

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

# 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
5. How to View/ Reply to Query
6. How to Export the SCC

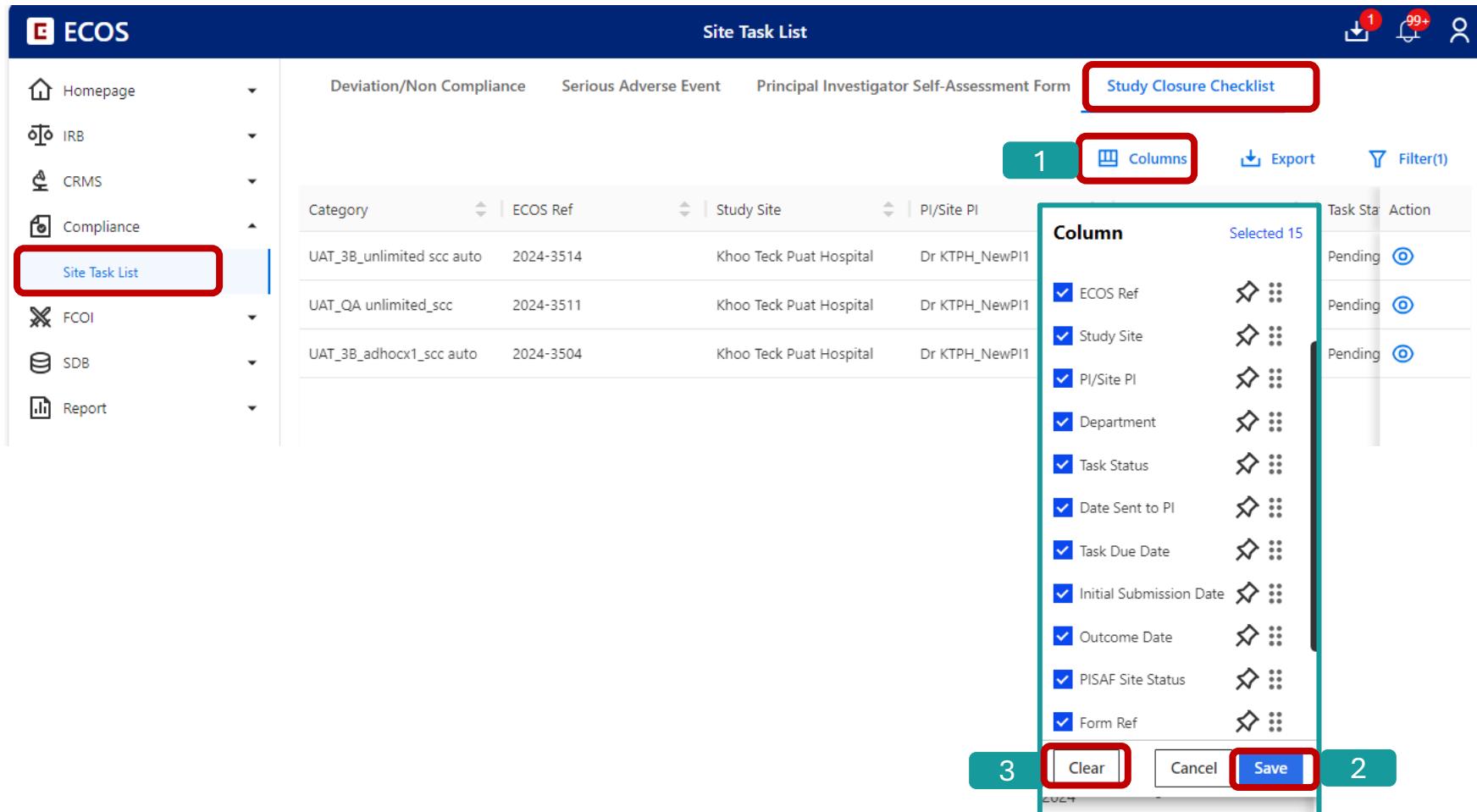
## 1) When does the SCC Task occur

- 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 image shows a screenshot of a web-based form titled "Principal Investigator Self-Assessment Form". At the top right are "Cancel" and "Save" buttons. The main content area contains a question: "\*PISAF Site Status (Please indicate the current site status at the point of completing this form)". Below this is a dropdown menu with the option "Terminated" selected. The entire "Site Status" input field is highlighted with a thick red border. At the bottom of the form is the text "PRINCIPAL INVESTIGATOR SELF-ASSESSMENT FORM (PISAF)".

