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# Navigating ECOS

(Ethics and Compliance Online System)

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## Compliance Module

- **Principal Investigator Self-Assessment Form (PISAF)**

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# 1) Purpose of the Module

The PISAF is a self-assessment tool to be completed by the PI. The PI will self-assess on study processes (e.g., study conduct and informed consent).

## 1. Annual completion for IRB approved studies:

- CIRB & DSRB approved studies for **all** study classifications (i.e., HBR, Clinical Trials, others)
- To be completed for **SingHealth sites only** (i.e., Submission will be done **at the site level (not study)** for SingHealth sites)
- Sites where SingHealth is providing RI oversight for HBRA studies
- **Excludes** industry sponsored, HSA-regulated Clinical Trials
- **Excludes** other healthcare clusters (non-SingHealth PIs) for multi-site studies

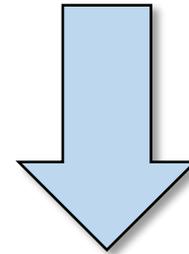
PISAF will not be triggered in ECOS

## 2. PISAF may be triggered at other timepoints for specific studies (TBC)

**Submission period: Jan 2025 to 14 Feb 2025, 23:59**

## 2) ECOS Workflow

RICE informs PIs via  
**ECOS**  
to complete PISAF



PIs completes the  
PISAF on **ECOS**

### 3) Module User Roles

User Roles	Level	Functions
PI / Site-PI	Site-specific	<ul style="list-style-type: none"><li>• Receive email and system notification on pending tasks.</li><li>• Submit the PISAF.</li></ul>
Co-I & Study Team Member(s)	Site-specific	<ul style="list-style-type: none"><li>• Receive email and system notification on pending tasks.</li><li>• Able to draft the PISAF.</li></ul>
PISAF Reviewer	SingHealth Cluster	<ul style="list-style-type: none"><li>• Reviews the PISAF.</li></ul>
Research Office	Institution	<ul style="list-style-type: none"><li>• View all tasks for its respective institution(s).</li><li>• View and download reports on the PISAF task statuses and responses submitted.</li></ul>

### 3) Module User Roles

- Information of site-specific Study Team Members (STMs) are taken from the CRMS Module – User Authorisation List (UAL).
- Site-specific PI, Co-I and STMs can complete the PISAF. There is no function for the Study Administrator and Study Sponsor in the Compliance Module.**

The screenshot shows the 'User Authorisation List' for a specific study. The table contains the following data:

Member Name	Role	Cluster	Institution	Department	Designation	Email	Action
KKH_PI 1	PI	Singapore Health Services Pte Ltd	KK women's and Children's Hospital	family medicine Service	Senior Consultant	shs-sitester@...	
KKH_Co-I 1	Co-I	Singapore Health Services Pte Ltd	KK Women's and Children's Hospital	Family Medicine Service	Consultant	shs-sitester@...	
KKH_Basic1	Study Team Member	Singapore Health Services Pte Ltd	KK Women's and Children's Hospital	Family Medicine Service	Executive	shs-sitester@...	
SGH_Basic1	Study Administrator	Singapore Health Services Pte Ltd	Singapore General Hospital	Renal Medicine	Senior Resident	shs-sitester@...	
OCH_Basic user	Study Team Member	Singapore Health Services Pte Ltd	Outram Community Hospital	Medical	Dr	shs-sitester@...	

Please add the Study Team Member(s) in CRMS UAL if this has not been done.

## 4) Navigating the Module: When will you receive a task?

You will receive a task when:	Task Status
a) There is a PISAF for you to complete.	<ul style="list-style-type: none"><li data-bbox="1439 421 1694 478">• Pending</li></ul>

## 4) Navigating the Module: Where to find your tasks?

To find pending tasks **assigned for your action**, there are 2 ways:

**1A**

Click on 'Dashboard', under 'Homepage'

