

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)

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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 displays the eSitePro interface for the Site Task List. The 'Principal Investigator Self-Assessment Form' tab is active. A table lists tasks with columns for PI/Site PI, ECOS Ref, Category, Study Site, Department, Task Status, and Action. A 'Columns' configuration dialog is open, showing a list of columns with checkboxes and drag handles. The 'Clear' and 'Save' buttons are highlighted with red boxes and numbered 3 and 2 respectively. A '1' in a green box highlights the 'Columns' button in the top right of the table area.

PI/Site PI	ECOS Ref	Category	Study Site	Department	Task Status	Action
Dr TTSH_NewPI1	2024-3493	UAT_Test reminders	Tan Tock Seng Ho		Closed	👁
Dr TTSH_NewPI1	2024-3503	UAT_QA unlimited_scc	Tan Tock Seng Ho		Pending	👁
Dr TTSH_NewPI1	2024-3490	UAT_3B_unlimited_scc	Tan Tock Seng Ho		Closed	👁

Column Selected 15

- 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

3 Clear Cancel Save 2

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. The top navigation bar includes the eSitePro logo, a 'Site Task List' tab, and user profile icons. The left sidebar contains navigation options: Homepage, IRB, CRMS, Compliance (with 'Site Task List' highlighted), FCOI, SDB, and Report. The main content area displays a table of tasks under the 'Principal Investigator Self-Assessment Form' tab. The table has columns for PI/Site PI, ECOS Ref, Category, Study Site, Department, Task Status, and Action. An 'Export' button is highlighted with a red box and a green '1' callout. A dropdown menu is open below it, showing 'Download Original' and 'Safe Download (PDF)' options, with a green '2' callout pointing to the menu.

PI/Site PI	ECOS Ref	Category	Study Site	Department	Task Status	Action
Dr TTSH_NewPI1	2024-3493	UAT_Test reminders	Tan Tock Seng Hospital	Geriatric Medicine	Closed with Satisfaction	👁
Dr TTSH_NewPI1	2024-3503	UAT_QA unlimited_scc	Tan Tock Seng Hospital	Geriatric Medicine	Pending	👁
Dr TTSH_NewPI1	2024-3490	UAT_3B_unlimited scc	Tan Tock Seng Hospital	Geriatric Medicine	Closed with Satisfaction	👁

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 shows the eSitePro interface. The left sidebar has a menu with 'Site Task List' highlighted. The main header has 'Site Task List' and 'Principal Investigator Self-Assessment Form' tabs. A table lists tasks with columns: PI/Site PI, ECOS Ref, Category, Study Site, Department, Task Sta, and Action. A 'Filter' dialog box is open, showing fields for Category, ECOS Ref, Study Site, PI/Site PI, Department, Task Status (with 'Pending' and 'Queried' selected), Date Sent to PI, and Task Due Date. 'Reset' and 'Search' buttons are at the bottom of the dialog.

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

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

The screenshot shows the ECOS system interface. The top navigation bar includes 'ECOS' and 'Dashboard'. The left navigation panel has 'Homepage' and 'Dashboard' highlighted with a red box and a green '1'. The main content area shows 'IRB 0', 'CRMS 0', and 'FCOI 0' tiles. Below these is a 'Compliance' tile with a red box and a green '2'. The 'Compliance' tile lists 'Deviation/Non Compliance - Site (0)', 'Serious Adverse Event - Site (0)', 'PI Self-Assessment Form - Site (3)', and 'Study Closure Checklist - Site (0)'. The 'PI Self-Assessment Form - Site' tile is highlighted with a red box. The bottom screenshot shows the 'My Tasks' page. The left navigation panel has 'My Tasks' highlighted with a red box and a green '3'. The main content area shows 'IRB 0', 'CRMS 0', and 'FCOI 0' tiles. Below these is a 'Compliance' tile with a red box and a green '4'. The 'Compliance' tile lists 'Deviation/Non Compliance - Site (0)', 'Serious Adverse Event - Site (0)', 'PI Self-Assessment Form - Site (2)', and 'Study Closure Checklist - Site (0)'. The 'PI Self-Assessment Form - Site (2)' tile is highlighted with a red box. Below the tiles is a table with columns: Form Type, Form Ref/Task ID, Study Title, PI/Site-PI, Latest Submission Date, Task Status, and Action. The table has two rows of PISAF tasks. The 'Action' column for the second row is highlighted with a red box and a green '5'. The 'Action' column contains a magnifying glass icon.

