

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

# Compliance Module: Principal Investigator Self-Assessment Form (PISAF)



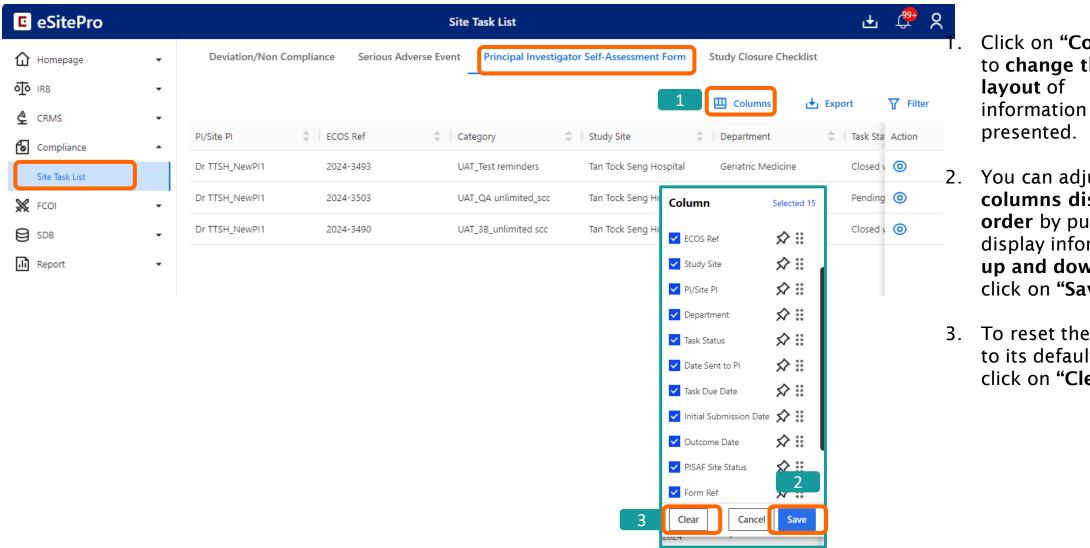
### **Contents**

#### 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)

- 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

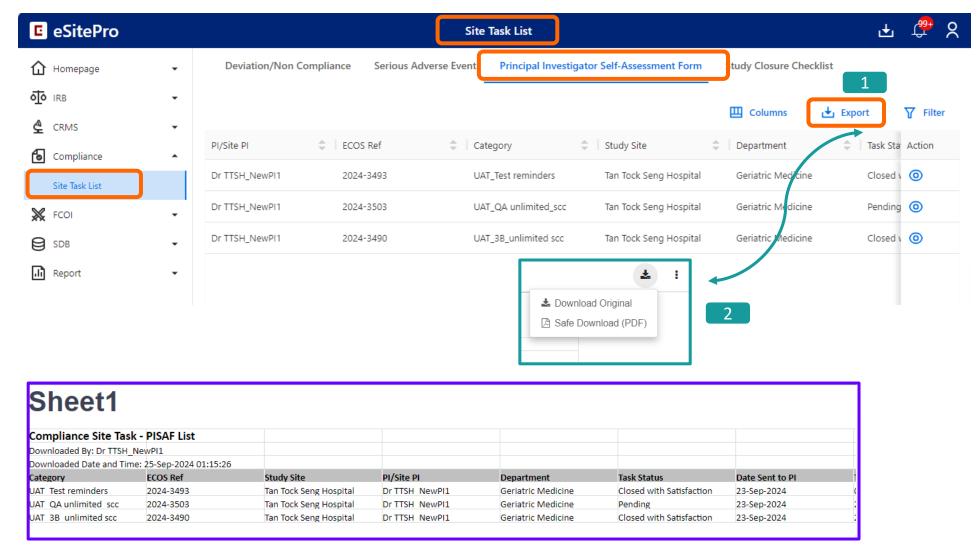
#### 1) PISAF Module General Interface - Columns