The screenshot shows the ECOS Dashboard interface. The left sidebar contains navigation options: Homepage, My Tasks, My Notices, IRB, CRMS, Compliance, FCOI, SDB, and Report. The 'Dashboard' option under 'Homepage' is highlighted with a red box and a red arrow pointing to it. The main content area displays three summary tiles: IRB (19), CRMS (1), and FCOI (0). Below these is a 'Compliance' section with a total of 15 tasks. A table lists the following tasks and their counts:

Task Category	Count
Deviation/Non Compliance - Site	8
Serious Adverse Event - Site	4
PI Self-Assessment Form - Site	3
Study Closure Checklist - Site	0

The 'PI Self-Assessment Form - Site' row is highlighted with a red box. A red arrow points from this row to a callout box on the right. The callout box contains the following text:

The Compliance tile will display the total number of pending tasks assigned for your action.

Click on "PISAF – Site" to view the tasks

**The Study Closure Checklist will not be used.**

**1B**

## 4) Navigating the Module: Where to find your tasks?

To find pending tasks **assigned for your action**, there are 2 ways:

**2A** Click on 'My Tasks'

**2B** Click on the 'Compliance' tile.

**2C** Click on the PISAF tab.

**3** Click 'View' to see the task details.

Latest Submission Date	Task Status	Form Type	Form Status	Form Ref/Task ID	Study Title	Action
23-Sep-2024	Pending	PISAF	Pending	2024-3314-KK Women's and Children's Hospital-PISAF-001	FOR SINGHEALTH_Compliance DNC/SAE UAT 1 - Multi-Cluster, Multi-Site Clinical Trial	
23-Sep-2024	Pending	PISAF	Pending	2024-3267-KK Women's and Children's Hospital-PISAF-001	Compliance DNC/SAE UAT 1 - Multi-Cluster, Multi-Site Restricted HBR	
23-Sep-2024	Pending	PISAF	Pending	2024-3265-KK Women's and Children's Hospital-PISAF-001	Compliance DNC/SAE UAT 1 - Multi-Cluster, Multi-Site Other Study	

Rows per page: 100 1-3 of 3

## 4) Navigating the Module: Where to find your tasks?

To find **ALL** pending tasks for **ALL** your studies:

**1** Click on 'Site Task List' under the 'Compliance' Module

**2** Click on the PISAF tab.

**3** Tasks will be listed in the main page. The default view will display only pending tasks.

**4** Task Due Date

**5** Click 'View' to open the task.

**6** Completed tasks can be displayed by filtering for them.

ECOS Site Task List

Deviation/Non Compliance Serious Adverse Event **Principal Investigator Self-Assessment Form** Study Closure Checklist

Columns Export Filter(1)

Department	Task Status	Date Sent to PI	Task Due Date	Initial Submission	Action
Neurology (SGH Campus)	Pending	11-Dec-2024	14-Feb-2025	-	
Neurology (SGH Campus)	Pending	24-Sep-2024	14-Feb-2025	-	
Neurology (SGH Campus)	Pending	24-Sep-2024	14-Feb-2025	-	
Neurology (SGH Campus)	Pending	24-Sep-2024	14-Feb-2025	-	
Neurology (SGH Campus)	Pending	23-Sep-2024	14-Feb-2025	-	

Filter

Category:

ECOS Ref:

Study Site:

PI/Site PI:

Department :

Task Status:

Pending x Queried x

Date Sent to PI:

Start Date → End Date

Task Due Date:

Start Date → End Date

Initial Submission Date:

Reset Search

Rows per page: 100 1-5 of 5

## 4) Navigating the Module: How to complete the PISAF?

The screenshot displays the 'Site Task Detail' page for a task titled '2024-3263-National Neuroscience Institute-PISAF-001 | National Neuroscience Institute'. The status is 'Pending'. The page includes a 'Submit' button and a 'Back to Site Task List' link. Below the task details, there is a section for the 'Principal Investigator Self-Assessment Form'. This section contains an 'Export' button and an 'Edit' button, which is highlighted with a red box. A callout box with a yellow background and a red arrow points to the 'Edit' button, containing the text: 'Click on 'Edit' to complete the PISAF.' A yellow circle with the number '1' is also present next to the callout box. The form itself is titled '\*PISAF Site Status(Please indicate the current site status at the point of completing this form)' and has a dropdown menu. Below this, there are sections for 'PI Self Assessment Form' and 'Study Site Team', with the first question being '\*1. Is there a study coordinator or a dedicated study team member to support the coordination or administrative matters at the study site?'.

