

---

# Navigating ECOS

(Ethics and Compliance Online System)

---

## Compliance Module

- Deviation / Non-Compliance
- Serious Adverse Event

# Table of Contents

- 1) Purpose of the Compliance Module
- 2) ECOS Workflow
- 3) Roles in the Module
- 4) Navigating the Module

## For Site

- When will you receive a task
- Where to find your task(s)
- How to reply to a query
- How to complete the MOH report
- How to endorse the MOH report (PI / Site-PI only) – Endorsement triggered if the final submitter is not Site-PI
- What notifications there are

## For Research Office (RO)

- Where to view all tasks for the institution
- How to generate the Tiered SOC report

# 1) Purpose of the Module

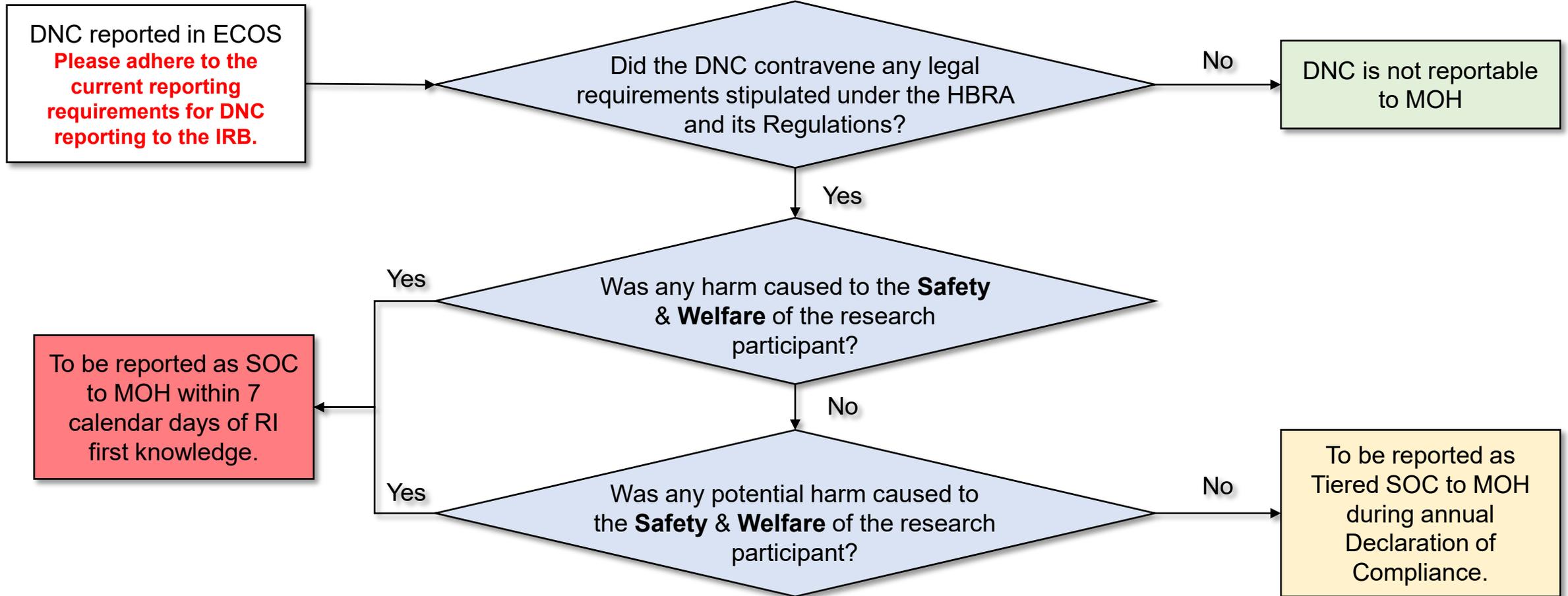
To facilitate the SingHealth Research Institution (RI) review of all Deviation / Non-Compliance (DNC) and Serious Adverse Event (SAE) reports,

- a) for Human Biomedical Research (HBR),
- b) that occurred at any SingHealth site, and
- c) submitted to either CIRB or DSRB,

as required by **Human Biomedical Research Act 2015**.