Click on "Columns" to change the

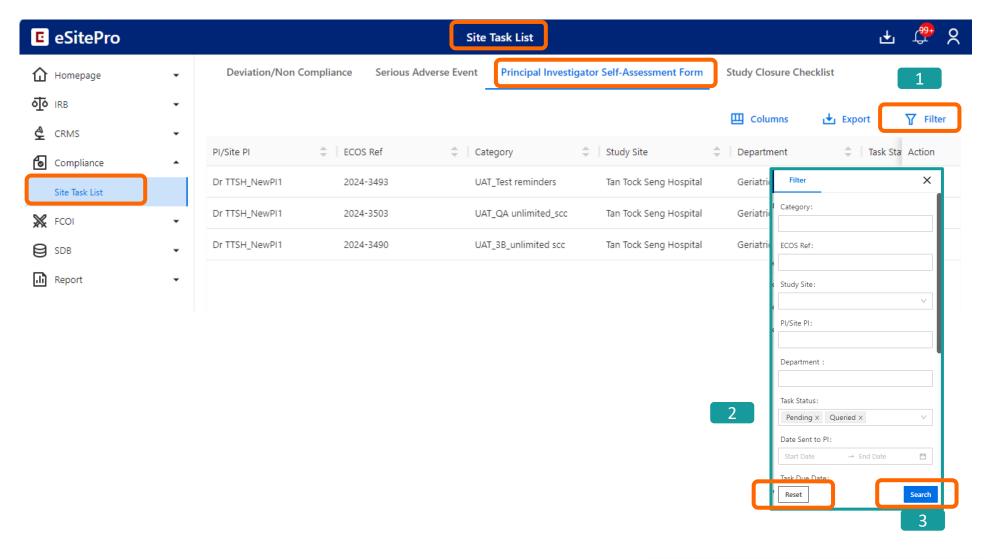
- You can adjust the columns display order by pulling the display information up and down and click on "Save".
- To reset the columns to its default view. click on "Clear"

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



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

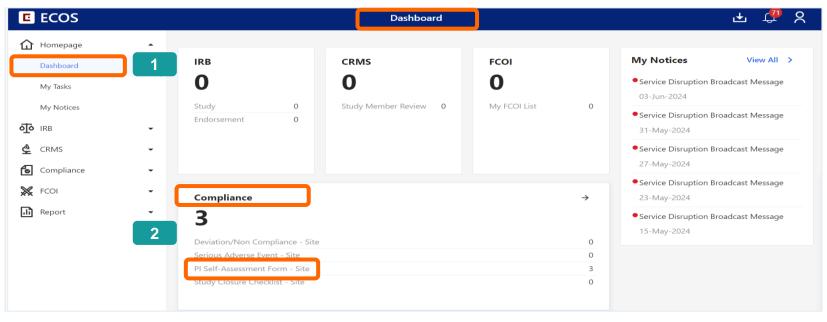
#### 1) PISAF Module General Interface - Filter