Home | Back to Site Task List | Site Task Detail | 99+ | User Profile

2024-3263-National Neuroscience Institute-PISAF-001 | National Neuroscience Institute Pending 🕒 Submit

ECOS Ref: 2024-3263 📄

PI/Site-PI: Mr NNI\_PI 1 | Last Updated By: - | Initial Submission Date: -

Current Editor: -

Study Title: Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site Clinical Trial

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

Principal Investigator Self-Assessment Form Export Edit

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

PI Self Assessment Form

Study Site Team

\*1. Is there a study coordinator or a dedicated study team member to support the coordination or administrative matters at the study site?

## 4) Navigating the Module: How to complete the PISAF?

Site Task Detail

2024-3592-National Neuroscience Institute-PISAF-001 | National Neuroscience Institute Pending 🕒 Submit

ECOS Ref: 2024-3592 📄

PI/Site-PI: Mr NNI\_PI 1      Last Updated By: Mr NNI\_PI 1      Initial Submission Date: -

Current Editor: NNI\_PI 1

Study Title: SHS\_AUD-UAT\_Study-A01\_CC\_HSA CT

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

**Principal Investigator Self-Assessment Form** Cancel Save Track Changes

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

Not Yet Initiated

**PI Self Assessment Form**

**Study Site Team**

\*1. Is there a study coordinator or a dedicated study team member to support the coordination or administrative matters at the study site?

Yes

No

**1** Click on 'Save' to save a draft of the PISAF.

**2** Click on 'Track Changes' to view the edits made from the last version which could be made by another person.

## 4) Navigating the Module: How to complete the PISAF?

Site Task Detail

2024-3592-National Neuroscience Institute-PISAF-001 | National Neuroscience Institute Pending

ECOS Ref: 2024-3592

PI/Site-PI: Mr NNI\_PI 1      Last Updated By: Mr NNI\_PI 1      Initial Submission Date: -

Current Editor: -

Study Title: SHS\_AUD-UAT\_Study-A01\_CC\_HSA CT

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

**Principal Investigator Self-Assessment Form**      [Export](#)      [Edit](#)      [Track Char](#)

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

Not Yet Initiated

**PI Self Assessment Form**

**Study Site Team**

\*1. Is there a study coordinator or a dedicated study team member to support the coordination or administrative matters at the study site?

Yes

No

3

Click on 'Submit' to submit the PISAF to the PISAF Reviewer. The form will be locked and cannot be edited further.

**Note:** Only the PI of the site can submit the PISAF.

## 4) Navigating the Module: PISAF Acknowledged

Site Task Detail

2024-3267-National Neuroscience Institute-PISAF-001 | National Neuroscience Institute **Acknowledged**

ECOS Ref: 2024-3267

PI/Site-PI: Mr NNI\_PI 1      Last Updated By: Mr NNI\_PI 1      Initial Submission Date: 20-Dec-2024

Current Editor: -

Study Title: Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site Restricted HBR

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

**Export**    Track Changes    Query List

**PI Self Assessment Form**

**Study Site Team**

\*1. Is there a study coordinator or a dedicated study team member to support the coordination or administrative matters at the study site?

1 After submission, the PISAF reviewer will acknowledge the submission. The "Query" function in PISAF will not be used at this moment.