Note: The module excludes review of DNC/SAE for HSA clinical trials. The **Sponsor (e.g. institution) of an IIT** remains responsible for maintaining oversight for the HSA clinical trial. The Sponsor shall report **serious breaches and SAEs** to HSA separately.

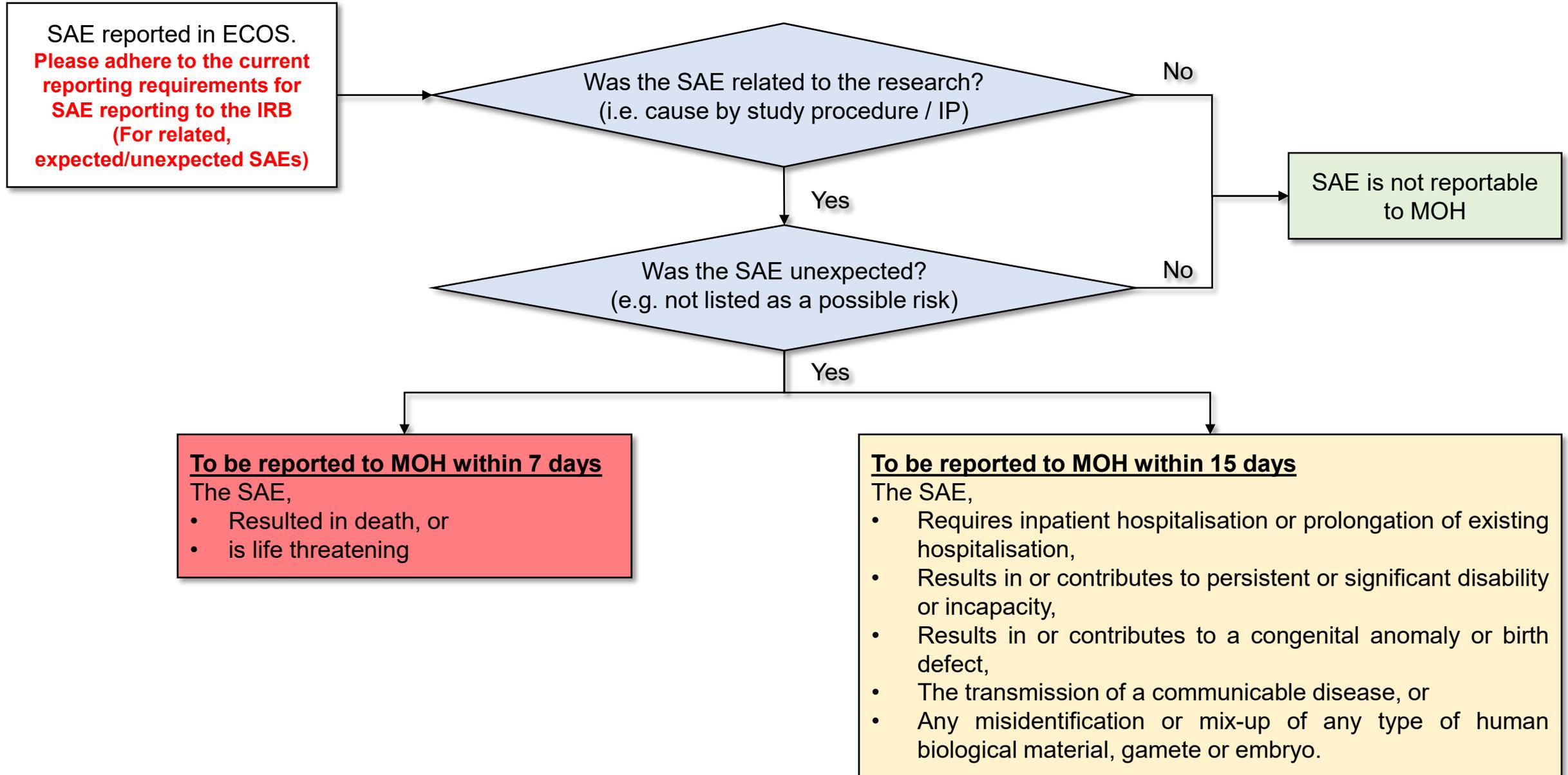
# Refresher: Suspected Offense or Contravention (SOC) Reporting to MOH by RI