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

Category	ECOS Ref	Study Site	PI/Site PI	Department	Task Status	Date Sent to PI	Task Due Date	Initial Submission Date	Action
NHG 3B	2024-3509	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	10-Sep-2024	10-Mar-2025	-	👁
NHG 3B		Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Closed with Satisfaction	01-Aug-2024	03-Mar-2025	03-Sep-2024	👁
NHG 3B		Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Closed with Satisfaction	02-Mar-2024	03-Mar-2025	03-Sep-2024	👁
NHG 3B	2024-3505	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Closed with Satisfaction	02-Sep-2024	02-Mar-2025	02-Sep-2024	👁
Ad Hoc Unlimited Form Endorsed SCC	2024-3508	Khoo Teck Puat Hospital	Dr KTPH_NewPI1	Anaesthesia	Pending	20-Sep-2024	21-Sep-2024	-	👁

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

ECOS My Tasks

IRB 0 CRMS 0 FCOI 0 Compliance 2

Deviation/Non Compliance - Site (0) Serious Adverse Event - Site (0) **PI Self-Assessment Form - Site (2)** Study Closur > ↻

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	View
PISAF	2024-3508/Khoo Teck Puat Hospital/PISAF/001	009	Dr KTPH_NewPI1	02-Sep-2024	Pending	View

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.

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.

3) How to View/ Edit/ Submit PISAF

1

Site Task Detail

2024-3504/Khoo Teck Puat Hospital/PISAF/001 Khoo Teck Puat Hospital Pending 2

ECOS Ref: 2024-3504

PI/Site PI: Dr KTPH_NewPI1 Last Updated By: - Initial Submission Date: -

Current Editor: -

Study Title: 005

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

Principal Investigator Self-Assessment Form

*PISAF Site Status

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.

Form History

✔ 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

4 Edit

Submit

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

The screenshot shows the 'Site Task Detail' page for a study at Tan Tock Seng Hospital. The status is 'Pending'. The form is titled 'Principal Investigator Self-Assessment Form'. A red box highlights the 'PISAF Site Status' dropdown menu, with a callout '3' pointing to the 'Save' button. Another red box highlights the '1. IRB REQUIREMENTS' section, with a callout '2' pointing to the first question. A third red box highlights the 'Save' button, with a callout '1' pointing to it. The 'Submit' button is also visible in the top right corner.

2024-3501-Tan Tock Seng Hospital-PISAF-001 | Tan Tock Seng Hospital Pending Submit

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 Cancel Save

*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.gri.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

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

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

ECOS Ref: 2024-3501

PI/Site PI: Dr TTSH_NewPI2 Last Updated By: Dr TTSH_NewPI2 Initial Submission Date: -

Current Editor: -

Study Title: 007

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

Principal Investigator Self-Assessment Form Export Edit Track Changes

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

Approved

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://ethics.qri.nhg.com.sg/pcr-sop-templates/>

