

ECOS User Guide: Compliance Module - Principal Investigator Self-Assessment Form (PISAF)

Contents

Principal Investigator Self-Assessment Form (PISAF) User Guide for: Principal Investigator (PI) / Site Principal Investigator (Site PI)/ Co-Investigator (Co-I) and Study Team Member (STM)

1. PISAF Module General Interface
2. How to Locate the PISAF task
3. How to View/ Edit/ Submit the PISAF
4. How to View/ Reply to Query
5. How to Export the PISAF

1) PISAF Module General Interface - Columns

The screenshot shows the eSitePro PISAF 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 header has tabs for Deviation/Non Compliance, Serious Adverse Event, Principal Investigator Self-Assessment Form (highlighted with a red box), and Study Closure Checklist. The 'Principal Investigator Self-Assessment Form' tab is active. A 'Columns' button (number 1) is highlighted with a red box. A 'Columns' configuration dialog is open, showing a list of columns with checkboxes and a 'Selected 15' label. The columns listed are: 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 'Selected' checkbox and a 'Move' icon. The dialog has 'Clear', 'Cancel', and 'Save' buttons at the bottom, with 'Save' highlighted with a red box. The main table below shows three rows of task data: Dr TTSH_NewPI1 (2024-3493, UAT_Test reminders, Tan Tock Seng H), Dr TTSH_NewPI1 (2024-3503, UAT_QA unlimited_scc, Tan Tock Seng H), and Dr TTSH_NewPI1 (2024-3490, UAT_3B_unlimited scc, Tan Tock Seng H).

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 Module General Interface – Export Listing

The screenshot shows the eSitePro interface for the PISAF Module. The top navigation bar includes 'Site Task List', '99+', and a user icon. The left sidebar has links for 'Homepage', 'IRB', 'CRMS', 'Compliance', 'Site Task List' (which is highlighted with a red box), 'FCOI', 'SDB', and 'Report'. The main content area shows a table titled 'Principal Investigator Self-Assessment Form' with columns: PI/Site PI, ECOS Ref, Category, Study Site, Department, Task Status, and Action. Three rows of data are listed. At the top of the table are buttons for 'Columns', 'Export' (which is highlighted with a red box), and 'Filter'. A callout '1' points to the 'Export' button. A callout '2' points to a modal dialog box with 'Download Original' and 'Safe Download (PDF)' options. A red box at the bottom highlights the 'Sheet1' tab of the download, which contains a table titled 'Compliance Site Task - PISAF List' with columns: Category, ECOS Ref, Study Site, PI/Site PI, Department, Task Status, and Date Sent to PI. The table data matches the entries in the main table.

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 eSitePro PISAF Module General Interface. The top navigation bar includes 'Site Task List' (highlighted with a red box), 'Principal Investigator Self-Assessment Form' (highlighted with a red box), and a 'Filter' button (highlighted with a red box and labeled '1'). The left sidebar has a 'Site Task List' button highlighted with a red box. The main content area displays a table of tasks with columns: PI/Site PI, ECOS Ref, Category, Study Site, Department, and Task Status. A 'Filter' dialog box is open, containing fields for Category, ECOS Ref, Study Site, PI/Site PI, Department, Task Status (set to 'Pending' and 'Queried'), Date Sent to PI, Task Due Date, and a 'Reset' button (highlighted with a red box and labeled '2'). A 'Search' button (highlighted with a red box and labeled '3') is located at the bottom right of the filter dialog.

PI/Site PI	ECOS Ref	Category	Study Site	Department	Task Status
Dr TTSH_NewPI1	2024-3493	UAT_Test reminders	Tan Tock Seng Hospital	Geriatric	Pending
Dr TTSH_NewPI1	2024-3503	UAT_QA unlimited_scc	Tan Tock Seng Hospital	Geriatric	Queried
Dr TTSH_NewPI1	2024-3490	UAT_3B_unlimited scc	Tan Tock Seng Hospital	Geriatric	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.