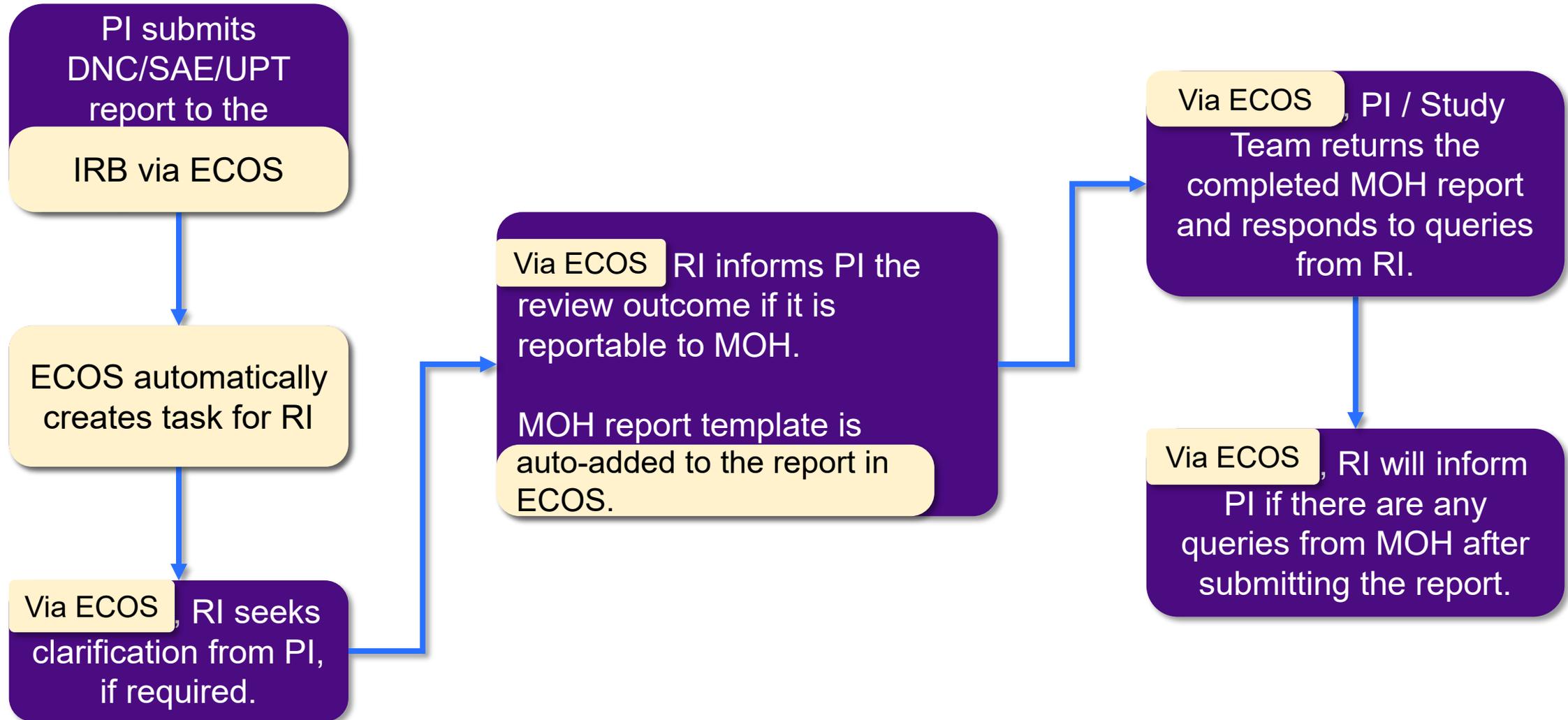
Harm to **Safety** refers to physiological harm (e.g. physical injury, loss of organ function, etc.)

Harm to **Welfare** can be psychological, social, financial or affecting one's autonomy.