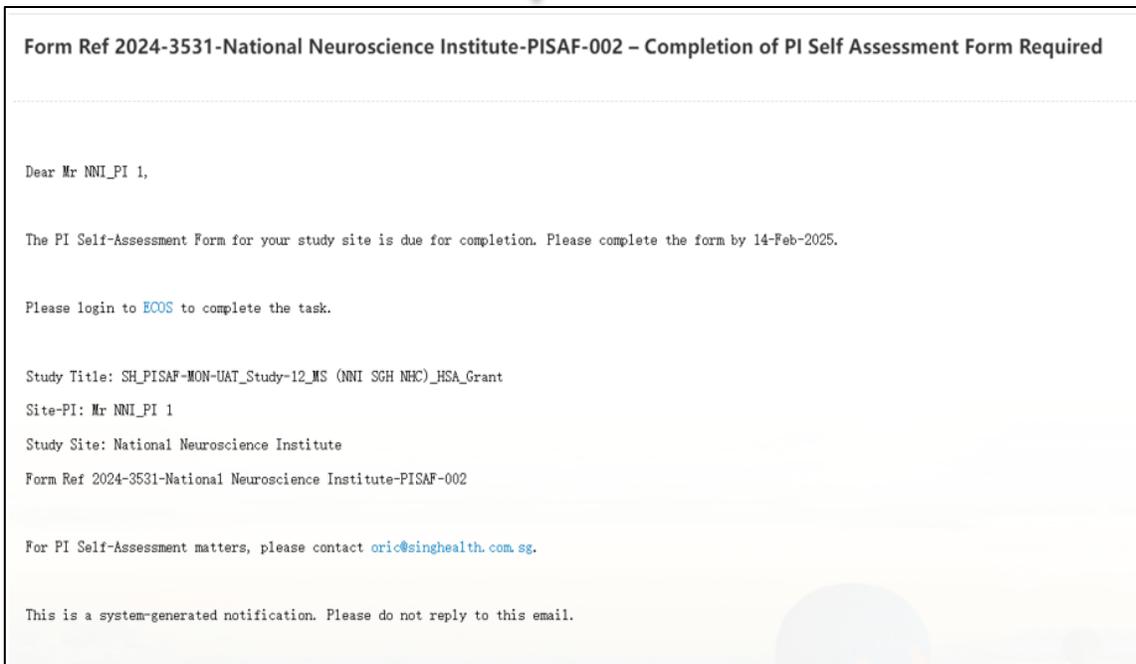
2 Click on 'Export' to view a copy in PDF.

## 4) Navigating the Module: What notifications are there?

1

An email notification will be sent to the PI / Site PI / Co-I / STMs.

The email will contain the study title, PI/Site-PI name, study site, and form reference number. There will also be a direct link to ECOS to bring the recipient directly to the platform.



2

A system notification will be sent to the PI / Site PI / Co-I / STM's user account.

It can be access via the bell icon, found on the top right corner. A bubble will indicate the number of system notifications.



3

Reminder emails will be sent every weekly (7 days).

The task will auto-close if the PISAF is not submitted by 14 Feb 2025, 2359hr.

## 4) Navigating the Module: Where to view all tasks for the institution?

**3** Click on the PISAF tab.

**1** Click on the 'Compliance' module.

**2** Click on 'Task Management'.

**4** By default, pending tasks will be displayed. Click on 'Filter' to search for a specific study.

The screenshot displays the ECOS Task Management interface. The left sidebar shows the navigation menu with 'Compliance' and 'Task Management' highlighted. The main content area shows the 'Principal Investigator Self-Assessment Form' tab selected. Below the tab, there is a table with the following data:

Category	ECOS Ref	PI/Site PI	Study Site	Department	Task Status	Action
SingHealth Annual PISAF	2024-3539	Dr SGH_Site-PI1	Singapore General Hospital	Department of Clinical Pathology	Pending	

At the bottom of the table, there is a pagination control showing 'Rows per page: 100' and '1-1 of 1'.

# Navigating the Module: How to generate the PISAF Reports?

The screenshot shows the ECOS interface for generating a PISAF report. The left sidebar contains a navigation menu with 'Report' selected. The main content area displays a list of report templates, including 'SingHealth - PISAF Response Report' and 'SingHealth - PISAF Status Report'. A red box highlights a warning: 'Other Report Templates. Do not use for now.' The top right of the interface features 'Columns', 'Export', and 'Filter' buttons. Five numbered callouts provide step-by-step instructions:

1. Click on the 'Report' module.
2. Click on 'Compliance Institution Report'.
3. Click on 'SingHealth - PISAF Response Report' or 'SingHealth - PISAF Status Report'.
4. Click on 'Filter' and select the filter conditions to display the required data. If no filter conditions are selected, the report will display all data for the report.
5. Click on 'Export' to download the report. It is possible to customise the columns to display and filter for specific conditions before downloading the report.