1.IRB REQUIREMENTS

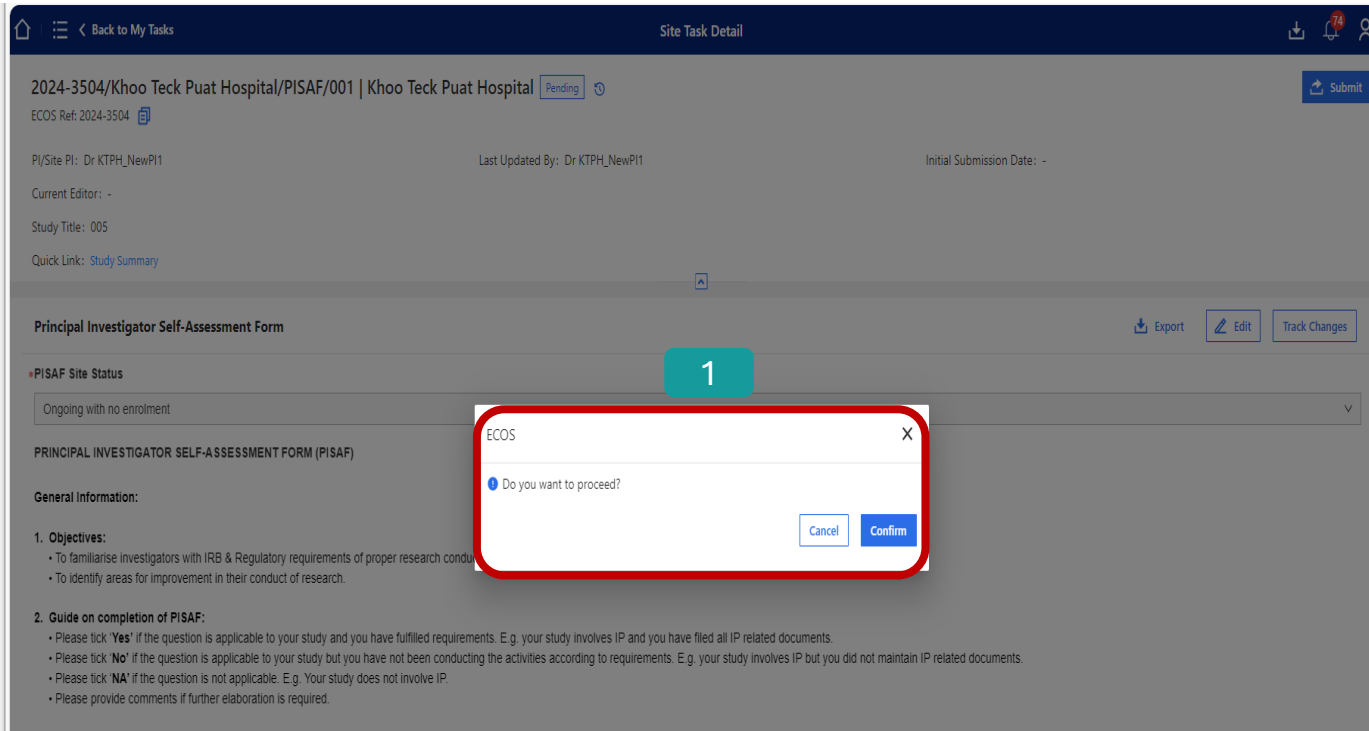
1.1 Have you filed all the IRB related records in the investigator file? E.g. approval letters, approved study documents, IRB submissions, safety reports, non-compliance report (NCR).
*You may refer to NHG PCR 507-002 Investigator File Content Template for guidance on what to file.

ite: -

Export Edit Track Changes

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.