2) Locate your PISAF task – via Homepage

ECOS

Dashboard

1

IRB 0

CRMS 0

FCOI 0

My Notices

View All >

- Service Disruption Broadcast Message 03-Jun-2024
- Service Disruption Broadcast Message 31-May-2024
- Service Disruption Broadcast Message 27-May-2024
- Service Disruption Broadcast Message 23-May-2024
- Service Disruption Broadcast Message 15-May-2024

Compliance

2

3

Deviation/Non Compliance - Site

Serious Adverse Event - Site

PI Self-Assessment Form - Site

Study Closure Checklist - Site

0 0 3 0

ECOS

My Tasks

74

IRB 0

CRMS 0

FCOI 0

Compliance 2

4

PI Self-Assessment Form - Site (2)

Study Closur >

Columns Export Filter(1)

Form Type	Form Ref/Task ID	Study Title	PI/Site-PI	Latest Submission Date	Task Status	Action
PISAF	2024-3504/Khoo Teck Puat Hospital/PISAF/001	005	Dr KTPH_NewPI1	02-Sep-2024	Pending	5
PISAF	2024-3508/Khoo Teck Puat Hospital/PISAF/001	009	Dr KTPH_NewPI1	02-Sep-2024	Pending	

My Tasks

3

My Notices

74

IRB

CRMS

Compliance

FCOI

Report

Via Homepage > Dashboard

1. You can locate your outstanding PISAF task via “Homepage” > “Dashboard” on the left navigation panel.
2. Locate the “Compliance” tile and click on “PI Self-Assessment Form - 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 “PI Self-Assessment Form - Site”.
5. To view the PISAF task, click on  under the “Action” column.

2) Locate your PISAF task – via Compliance module

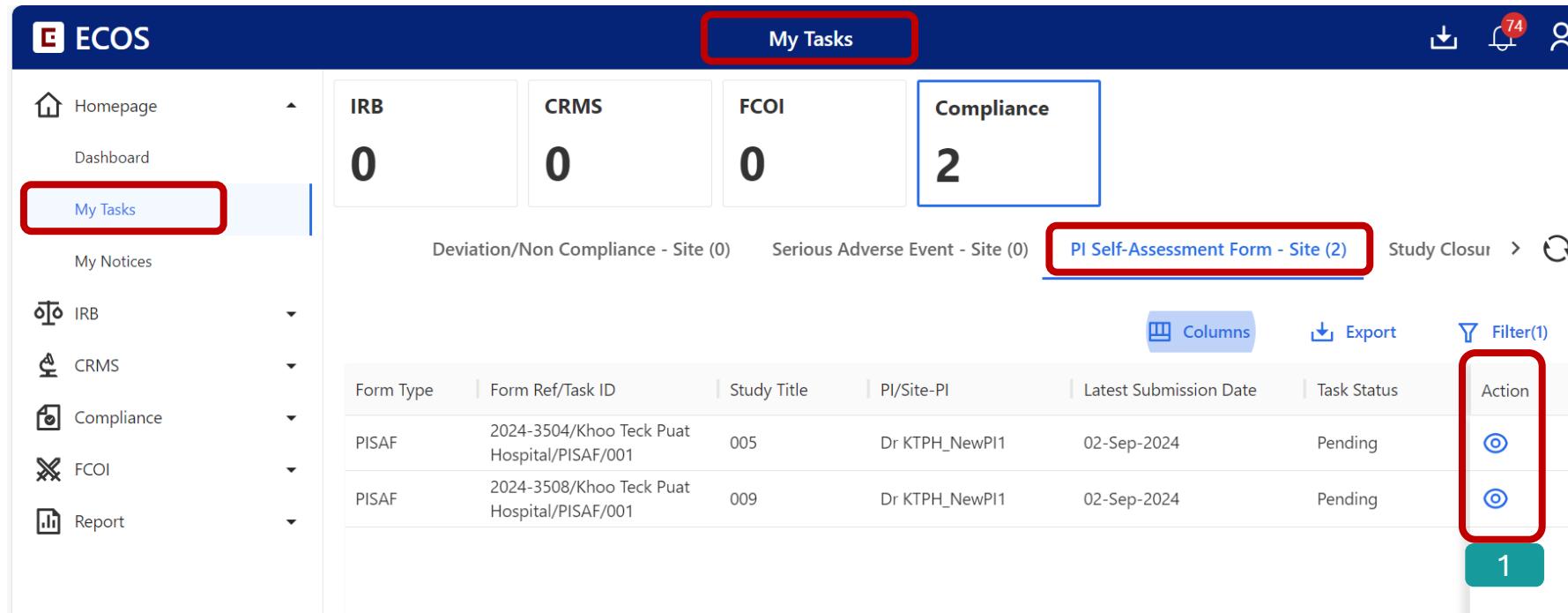
PISAF and Study Closure Checklist (SCC) share the same navigation panel with Compliance > Deviation/Non Compliance & Serious Adverse Event.