# 1) PISAF-SCC Module General Interface - Columns



The screenshot shows the ECOS Site Task List interface. On the left, a sidebar lists various modules: Homepage, IRB, CRMS, Compliance, Site Task List (which is selected and highlighted with a red box), FCOI, SDB, and Report. The main content area is titled "Site Task List" and shows a table with three rows of data. The columns are: Category, ECOS Ref, Study Site, and PI/Site PI. A red box highlights the "Study Closure Checklist" button in the top right. A modal dialog box is open, titled "Columns", with the number "1" above it. This dialog lists "Selected 15" columns with checkboxes: 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, and Form Ref. Each column has a "Move" icon (a horizontal arrow inside a box) to its right. The dialog has three buttons at the bottom: "Clear" (red box), "Cancel", and "Save" (red box). The number "2" is to the right of the "Save" button, and the number "3" is to the left of the "Clear" button.

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 PISAF-SCC Module General Interface. The left sidebar includes links for Homepage, IRB, CRMS, Compliance, Site Task List (highlighted with a red box), FCOI, SDB, and Report. The main content area is titled 'Site Task List' and shows a table with columns: Category, ECOS Ref, Study Site, PI/Site PI, Department, Task Status, and Action. The table contains three rows of data. At the top right of the table is a 'Study Closure Checklist' button, a 'Columns' button, an 'Export' button (highlighted with a red box and a green number '1'), and a 'Filter(1)' button. A green arrow points from the 'Export' button to a modal dialog box labeled '2' at the bottom right. The dialog box contains two options: 'Download Original' (with a file icon) and 'Safe Download (PDF)' (with a PDF icon). Below the table is a preview of the 'Sheet1' Excel file, which shows the same data structure with three rows of data. The preview includes the title 'Compliance Site Task - PISAF List', download information ('Downloaded By: Dr TTSH\_NewPI1' and 'Downloaded Date and Time: 25-Sep-2024 01:15:26'), and the table data.

| 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. 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.

# 1) PISAF Module General Interface – Filter

The screenshot shows the ECOS PISAF Module General Interface. The top navigation bar includes 'Site Task List' (highlighted with a red box), 'Study Closure Checklist' (highlighted with a red box), and a 'Filter(1)' button (highlighted with a red box). The main content area displays a table of tasks with columns: Category, ECOS Ref, Study Site, PI/Site PI, and Department. The table shows three rows of data. A 'Filter' dialog box is overlaid on the table, containing fields for Category, ECOS Ref, Study Site, PI/Site PI, Department, Task Status (with 'Pending' and 'Queried' selected), Date Sent to PI (with 'Start Date' and 'End Date' fields), and Task Due Date. The 'Reset' and 'Search' buttons at the bottom of the dialog are also highlighted with red boxes. The left sidebar contains links for 'Homepage', 'IRB', 'CRMS', 'Compliance' (highlighted with a red box), 'FCOI', 'SDB', and 'Report'.

| Category                  | ECOS Ref  | Study Site              | PI/Site PI     | Department  |
|---------------------------|-----------|-------------------------|----------------|-------------|
| UAT_3B_unlimited_scc auto | 2024-3514 | Khoo Teck Puat Hospital | Dr KTPH_NewPI1 | Anaesthesia |
| UAT_QA unlimited_scc      | 2024-3511 | Khoo Teck Puat Hospital | Dr KTPH_NewPI1 | Anaesthesia |
| UAT_3B_adhocx1_scc auto   | 2024-3504 | Khoo Teck Puat Hospital | Dr KTPH_NewPI1 | Anaesthesia |

Filter Dialog:

- Category:
- ECOS Ref:
- Study Site:
- PI/Site PI:
- Department :
- Task Status:
  - Pending
  - Queried
- Date Sent to PI:
  - Start Date
  - End Date
- Task Due Date:

Buttons at the bottom of the dialog:

- Reset
- Search

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

CRMS 0

FCOI 0

My Tasks

Study Member Review 0

My FCOI List 0

Study 0

Endorsement 0

IRB

CRMS

Compliance

FCOI

SDB

Report

Compliance

2

Deviation/Non Compliance - Site 0

Serious Adverse Event - Site 0

PI Self-Assessment Form - Site 2

Study Closure Checklist - Site 4

ECOS

Homepage

Dashboard

3

My Tasks

My Notices

IRB 0

CRMS 0

FCOI 0

Compliance 4

Deviation/Non Compliance - Site (0)

Serious Adverse Event - Site (0)

PI Self-Assessment Form - Site (2)

Study Closure Checklist - Site (2)

Columns Export Filter(1)

| Latest Submission Date | Task Status | Form Type | Form Status | Form Ref/Task ID                          | Study Title | PI/Site-PI     |
|------------------------|-------------|-----------|-------------|---|-------------|----------------|
| 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 |

Action

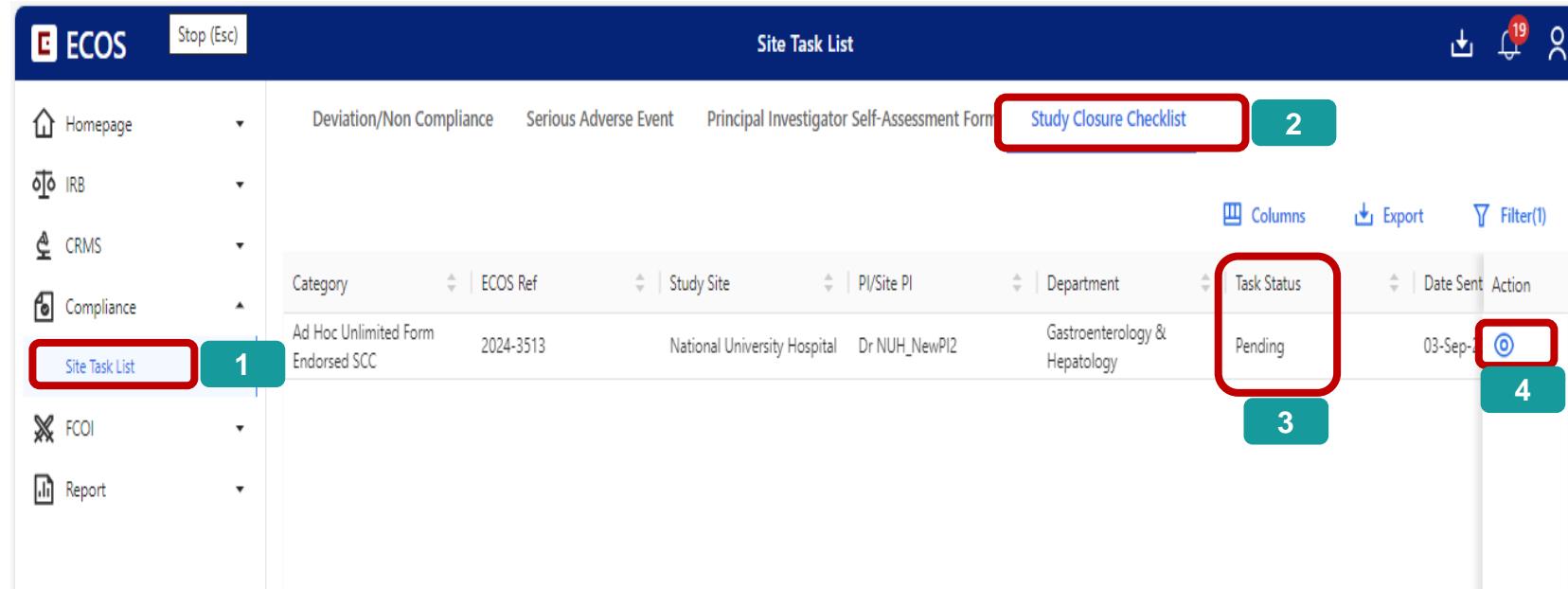
4

#### 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 “

Restricted, Sensitive - Normal

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



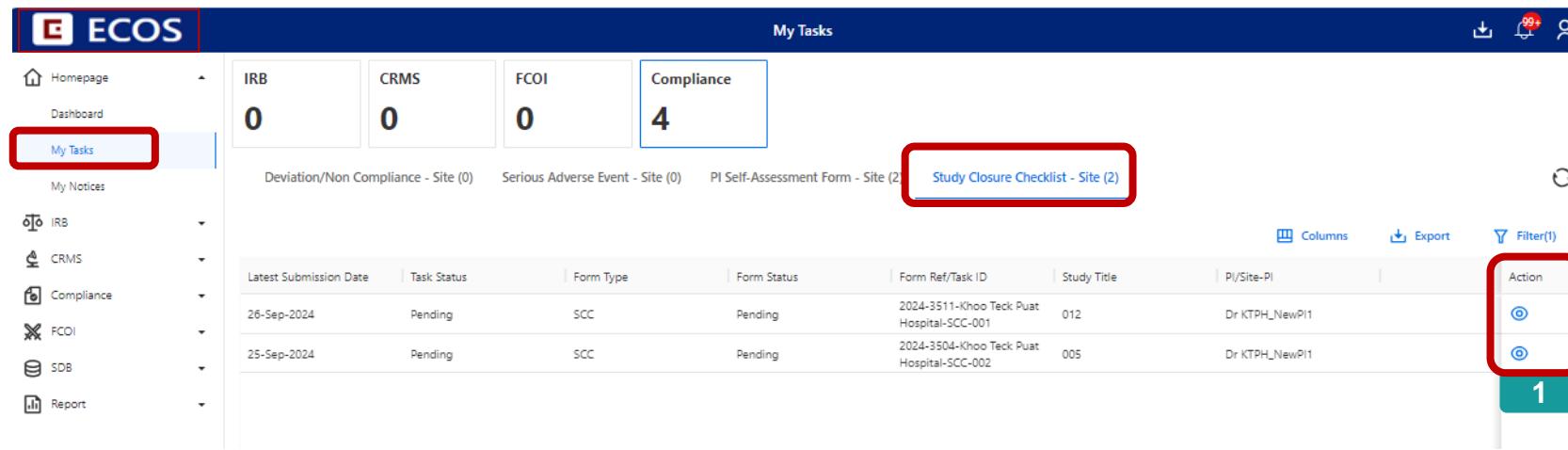
The screenshot shows the ECOS Site Task List interface. The left sidebar has a 'Compliance' section with 'Site Task List' selected, indicated by a red box and the number '1'. The main area is titled 'Site Task List' and shows a table of tasks. The table has columns: Category, ECOS Ref, Study Site, PI/Site PI, Department, Task