Reminder: The report will only be able to include data up to the day before the day of report generation.

# PISAF – Site Status, Site Team

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

- Approved
- Not Yet Initiated
- Ongoing with No Enrolment
- Ongoing with Active Enrolment
- Ongoing (Enrolment Closed, Participant Follow Up Only)
- Ongoing (Last Participant Last Visit Completed, Data Analysis Ongoing)
- Suspended
- Terminated

## Study Site Team

\*1. Is there a study coordinator or a dedicated study team member to support the coordination or administrative matters at the study site?

Yes

No

1.1 Comments:

Please complete this section if you have responded “No” to the question above.

# PISAF – Study File

## Study File

**\*2. Does your site keep any physical file(s) containing study documents?**

- Yes  
 No

**2.1 Please indicate the documents that are filed in your study files. If the document was not filed or not relevant for your study, please leave the checkbox blank.**

- IRB submission documents
- IRB approval, renewal or acknowledgement letter/s
- Regulatory (i.e. MOH or HSA) submission documents
- Regulatory (i.e. MOH or HSA) approval documents (e.g. CTC/CTA/CTN, MOH approval for restricted HBR)
- Clinical Research Material Notification (CRM-N) from HSA (eg. For use of Therapeutic Products, Medicinal Products, Medical Device, CTGTP, Radiopharmaceuticals)
- Original signed informed consent forms signed off by the participant and person obtaining consent (and witness, if applicable)
- Training documentation (e.g. Certificate for CITI, HBRA, ICH-GCP or Study-specific training)
- Site Delegation Log signed off by the site-PI
- Participant Screening and Enrolment Log
- Participant Identification Code list
- Data Collection Forms/ Case Report Forms (CRF)
- Human Biological Materials (HBM) collection/shipping records
- Investigational Product (IP) dispensing/returns records
- Medical Device (MD) management records
- Serious Adverse Event or Adverse Event Tracking Log

**\*3. Was a study agreement(s) signed prior to the start of your study? The study agreement(s) may include Clinical Trial Agreement, Research Collaborative Agreement, Service Agreement, Project Agreement, Material Transfer Agreement, Data Sharing Agreement, etc.**

- Yes  
 No, a study agreement was not signed prior to the start of the study. The study agreement was signed during the conduct of the study  
 No, the study does not require a study agreement  
 No, I am not sure

**4. Comments (Optional):**

Please complete this section if you have responded “No” to any of the questions above.

# PISAF – Study Specific training, Obtaining Written Informed Consent

## Study-Specific Training

**\*5. Has study-specific training (e.g. Site initiation meeting or other relevant training) been conducted and documented for the site team members?**

- Yes  
 No

**5.1 Please select the study-specific training topics that were covered. If the topic was not covered or not relevant for your study, please leave the checkbox blank.**

- Eligibility criteria (Inclusion/Exclusion criteria) of the study  
 Study design and study procedures required  
 Randomisation Process  
 Informed Consent Process and requirement of a witness (Note: A witness is required for studies under the scope of HBRA)  
 Handling of Investigational Product (IP) (e.g. Dispensing and return by the participant)  
 Handling of Medical Device  
 Data collection process  
 Safety Reporting  
 For a multi-site IIT or HBRA study, Communication Plan with lead site

**6. Comments (Optional):**

Please complete this section if you have responded “No” to the question above.

## Obtaining Written Informed Consent

**\*7. Has any written informed consent been obtained from study participants at this study site?**

Note: Indicate “NA” if Waiver of written consent granted by the IRB or Verbal consent will be obtained.