Only selected PIs will need to complete the SCC.

Via Compliance > Site Task List

1. You can also locate **all assigned PISAF tasks** via “**Compliance > Site Task List**”.
2. Click “**PI Self-Assessment Form**” sub-header.
3. By default, you will see tasks which are pending your action (**Task Status = Pending/Queried**).
4. The list is sorted by **Task Due Date** (latest to oldest).
5. Click on “” view button under the “**Action**” column to view the PISAF form.

3) How to View/ Edit/ Submit PISAF



The screenshot shows the ECOS platform interface. The top navigation bar includes the ECOS logo, a search bar, and user icons. The main menu on the left has 'My Tasks' highlighted with a red box. The dashboard summary shows 0 IRB, 0 CRMS, 0 FCOI, and 2 Compliance tasks. Below this, a table lists PISAF tasks with columns: Form Type, Form Ref/Task ID, Study Title, PI/Site-PI, Latest Submission Date, and Task Status. The table shows two entries: one for study 005 and one for study 009, both pending. The 'Action' column for the second row is highlighted with a red box. A note at the bottom left states that only the PI can submit the form.

Form Type	Form Ref/Task ID	Study Title	PI/Site-PI	Latest Submission Date	Task Status
PISAF	2024-3504/Khoo Teck Puat Hospital/PISAF/001	005	Dr KTPH_NewPI1	02-Sep-2024	Pending
PISAF	2024-3508/Khoo Teck Puat Hospital/PISAF/001	009	Dr KTPH_NewPI1	02-Sep-2024	Pending

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 PISAF.

By default, only the PI can submit the form.

Locate the PISAF task through the methods described in Section 2.

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

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

3) How to View/ Edit/ Submit PISAF

The screenshot shows the 'Site Task Detail' page for a PISAF task. The task reference number is 2024-3504/Khoo Teck Puat Hospital/PISAF/001, and the status is Pending. A large green arrow points down to the 'Form History' section, which lists the following events:

Event	Details	Date
PISAF was edited.	Dr TTSH_STM1	03-Sep-2024 09:53:45
PISAF was created.	A/Prof NHG_PISAF_3	03-Sep-2024 09:50:54
PISAF was triggered by the system.	A/Prof NHG_PISAF_3	03-Sep-2024 09:50:54

Callouts numbered 1 through 4 are overlaid on the interface:

- 1: Points to the task reference number.
- 2: Points to the status label 'Pending' and the 'Form History' icon.
- 3: Points to the 'Quick Link: Study Summary, CRMS' button.
- 4: Points to the 'Edit' button in the 'Form History' section.

1. This is the PISAF Form reference no.
2. The label indicates the task status of the PISAF. 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.

3) How to View/ Edit/ Submit PISAF

Site Task Detail

2024-3501-Tan Tock Seng Hospital-PISAF-001 | Tan Tock Seng Hospital Pending 99+

ECOS Ref: 2024-3501

PI/Site PI: Dr TTSH_NewPI2

Last Updated By: -

Initial Submission Date: -

Current Editor: -

Study Title: 007

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

Principal Investigator Self-Assessment Form

***PISAF Site Status**(Please indicate the current site status at the point of completing this form)

PRINCIPAL INVESTIGATOR SELF-ASSESSMENT FORM (PISAF)

General Information:

1. Guide on completion of PISAF:

- Please tick 'Yes' if the question is applicable to your study and you have fulfilled requirements. E.g. your study involves IP and you have filed all IP related documents.
- Please tick 'No' if the question is applicable to your study but you have not been conducting the activities according to requirements. E.g. your study involves IP but you did not maintain IP related documents.
- Please tick 'NA' if the question is not applicable. E.g. Your study does not involve IP.
- Please provide comments if further elaboration is required.