- 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

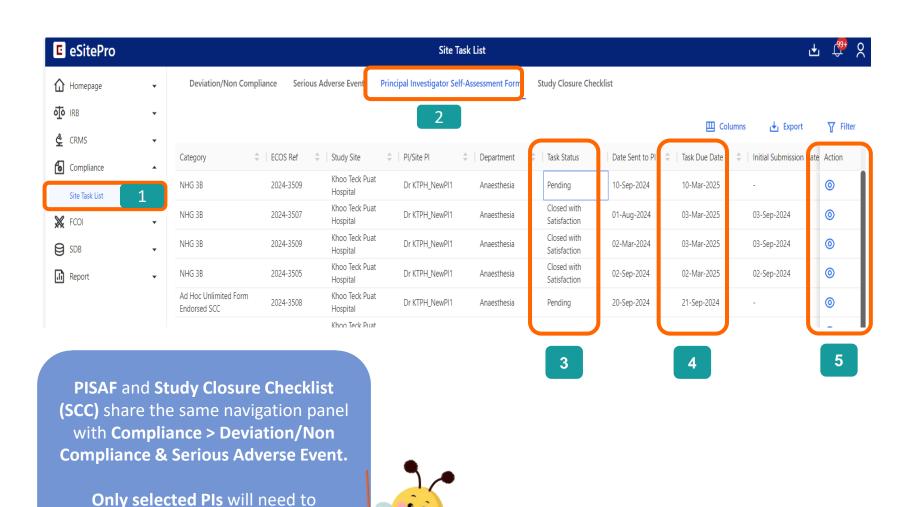




#### Via Homepage > Dashboard

- You can locate your outstanding PISAF task via "Homepage" > "Dashboard" on the left navigation panel.
- 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 ounder the "Action" column.

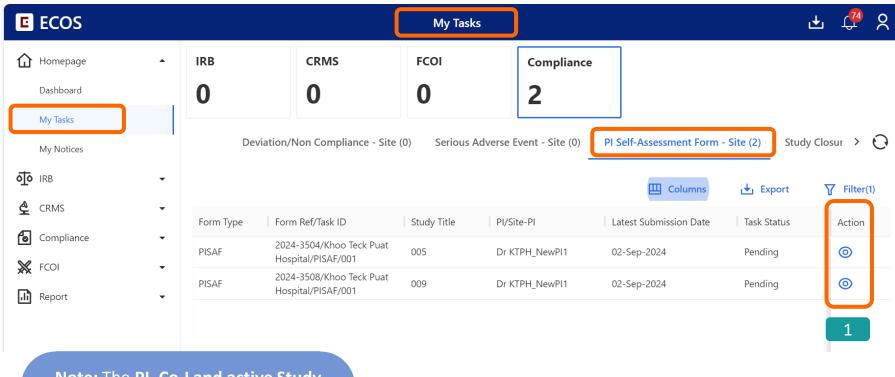
#### 2) Locate your PISAF task - via Compliance module



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 " o " view button under the "**Action**" column to view the PISAF form.



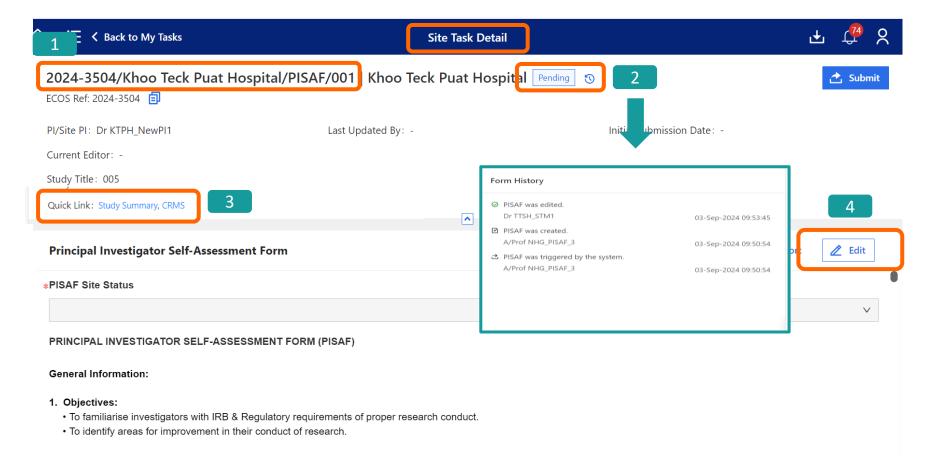
Locate the PISAF task through the methods described in Section 2.