Status, Date Sent, and Action. A task in the 'Pending' status is highlighted with a red box and the number '3'. The 'Action' column for this task contains a blue 'View' button with a circular icon, highlighted with a red box and the number '4'. The top navigation bar includes links for Deviation/Non Compliance, Serious Adverse Event, and Principal Investigator Self-Assessment Form, along with a 'Study Closure Checklist' sub-header, which is also highlighted with a red box and the number '2'.

**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



ECOS

My Tasks

Homepage Dashboard My Tasks My Notices

IRB CRMS FCOI Compliance

0 0 0 4

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

Columns Export Filter(I)

| 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 |  |

1

**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 an SCC form. The page has a dark header with a 'Back to Site Task List' button (1) and a title '2024-3511-Khoo Teck Puat Hospital-SCC-001 | Khoo Teck Puat Hospital' with a 'Pending' status (2). Below the header, there are sections for 'PI/Site PI', 'Current Editor', and 'Study Title'. A 'Quick Link' box (3) contains 'Study Summary, CRMS' and 'Study Closure Checklist'. The main content area shows 'Form History' with two entries: 'SCC sent to PI, System' on 26-Sep-2024 09:58:41 and 'SCC task created, A/Prof NHG\_PISAF\_2' on 26-Sep-2024 09:40:53. An 'Edit' button (4) is located in the top right corner of the history box.