- Yes  
 No  
 NA

**\*7.1 Please answer the following questions (Q7.1 to 7.6) with reference to the last 2 participants that were enrolled into the study. List the last 2 participant’s study number that were enrolled below:**

**\*7.2 The latest version of the IRB and HSA-approved (as applicable) informed consent form (ICF) was signed by the participant at the time of written consent.**

- Yes  
 No

**\*7.3 There is documentation in the research participant’s medical records and/or source document to describe the informed consent process and the research participant has voluntarily consented to the study.**

- Yes  
 No

**\*7.4 The participant has personally signed AND personally dated on the ICF.**

- Yes  
 No

# PISAF – Database and Study Records

**\*7.5** If your study is regulated under HBRA, informed consent has been obtained in the presence of a witness. If your study is not regulated under HBRA or a witness has been exempted or not required, please indicate as “NA”.

- Yes
- No
- NA

**\*7.6** The participants have received a copy of the signed ICF.

- Yes
- No

**8. Comments (Optional):**

Please complete this section if you have responded “No” to any of the questions above.

## Database and Study Records

**\*9.** The study team members have been authorised to access identifiable data for the research (e.g. SCM/Citrix, Financial/Operational portals, etc.). Please indicate NA if the study does not require access to identifiable data from hospital systems.

**Important: National Electronic Health Records (NEHR) cannot be used for research!**

- Yes
- No
- NA

**\*10.** There are processes put in place to safeguard all confidential, proprietary and personal data/information against security breaches.

- Yes
- No
- I don't know

**\*11.** Please indicate if the Clinical Research Management System (CRMS) module in Ethics and Compliance Online System (ECOS) has been completed with the 3 following information for your study site. To indicate which fields below has been completed.

- Milestones.** For important events such as planned/actual site initiation date, first participant screened, first participant enrolled etc.
- Participant - Recruitment Numbers.** To provide the actual recruitment number by per month
- Site Information.** To provide site contact personnel, funding information etc.
- No information has been entered in CRMS for the above mentioned fields**

**12. Comments (Optional):**

# PISAF – Declaration

## \*Declaration

- The research study is conducted in compliance with the IRB approved protocol and applicable regulations (Human Biomedical Research Act, Health Products (Clinical Trials) Regulation or Medicines (Clinical Trials) Regulations).
- The research study is conducted in accordance with SingHealth Research Institution's (RI) or sponsor's (if applicable) policies. This includes the policy on subject's re-identification in the case of an Incidental Finding (if applicable).
- Serious adverse events (including unexpected serious adverse events), safety lapses, protocol deviation and non-compliance are reported to the IRB, regulatory authorities and relevant bodies (eg. sponsor etc) where required.
- The SingHealth PI is actively supervising the overall study conduct and shall investigate areas of concern (if any that arises). Remedial measures will be taken to close the issues.
- The study team members have provided full support and cooperation to any study monitoring or quality review request(s) by SingHealth and/or the applicable regulatory authorities.
- The information provided are true and accurate at the time of submission.

# FAQ

## **Q1: What status of the studies will I get a notification to complete the PISAF?**

A1: All studies with a status of Approved, Ongoing, Ongoing (enrollment closed, participant on follow up), Ongoing (LPLV over, analysis ongoing), Suspended will get a notification to complete the PISAF.

## **Q2: Who can complete and submit the PISAF?**

A2: Any Study Team Member, including the Co-I and Site PI, can complete the PISAF. But only the Site PI can submit the PISAF in ECOS. The Study Team Member can help to complete the PISAF and the Site PI will review the completed form for submission in ECOS.

## **Q3: For my multi-site study involving SGH, CGH and KKH, do I have to complete the PISAF 3 times as it was mentioned that the PISAF is completed at site level?**

A3: Yes. The PISAF is completed for each site at the site level. The responses provided for the PISAF will pertain to that particular site.

