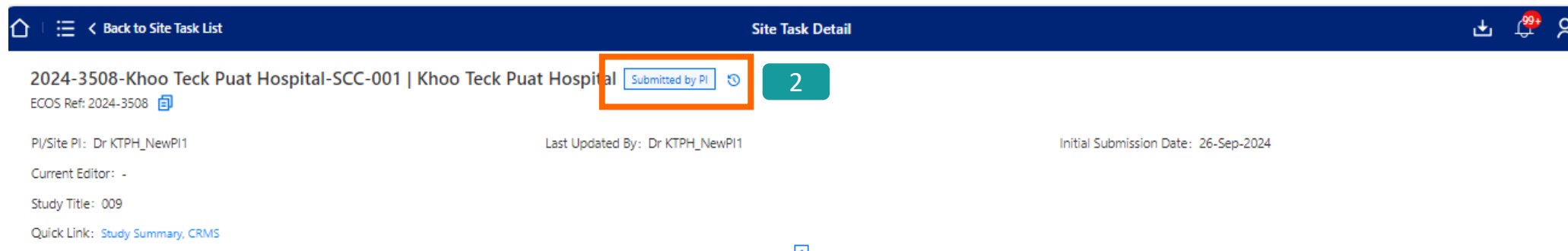
1.1 I have ensured that all case report forms/ data collection forms/ research data

☒ Yes

☐ NA

1.1 Comments:

1. After the PI clicks on the “**Submit**” button, a **pop-up window** will appear for the user’s confirmation to proceed with the task. Click on “**Confirm**” to proceed or “**Cancel**” to return to the Site Task detail page.
2. Click “**Confirm**” to proceed with the submission. The label will be changed from “**Pending**” to “**Submitted By PI**”. The form **cannot** be edited further.
3. An email notification will be triggered after the SCC has been submitted. The task is now with the PISAF Reviewer to complete the review.



The screenshot shows the 'Site Task Detail' page for '2024-3508-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital'. The status is now 'Submitted by PI'. A teal box with the number '2' highlights the 'Submitted by PI' label.

2024-3508-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital Submitted by PI 2

ECOS Ref: 2024-3508

PI/Site PI: Dr KTPH\_NewPI1 Last Updated By: Dr KTPH\_NewPI1 Initial Submission Date: 26-Sep-2024

Current Editor: -

Study Title: 009

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

## 4) How to View/ Edit/ Submit SCC

Site Task Detail

2024-3509-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital

ECOS Ref: 2024-3509

PI/Site PI: Dr KTPH\_NewPI1

Last Updated By: Dr KTPH\_NewPI1

Initial Submission Date: 23-Sep-2024

Current Editor: -

View Comment: [View](#)

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

Study Closure Checklist

Export Track Changes Query List

STUDY CLOSURE CHECKLIST (SCC)

1. The PISAF reviewer will endorse the SCC if there is no query or all queries have been adequately addressed by the PI/ Study Team.
2. Click on “**View**” to see the comment from the PISAF reviewer (if any).

## 4) How to View/ Reply to Query

Latest Submission Date	Task Status	Form Type	Form Status	Form Ref/Task ID	Study Title	PI/Site-PI	Action
26-Sep-2024	Pending	SCC	Queried	2024-3508-Khoo Teck Puat Hospital-SCC-001	009	Dr KTRH_NewPI1	[Red Dot]
26-Sep-2024	Pending	SCC	Pending	2024-3511-Khoo Teck Puat Hospital-SCC-001	012	Dr KTRH_NewPI1	[Blue Dot]
25-Sep-2024	Pending	SCC	Pending	2024-3504-Khoo Teck Puat Hospital-SCC-002	005	Dr KTRH_NewPI1	[Blue Dot]

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

By default, only the PI can re-submit/reply query to the PISAF reviewer.

1. Locate the SCC task from Home page or Compliance module. The status of the form will be reflected as **“Queried”**. Click on **“View”** button to enter **Site Task detail** page to view the SCC.
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). A **red dot** indicates that there is an action pending (i.e. to address the query).
3. Query(ies) are organised according to the respective sections of the SCC. 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 throughout the review under **“All Query”** tab.
5. Query response will be **auto-saved**. Click on the background page, **Site Task Detail**, to close the sliding window.
6. Where needed, you will also need to make the edits onto the form directly. Click on **“Edit”** to make the changes and **“Save”**.
7. When all the query(ies) have been **answered**, the red dot indicator will disappear.
8. The **“Reply Query”** button appears at the top of the form.

## 4) How to View/ Reply to Query

The screenshot shows the 'Site Task Detail' page for a study task. The task is titled '2024-3508-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital' and has a status of 'Queried'. The page includes a 'Study Closure Checklist' section. A 'Track Changes' button is highlighted with a red box and labeled '1'. A 'Reply Query' button is highlighted with a red box and labeled '2'. A 'Track Changes' pop-up window is shown with a red box and labeled '3'. The pop-up window displays a list of queries and a 'Reply Query' form. The 'Track Changes' button is also highlighted with a red box and labeled '1'.

1. If changes were made to the SCC, you can see the **prior changes** when you click on the “Track Changes” function.
2. Co-I and active STM listed in CRMS UAL can reply to query, but **only the PI can re-submit the form/ reply query**. Click on “Reply Query” button.

A confirmation pop-up window will appear with the list of query replies. Click “Confirm” to proceed or “Cancel” to return to Site Task Detail page.

3. The label will be changed from “Queried” to “Submitted By PI”. The form **cannot** be edited further.
4. An email notification will be triggered after the SCC has been submitted. The task is now with the PISAF Reviewer to review the query response.

## 6) How to Export the SCC

The screenshot shows the 'Site Task Detail' page for '2024-3509-Khoo Teck Puat Hospital-SCC-001'. The page includes a header with navigation links and a sidebar with a 'Study Closure Checklist' section. The main content area displays the 'STUDY CLOSURE CHECKLIST (SCC)' with a table containing one row for '1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.' The table has columns for 'Yes', 'NA', and 'Comments'. The 'Yes' column has a radio button selected. The 'NA' column has a radio button. The 'Comments' column is empty. The table is followed by a '1.1 Comments:' section. The 'Export' button is highlighted with a red box and labeled '1'. The 'Download List' button is highlighted with a red box and labeled '2'. The 'Download To Local' button is highlighted with a red box and labeled '3'.

Site Task Detail

2024-3509-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital Endorsed

ECOS Ref: 2024-3509

PI/Site PI: Dr KTPH\_NewPI1 Last Updated By: Dr KTPH\_NewPI1 Initial Submission Date: 23-Sep-2024

Current Editor: -

View Comment: [View](#)

Study Title: 010

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

Study Closure Checklist

STUDY CLOSURE CHECKLIST (SCC)

1.DATA
<p>1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.</p> <p><input checked="" type="radio"/> Yes</p> <p><input type="radio"/> NA</p> <p>1.1 Comments:</p>

1.1 Comments:

Export Track Changes Query List

Download List (1) Delete All

NHG CAT 3B SCC2024-3509-Khoo Teck Puat Hospital-SCC-001.pdf 99.10 KB Delete Download To Local

1. To export a copy of the SCC for record keeping, click on “**Export**”.
2. The “**Download List**” will appear at the bottom of the browser.
3. When the export is complete, click “**Download To Local**”. The PDF copy of the form will be saved to your computer local drive.





# Thank You

Please contact Research Quality (NHGHQ)  
[researchquality@nhg.com.sg](mailto:researchquality@nhg.com.sg) if you have any question  
about ECOS Compliance (PISAF-SCC) module.