2. All reference (NHG Proper Conduct of Research (PCR) SOPs, templates and logs) can be found via:
<https://cs.qri.nhg.com.sg/pcr-sop-templates/>

1.IRB REQUIREMENTS

*1.1 Have you filed all the IRB related records in the investigator file? E.g. approval letters, approved study documents, IRB submissions, safety reports, non-compliance report (NCR).
*You may refer to NHG PCR 507-002 Investigator File Content Template for guidance on what to file.

Yes

3 **1** **2**

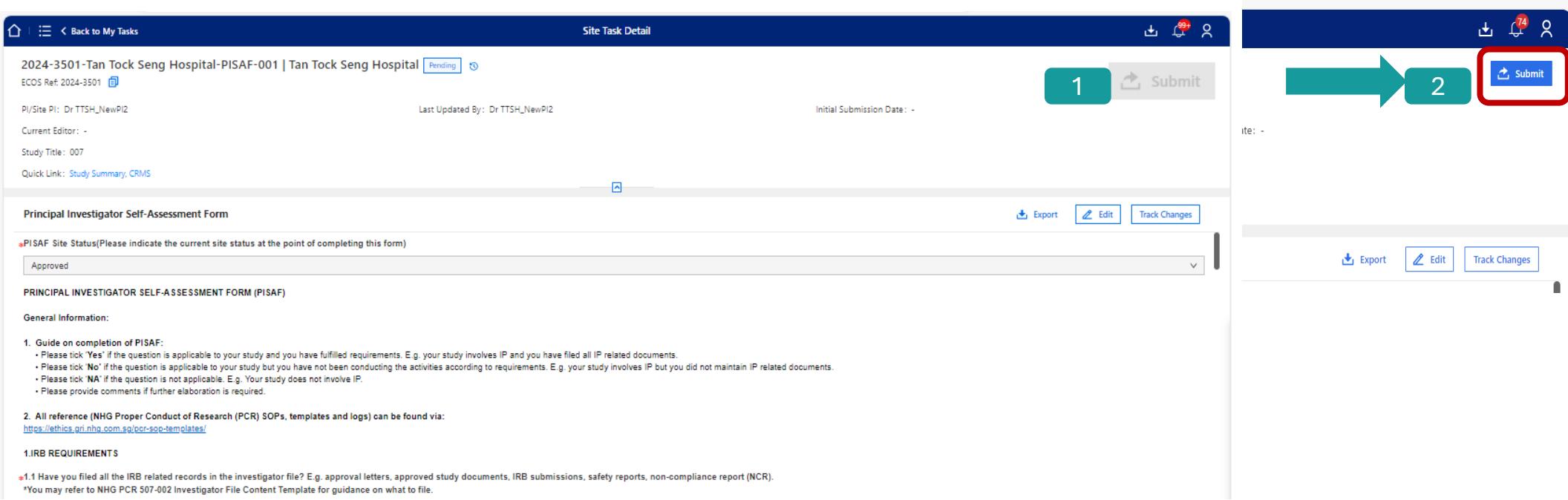
Save

1. Indicate the **Most Current Study Site Status** by clicking the drop-down arrow to select site's status e.g. Ongoing , Enrolment Closed, Participant Follow Up Only.