1. Click the **OView** button under **"Action"** column to edit the PISAF Form.

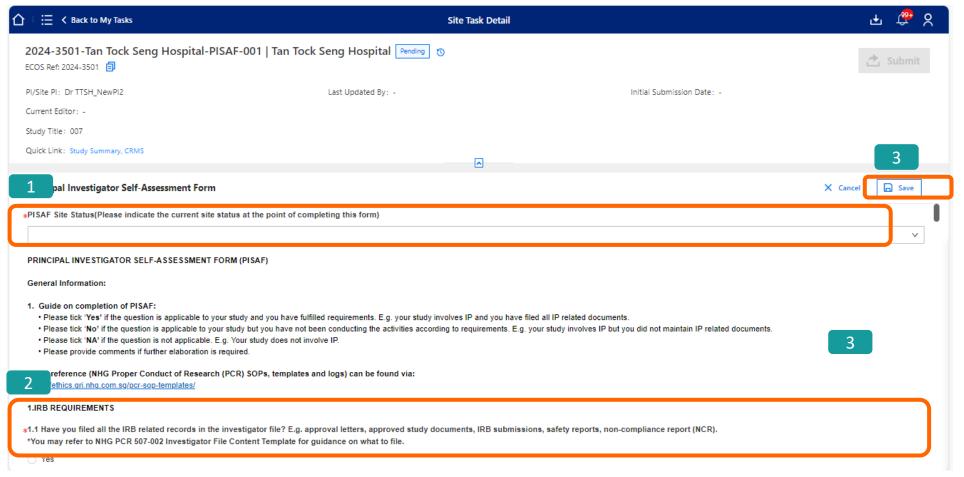
You will arrive at **Site Task Detail** page.

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.

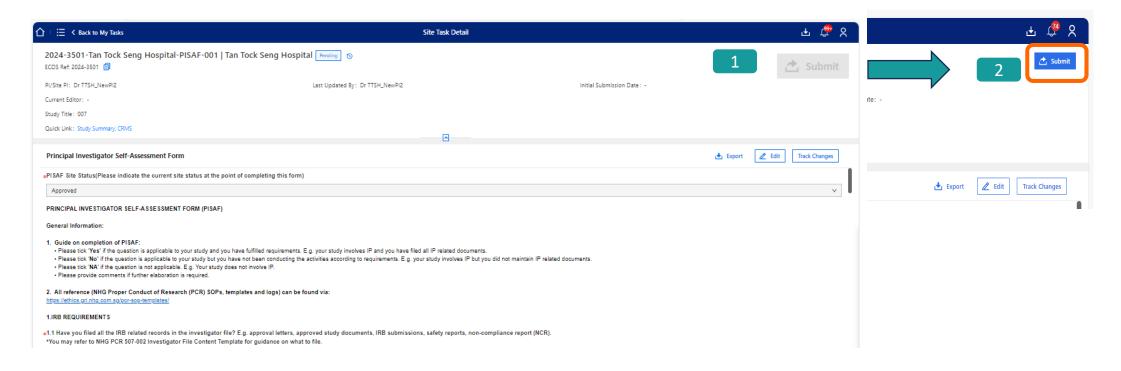
By default, only the PI can submit the
form.