1 Back to Site Task List

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

ECOS Ref: 2024-3511

PI/Site PI: Dr KTPH\_NewPI

Current Editor: -

Study Title: -012

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

3

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:

4

Form History

SCC sent to PI, System 26-Sep-2024 09:58:41

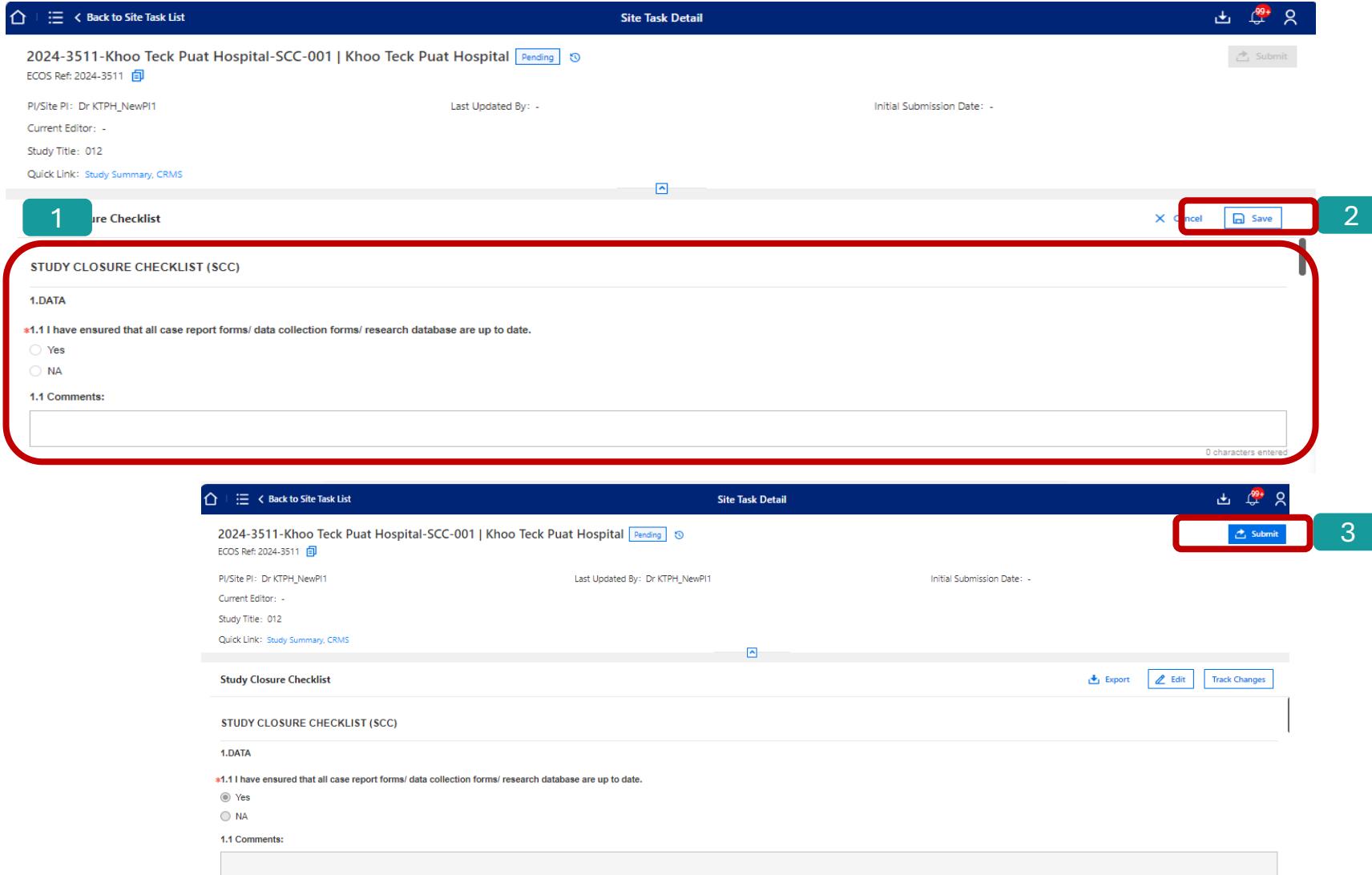
SCC task created, A/Prof NHG\_PISAF\_2 26-Sep-2024 09:40:53

Export

Edit

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] 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