2. Scroll down to complete the rest of the PISAF form. Fields marked with * are mandatory for completion.

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

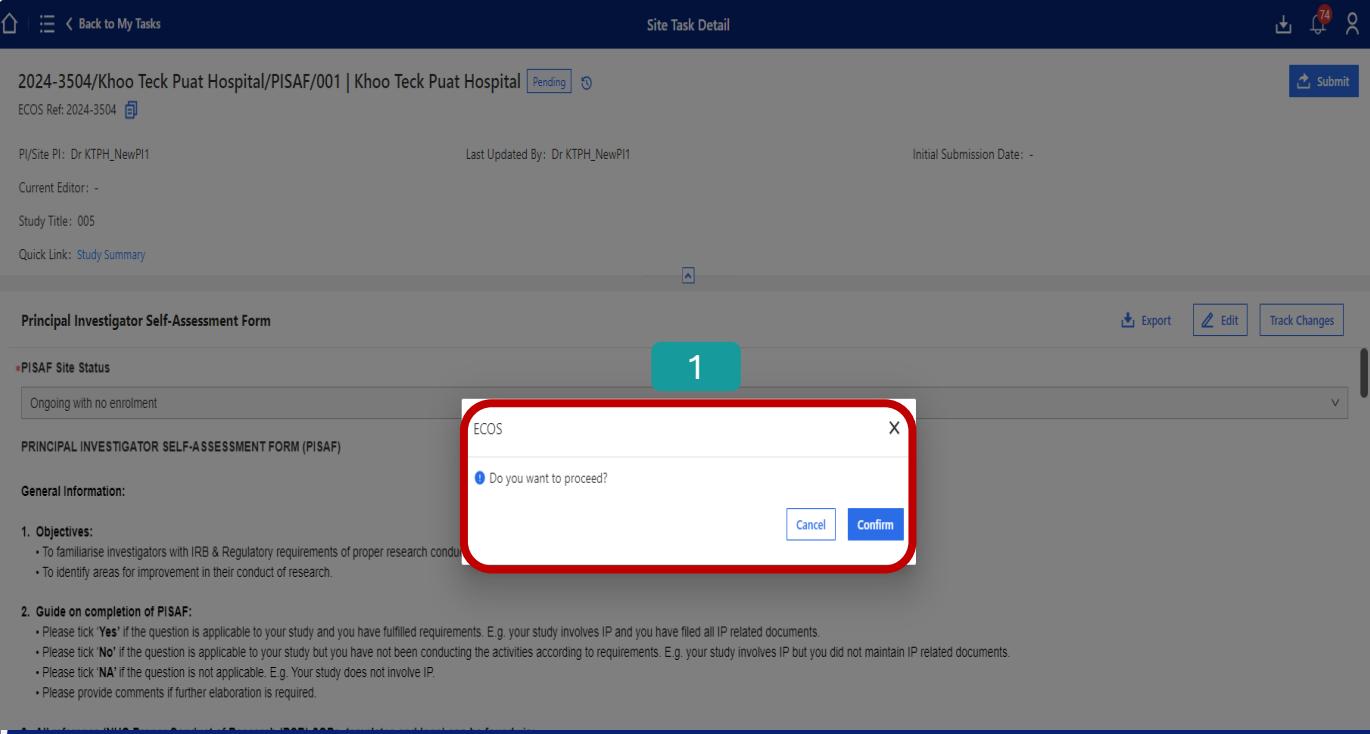
3) How to View/ Edit/ Submit PISAF



The image displays two side-by-side screenshots of a software interface for managing site tasks. The left screenshot shows a 'Site Task Detail' page for a PISAF submission. The top bar includes a 'Back to My Tasks' link, a 'Site Task Detail' title, and a 'Submit' button which is currently grey. The main content area shows basic study information: ECOS Ref: 2024-3501, PI/Site PI: Dr TTSH_NewPI2, Last Updated By: Dr TTSH_NewPI2, and Study Title: 007. Below this is the 'Principal Investigator Self-Assessment Form' (PISAF) itself. The first question, 'PISAF Site Status (Please indicate the current site status at the point of completing this form)', has a dropdown menu showing 'Approved'. The right screenshot shows the same interface after the form has been saved. The 'Submit' button is now highlighted in blue, indicating it is enabled. A large green arrow points to this blue button, and the number '2' is placed next to it, indicating the second step in the process.