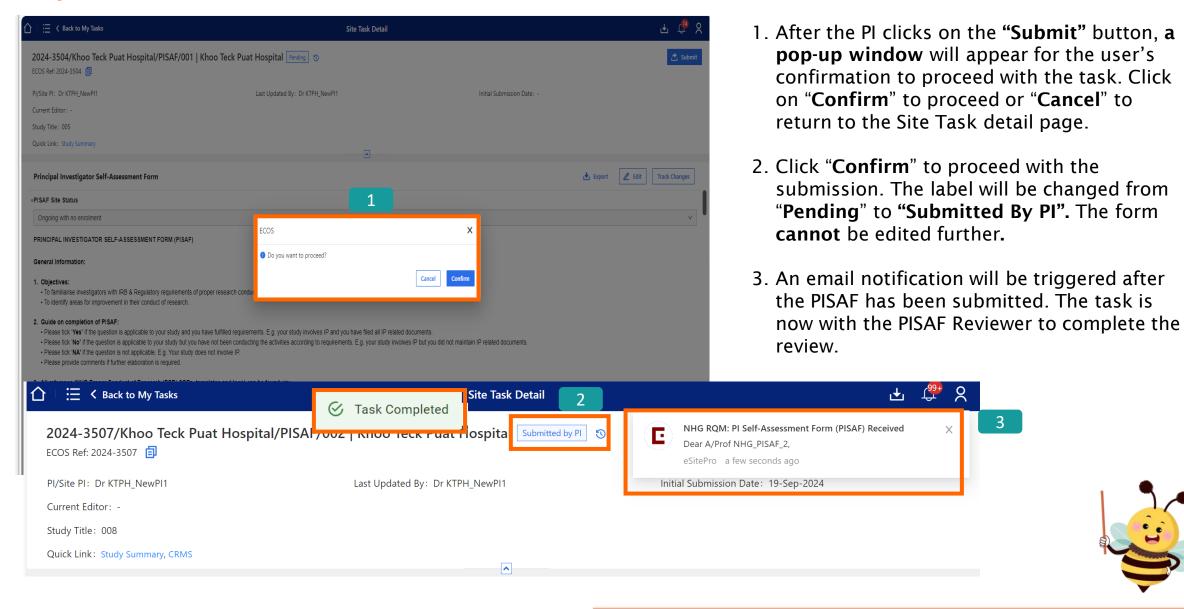
- 1. This is the PISAF Form reference no.
- 2. The label indicates the task status of the PISAF. Next to label is the "Form History" icon. You can click on the icon to view form history.
- 3. These quick links will bring you to IRB Module Study Summary and Clinical Research Management System (CRMS) information.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

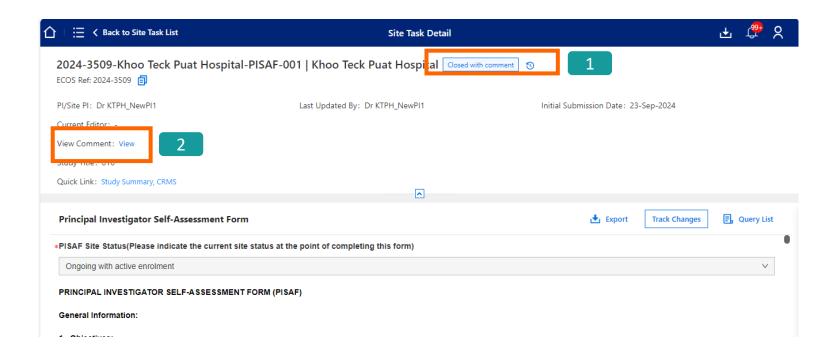


- 1.Indicate the Most Current Study Site Status by clicking the drop-down arrow to select site's status e.g. Ongoing, Enrolment Closed, Participant Follow Up Only.
- 2. Scroll down to complete the rest of the PISAF form. Fields marked with \* are mandatory for completion.
- 3.Click on "Save" to ensure the edits have been saved successfully.



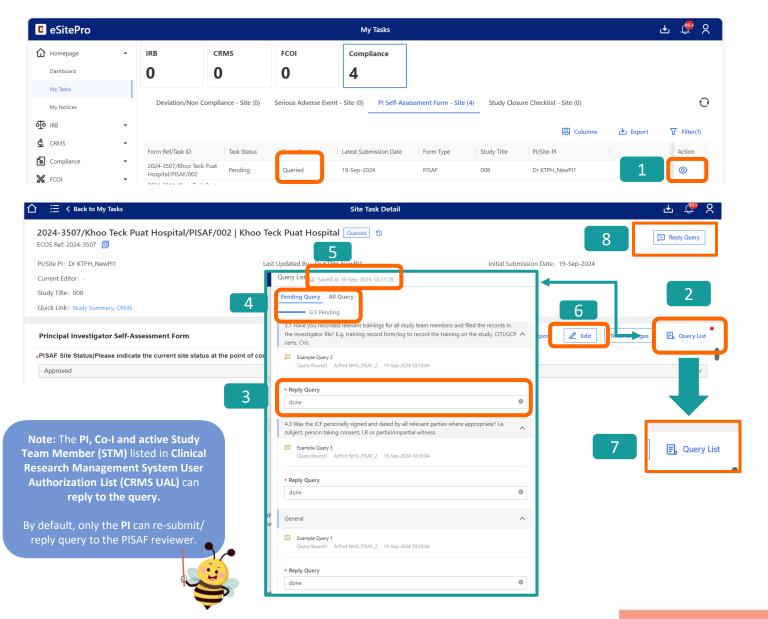
- 1. After the form has been saved, the "Submit" button will be enabled (color change from grey to blue).
- 2. By default, only the PI can be able to see and click on the "Submit" button. Co-I and active STM listed in CRMS UAL can only view and edit the PISAF.