**1** Study Closure Checklist

**2** Save

**3** Submit

**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:

0 characters entered

**STUDY CLOSURE CHECKLIST (SCC)**

**1. DATA**

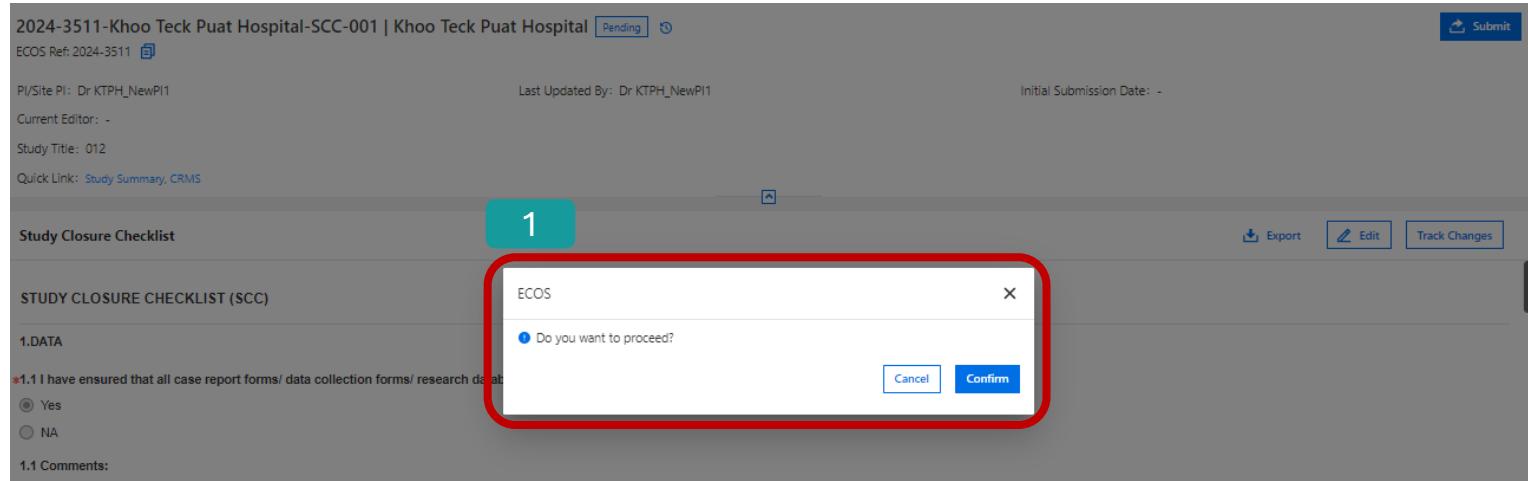
\*1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.

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**.