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

3) How to View/ Edit/ Submit PISAF



Site Task Detail

2024-3504/Khoo Teck Puat Hospital/PISAF/001 | Khoo Teck Puat Hospital Pending 99+

ECOS Ref: 2024-3504

PI/Site PI: Dr KTPH_NewPI1

Last Updated By: Dr KTPH_NewPI1

Initial Submission Date: -

Submit

Principal Investigator Self-Assessment Form

PISAF Site Status: Ongoing with no enrolment

PRINCIPAL INVESTIGATOR SELF-ASSESSMENT FORM (PISAF)

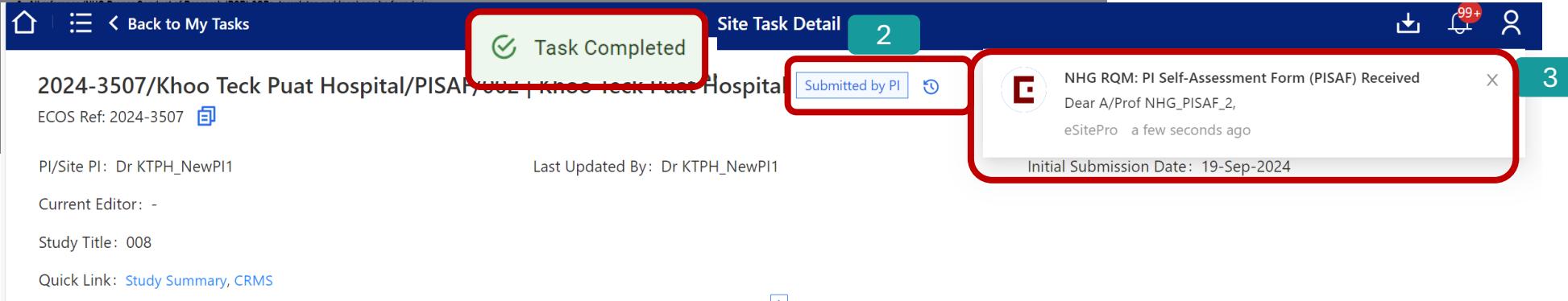
General Information:

1. Objectives:

- To familiarise investigators with IRB & Regulatory requirements of proper research conduct
- To identify areas for improvement in their conduct of research.

2. Guide on completion of PISAF:

- Please tick 'Yes' if the question is applicable to your study and you have fulfilled requirements. E.g. your study involves IP and you have filed all IP related documents.
- Please tick 'No' if the question is applicable to your study but you have not been conducting the activities according to requirements. E.g. your study involves IP but you did not maintain IP related documents.
- Please tick 'NA' if the question is not applicable. E.g. Your study does not involve IP.
- Please provide comments if further elaboration is required.



Site Task Detail

2024-3507/Khoo Teck Puat Hospital/PISAF/002 | Khoo Teck Puat Hospital Submitted by PI 99+

ECOS Ref: 2024-3507

PI/Site PI: Dr KTPH_NewPI1

Last Updated By: Dr KTPH_NewPI1

Initial Submission Date: 19-Sep-2024

Task Completed

NHG RQM: PI Self-Assessment Form (PISAF) Received

Dear A/Prof NHG_PISAF_2,
eSitePro a few seconds ago

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 PISAF has been submitted. The task is now with the PISAF Reviewer to complete the review.

3) How to View/ Edit/ Submit PISAF

Site Task Detail

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

ECOS Ref: 2024-3509

PI/Site PI: Dr KTPH_NewPI

Last Updated By: Dr KTPH_NewPI

Initial Submission Date: 23-Sep-2024

Current Editor: -

View Comment: [View](#) 2

Study Title: 010

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

Principal Investigator Self-Assessment Form

*PISAF Site Status(Please indicate the current site status at the point of completing this form)