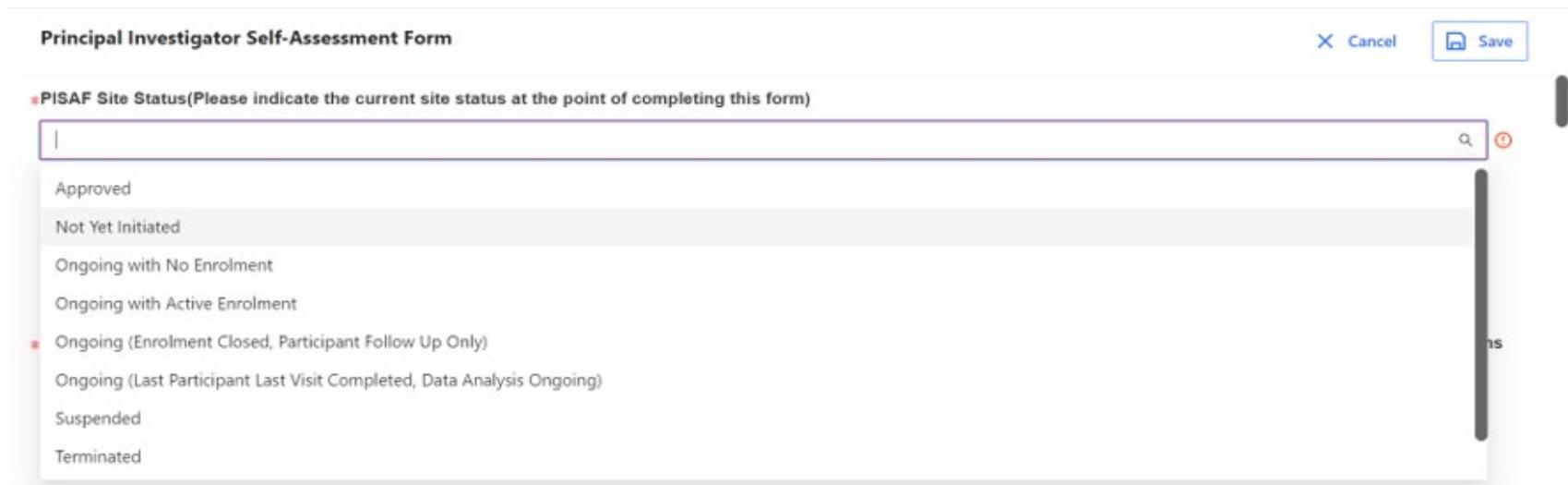
## **Q4. For my study, the Site PI and Co-I received the pending task to complete the PISAF in ECOS. As a CRC, I did not receive any pending task in ECOS. Why?**

A4: Please check your study role defined in CRMS under User Authorisation List (UAL). **The Study Administrator will not receive any tasks for PISAF.** Only **Site-specific PI, Co-I and Study Team Members (STM)** can complete the PISAF.

# FAQ

**Q5: I have received the PISAF task but my study has not yet been initiated, how do I complete the PISAF?**

A5: On the PISAF, there is a PISAF site status. The status can be updated here and to indicate “NA” for the questions where relevant.



The screenshot displays the 'Principal Investigator Self-Assessment Form' interface. At the top right, there are 'Cancel' and 'Save' buttons. Below the title, a section titled 'PISAF Site Status (Please indicate the current site status at the point of completing this form)' contains a search bar. A dropdown menu is open, listing the following site status options: Approved, Not Yet Initiated, Ongoing with No Enrolment, Ongoing with Active Enrolment, Ongoing (Enrolment Closed, Participant Follow Up Only), Ongoing (Last Participant Last Visit Completed, Data Analysis Ongoing), Suspended, and Terminated.

**Q6: I have received the PISAF task but my study site does not recruit participants, how do I complete the PISAF?**

A6: You should complete the questions where relevant to your study site. It is acceptable to indicate “No” or “NA” and provide comments where necessary.

# FAQ

## **Q7: How about for DSRB approved studies, will I need to complete the PISAF?**

A7: The PISAF will have to be completed for SingHealth sites, regardless whether CIRB or DSRB approves it. For example, for a multi-site study involving NUH, TTSH and SGH where the study has been submitted to DSRB for review, the PISAF will be completed for the SGH site by the SGH site PI. The ECOS system will trigger the PISAF for the SGH site.



# Need help?

- SingHealth Users

it.helpdesk@singhealth.com.sg  
1800-666-7777

- For Non-PHI Users

<https://for.sg/ecos-support-request>