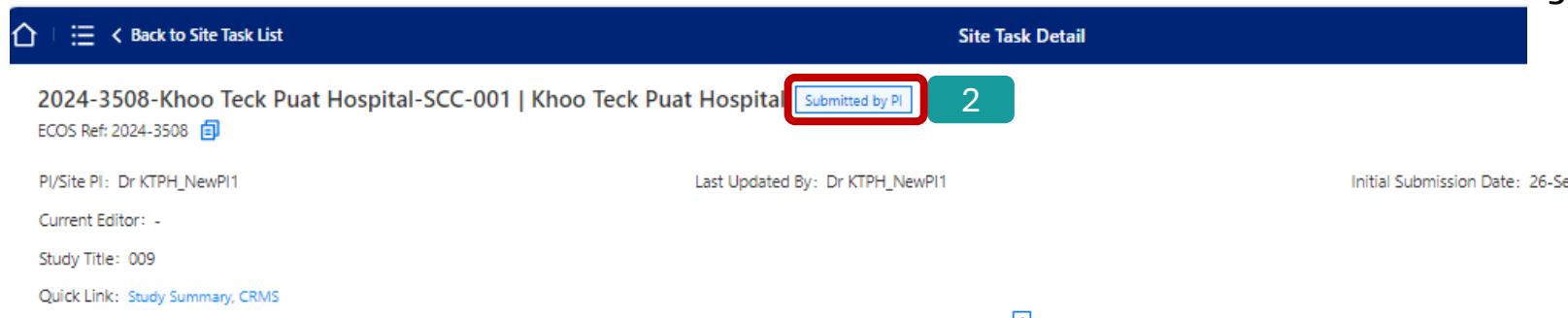
## 4) How to View/ Edit/ Submit SCC



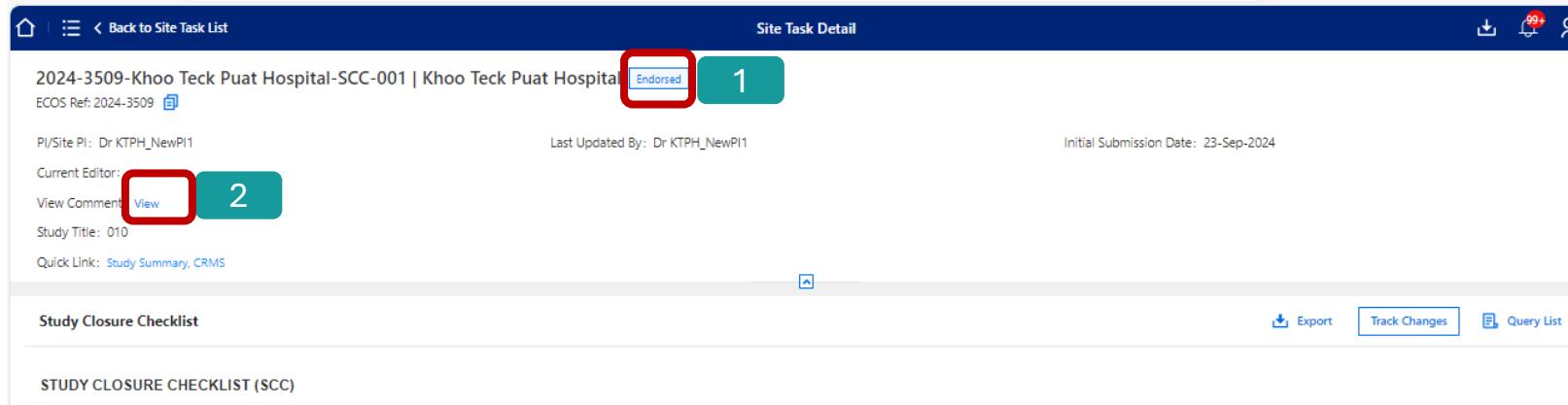
1. After the PI clicks on the “Submit” button, a **pop-up window** will appear for the user’s confirmation to proceed with the task. Click on “Confirm” to proceed or “Cancel” to return to the Site Task detail page.

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.



## 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

Current Editor:

View Comment **View**

Study Title: 010

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

Initial Submission Date: 23-Sep-2024

1

2

Study Closure Checklist

STUDY CLOSURE CHECKLIST (SCC)

Export Track Changes Query List

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

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 illustrates the workflow for viewing and replying to a query. It consists of three main panels:

- Panel 1:** A 'Site Task Detail' page. At the top right, there is a 'Reply Query' button (labeled 2). Below the main content, there is a 'Track Changes' button (labeled 1) highlighted with a red box.
- Panel 2:** A 'Reply Query' confirmation dialog box. It contains a list of query items and a 'Do you want to proceed?' checkbox. A green arrow points from the 'Reply Query' button in Panel 1 to this dialog.
- Panel 3:** A 'Site Task Detail' page showing the status has been updated to 'Submitted by PI' (labeled 3). The 'Reply Query' button is also highlighted with a red box.

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 a specific study. At the top, the study ID is 2024-3509-Khoo Teck Puat Hospital-SCC-001, and the status is 'Endorsed'. Below this, there are details like PI/Site PI: Dr KTPH\_NewPI1, Last Updated By: Dr KTPH\_NewPI1, and Initial Submission Date: 23-Sep-2024. The main content area is titled 'Study Closure Checklist' and contains a section for 'STUDY CLOSURE CHECKLIST (SCC)'. Under '1.DATA', there is a question: '1.1 I have ensured that all case report forms/ data collection forms/ research database are up to date.' with 'Yes' and 'NA' options. Below this is a '1.1 Comments:' section. At the top right of the page, there are three icons: a download (with a red '1' over it), a bell (with a red '99+' over it), and a magnifying glass. A modal window titled 'Download List (1)' is open, showing a single file: 'NHG CAT 3B SCC2024-3509-Khoo Teck Puat Hospital-SCC-001.pdf' (99.10 KB). The 'Download To Local' button is highlighted with a red box and a red '3' over it.

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.

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.



# 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