Ongoing with active enrolment

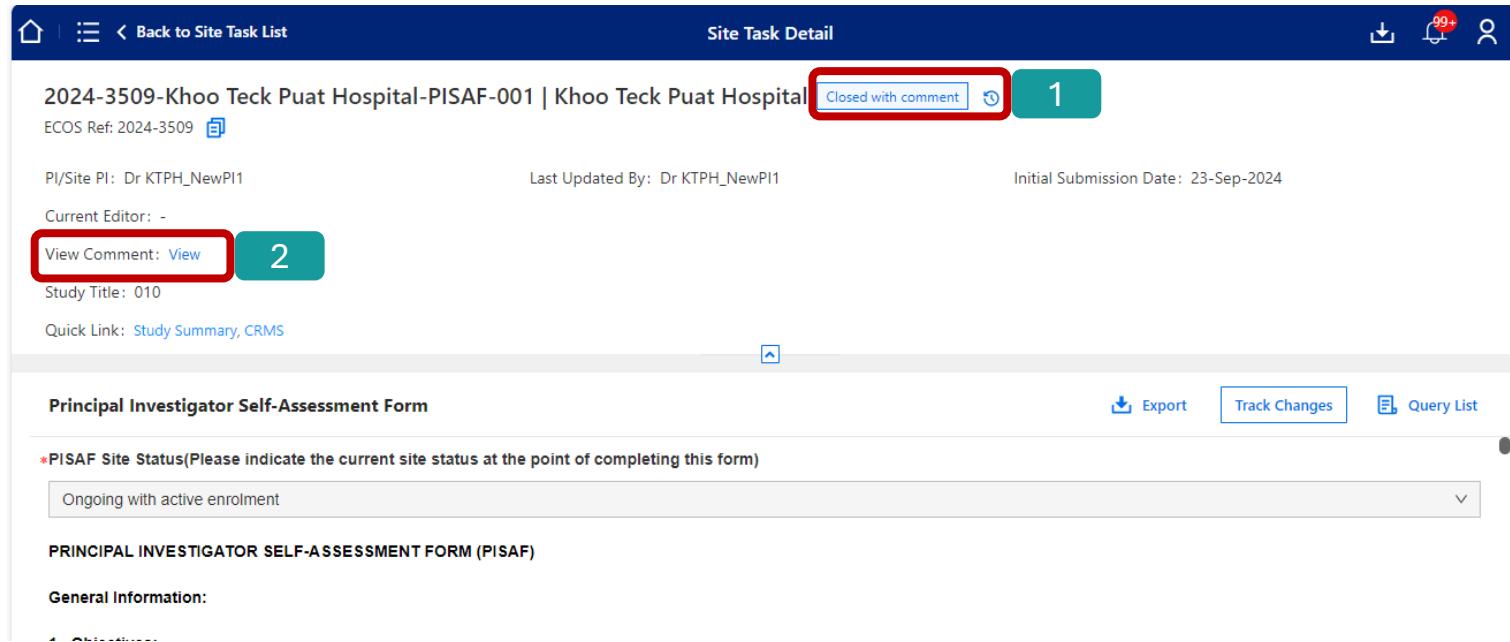
PRINCIPAL INVESTIGATOR SELF-ASSESSMENT FORM (PISAF)

General Information:

...

[Closed with comment](#) 1

Export Track Changes Query List



1. The PISAF reviewer will indicate a **review outcome** 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

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 resubmit/reply query to the PISAF reviewer.