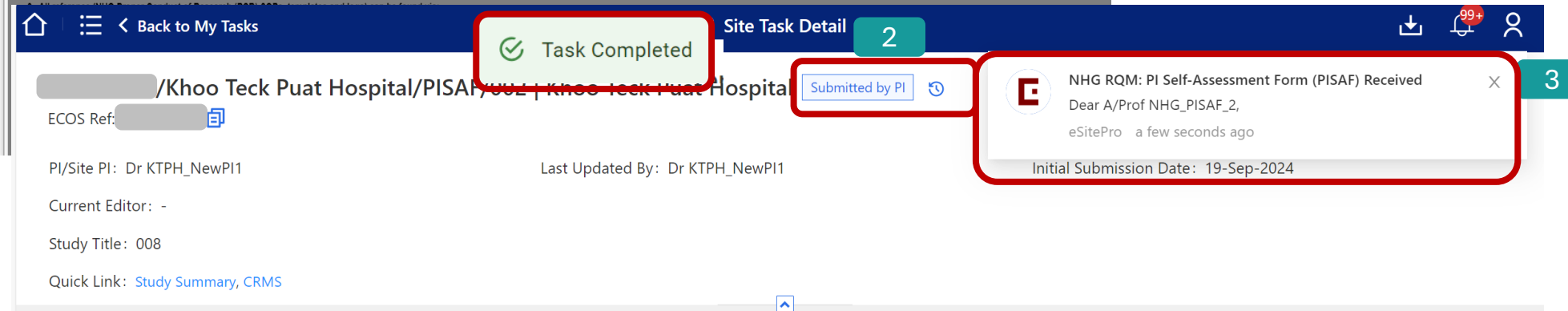
3) How to View/ Edit/ Submit PISAF



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

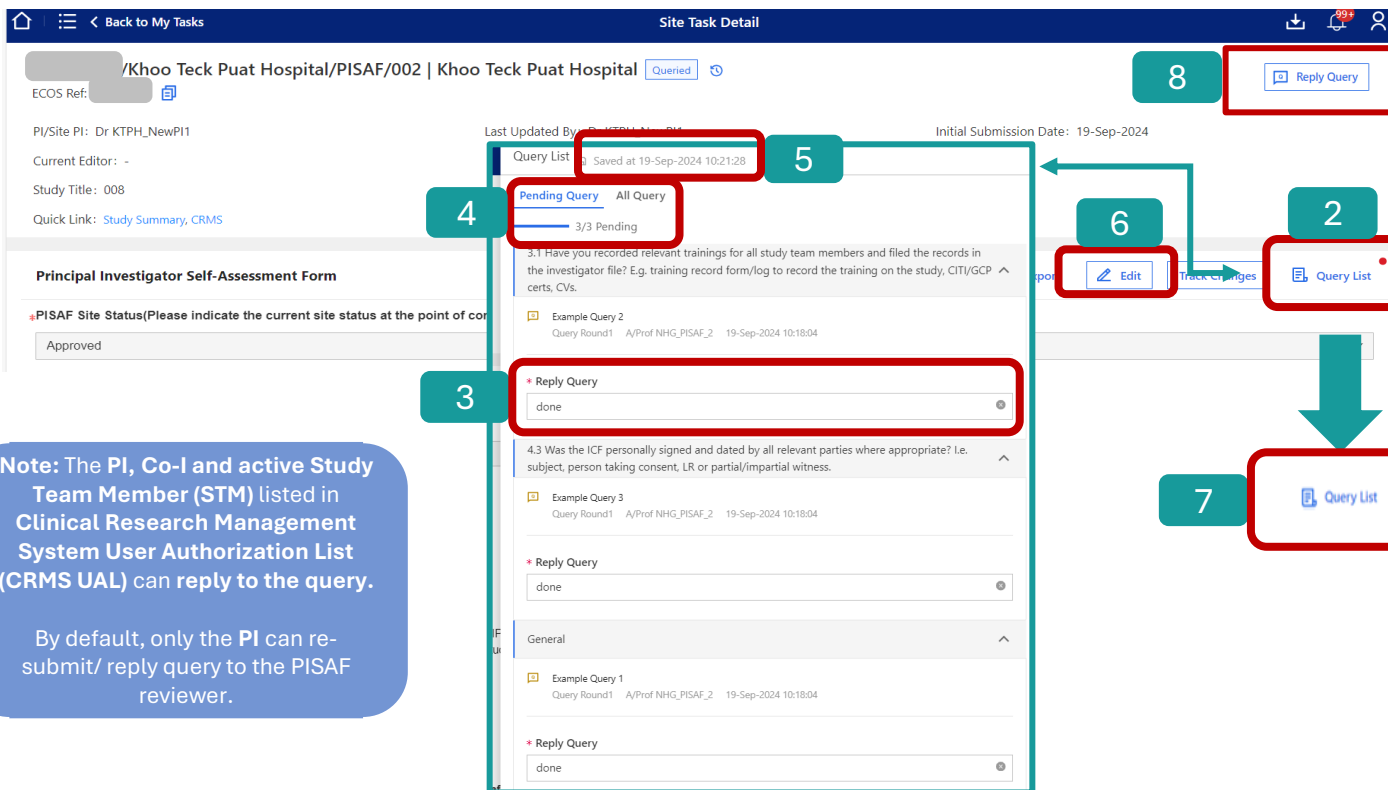
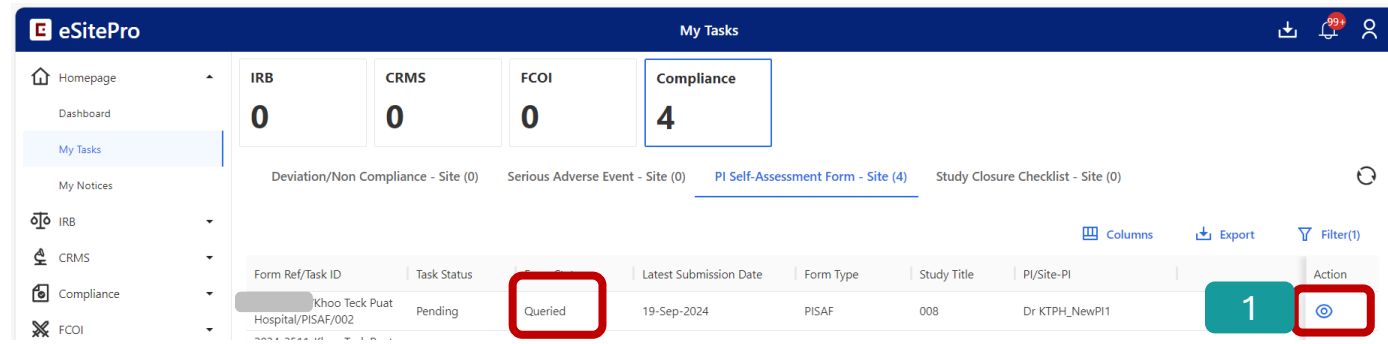
The screenshot shows a web interface for a 'Site Task Detail'. At the top, there is a navigation bar with a home icon, a menu icon, and a back arrow labeled 'Back to Site Task List'. The page title is 'Site Task Detail'. On the right side of the header, there are icons for a download, a notification bell with '99+', and a user profile icon. Below the header, the main content area displays the following information:

- ECOS Ref: [Redacted] - Khoo Teck Puat Hospital-PISAF-001 | Khoo Teck Puat Hospital
- PI/Site PI: Dr KTPH_NewPI1
- Last Updated By: Dr KTPH_NewPI1
- Initial Submission Date: 23-Sep-2024
- Current Editor: -
- View Comment: View (2)
- Study Title: 010
- Quick Link: Study Summary, CRMS

Below this information, there is a section titled 'Principal Investigator Self-Assessment Form' with buttons for 'Export', 'Track Changes', and 'Query List'. A dropdown menu shows the status 'Ongoing with active enrolment'. The section is titled 'PRINCIPAL INVESTIGATOR SELF-ASSESSMENT FORM (PISAF)' and includes a 'General Information:' section.

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

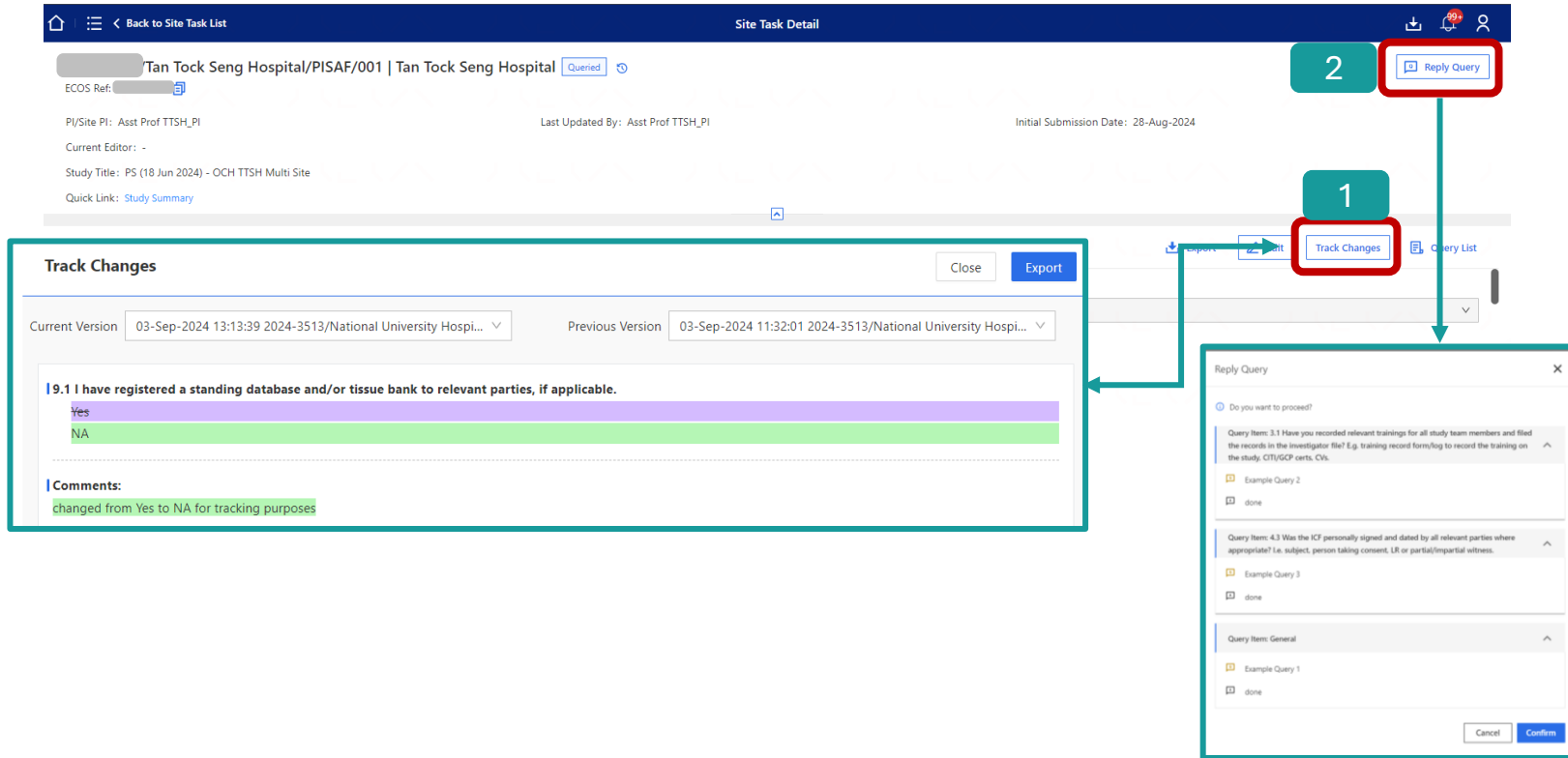


Note: The PI, Co-I and active Study Team Member (STM) listed in Clinical Research Management System User Authorization List (CRMS UAL) can reply to the query.

By default, only the PI can re-submit/ 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

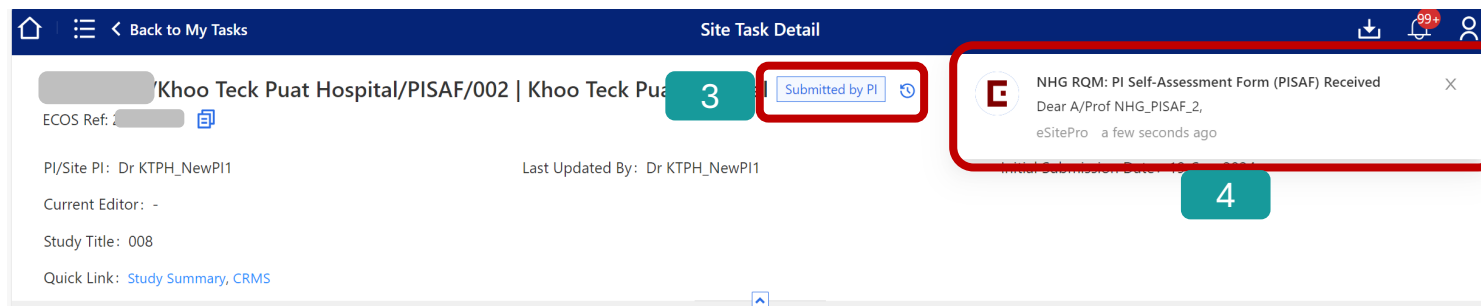


1. If changes were made to the PISAF, you can see the **prior changes** when you click on the “**Track Changes**” function.
2. **Co-I and active STM** listed in CRMS UAL can **reply to query**, but **only the PI can re-submit the form/ reply query**. Click on “**Reply Query**” button.

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 displays the 'Site Task Detail' page for a study at Khoo Teck Puat Hospital. The page includes a header with navigation options and a main content area with various fields and buttons. A dropdown menu is open, showing the 'Export' button (1) and a 'Download List (2)' containing two PDF files. The 'Download To Local' button (3) is highlighted for the second file.

Principal Investigator Self-Assessment Form

1 [Export](#) [Track Changes](#) [Query List](#)

2 **Download List (2)** [Delete All](#) [X](#)

- NHG RQA PISAF2024-3570-National University Hospital-PISAF-002.pdf**
Preparing for download... [Delete](#)
- NHG RQA PISAF2024-3503-National University Hospital-PISAF-006.pdf**
121.61 KB [Delete](#) [Download To Local](#) 3

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

Completed

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 f
- Please tick 'No' if the question is applicable to your study but you have not been conducting the activities according to requirements. E.g.

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