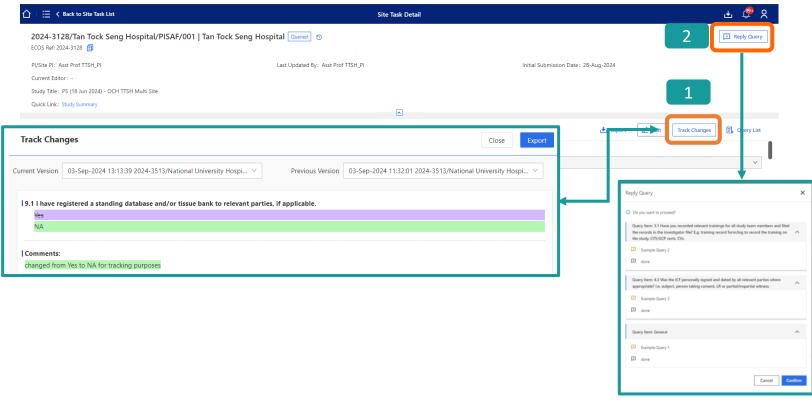
- 1. The PISAF reviewer will indicate a review outcome if there is no query or all queries have been adequately addressed by the PI/ Study Team.
- 2. Click on "**View**" to see the comment from the PISAF reviewer (if any).

#### 4) How to View/ Reply to Query



- Locate the PISAF task from Home page or Compliance module. The status of the form will be reflected as "Queried". Click on "View" button o 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).
- 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".
- 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.
- Where needed, you will also need to make the edits onto the form directly. Click on "Edit" to make the changes and "Save".
- 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



Site Task Detail

2024-3507/Khoo Teck Puat Hospital/PISAF/002 | Khoo Teck Pu 3 ta Submitted by PI So

ECOS Ref: 2024-3507 PI/Site PI: Dr KTPH\_NewPI1

Current Editor: 
Study Title: 008

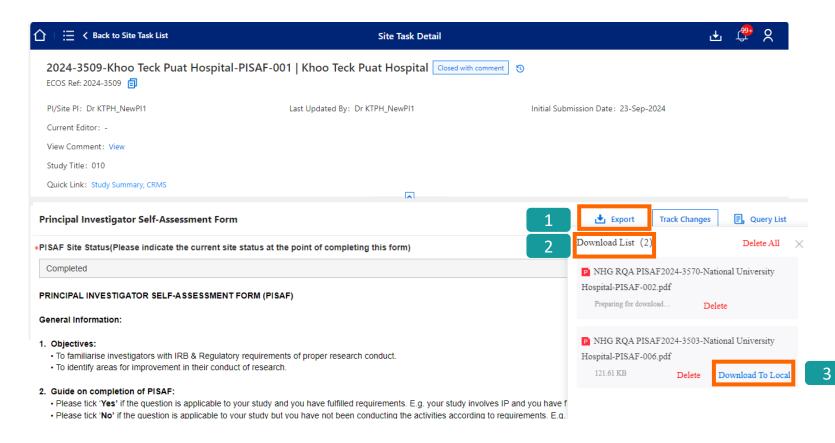
Quick Link: Study Summary, CRMS

- 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.

- 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



- 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.



## Thank You

Please contact Research Quality (NHGHQ)
<a href="mailto:researchquality@nhg.com.sg">researchquality@nhg.com.sg</a> if you have any question about ECOS Compliance (PISAF) module.