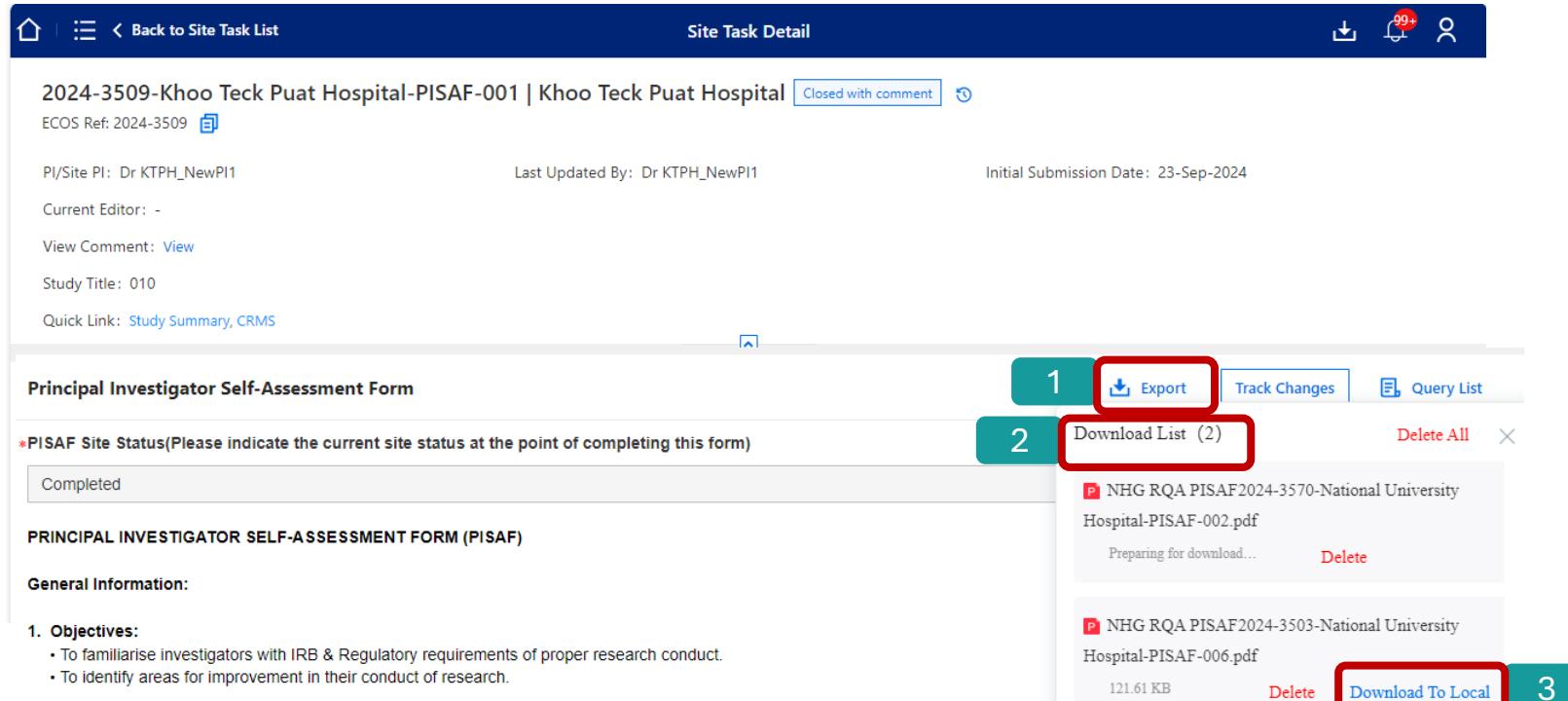
1. Locate the PISAF task from Home page or Compliance module. The status of the form will be reflected as “Queried”. Click on “View” button to enter Site Task detail page to view the PISAF.
2. To view query(ies), click on the “Query List” button. A sliding window will appear, where you can **view and 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 PISAF. 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 PISAF form. The top navigation bar includes a back button, a 'Site Task Detail' title, and a 'Reply Query' button (Step 2, highlighted with a red box). Below the title, the task details are listed: Study ID (2024-3128), Site (Tan Tock Seng Hospital), Status (Queried), and Submission Date (28-Aug-2024). The main content area shows the 'Track Changes' section (Step 1, highlighted with a red box), which displays a list of changes made to the form, such as 'changed from Yes to NA for tracking purposes'. A 'Reply Query' pop-up window is also visible, prompting the user to proceed with the reply (Step 2, highlighted with a red box). The bottom section shows the 'Site Task Detail' page again, with the status now changed to 'Submitted by PI' (Step 3, highlighted with a red box) and an incoming email notification from 'NHG RQM: PI Self-Assessment Form (PISAF) Received' (Step 4, highlighted with a red box).

1. If changes were made to the PISAF, 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 PISAF has been submitted. The task is now with the PISAF Reviewer to review the query response.

5) How to Export the PISAF



The screenshot shows the Site Task Detail page for a task titled "2024-3509-Khoo Teck Puat Hospital-PISAF-001 | Khoo Teck Puat Hospital". The page includes details like "ECOS Ref: 2024-3509", "PI/Site PI: Dr KTPH_NewPI1", "Last Updated By: Dr KTPH_NewPI1", and "Initial Submission Date: 23-Sep-2024". The main content is the "Principal Investigator Self-Assessment Form". A red box labeled "1" highlights the "Export" button in the top right corner of the form area. A red box labeled "2" highlights the "Download List (2)" button. A red box labeled "3" highlights the "Download To Local" button for the second item in the download list, which is a PDF file named "NHG RQA PISAF2024-3570-National University Hospital-PISAF-002.pdf".

1. To export a copy of the PISAF 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@nhghealth.com.sg
if you have any question about ECOS
Compliance (PISAF) 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