# Refresher: Serious Adverse Event (SAE) Reporting to MOH by RI



## 2) ECOS Workflow



### 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>• Respond to queries on the DNC/SAE/UPT report and requests for additional information from the RI Secretariat.</li> <li>• Submit the MOH report (SOC/Tiered SOC/SAE), if DNC/SAE/UPT is to be reported to MOH.</li> <li>• Endorse the MOH report, if other Study Team Members assisted to draft the form.</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 assist the PI / Site-PI to respond to RI queries and requests.</li> <li>• Able to draft MOH report and submit to PI / Site-PI for endorsement.</li> </ul>
Research Institution (RI) Secretariat / Manager	SingHealth Cluster	<ul style="list-style-type: none"> <li>• Reviews the DNC/SAE/UPT report.</li> <li>• Reviews the MOH report for reportable events.</li> <li>• Issue queries to PI / Site-PI / other Study Team Members.</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 report for Tiered SOCs</li> </ul>

### 3) Module User Roles

- Information of site-specific Study Team Members (STM) are taken from the CRMS Module – User Authorisation List (UAL).
- Site-specific PI, Co-I and STMs can complete and submit the MOH report. 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.com.sg	
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.com.sg	
KKH_Basic1	Study Team Member	Singapore Health Services Pte Ltd	KK Women's and Children's Hospital	Family Medicine Service	Executive	shs-sitester@kkh.com.sg	
SGH_Basic1	Study Administrator	Singapore Health Services Pte Ltd	Singapore General Hospital	Renal Medicine	Senior Resident	shs-sitester@sggh.com.sg	
OCH_Basic user	Study Team Member	Singapore Health Services Pte Ltd	Outram Community Hospital	Medical	Dr	shs-sitester@och.com.sg	

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

### 3) Module User Roles

- Ensure the names of the 'Primary Site Coordinator' and 'Backup Site Coordinator' are added in the Site Information page in CRMS. This is especially important if a PI/Site-PI has a large study team with many STMs added into the UAL but only wants specific STMs to respond to tasks.

The screenshot shows the 'Study Details' page in CRMS. The breadcrumb trail is 'Compliance / Review Task / Review Task Detail / Study Details'. The study ID is '2024-3262, Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR / KK Women's and Children's Hospital'. The left sidebar shows 'Site Information' selected. The main content area has three sections: 'Contact Personnel', 'ACP Involved In This Study (For SingHealth Only)', and 'Funding (Including Grant)'. The 'Contact Personnel' section has a table with columns: 'Primary Site Coordinator', 'Backup Site Coordinator', and 'Last Edited By'. The 'Primary Site Coordinator' and 'Backup Site Coordinator' cells are empty and highlighted with a red box. The 'Last Edited By' cell contains 'KKH\_PI 1'. Below this is the 'ACP Involved In This Study' section with a dropdown menu and a table with columns: 'ACP Involved In This Study (For SingHealth Only)', 'Last Edited By', and 'La:'. The dropdown menu is empty, and the table has one row with 'KKH\_PI 1' and '1'. The 'Funding (Including Grant)' section has a table with columns: 'Name of Funding/Grant Agency', 'Reference Number', 'Title', and 'Funding/G'.

Primary Site Coordinator	Backup Site Coordinator	Last Edited By
Name of primary person	Name of back-up person	KKH_PI 1

ACP Involved In This Study (For SingHealth Only)	Last Edited By	La:
	KKH_PI 1	1

Name of Funding/Grant Agency	Reference Number	Title	Funding/G
------------------------------	------------------	-------	-----------

Please update this section in CRMS if it has not been done.

### 3) Module User Roles

Q1

In a multi-site study, will the main site be able to access or edit the SOC/Tiered SOC/SAEs occurring at the other sites?

No, the completion of SOC/Tiered SOC/SAE report will be site-specific. Site-specific STM/Co-I/PI/Site-PI will be responsible for their own completion of SOC/Tiered SOC/SAE report that occurs at their site. For example, a SOC occurring at SGH for a multi-site study, only the SGH site STM/Co-I/Site-PI will receive the task to complete the SOC report.

Q2

Can the research office personnels help to complete part of the SOC/Tiered SOC/SAE report?

No, the Research Office only has view access to all the queries and SOC/Tiered SOC/SAE reports completed by site teams. The Research Office does not have edit access. The Research Office will also be copied in the e-mail notifications.

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

You will receive a task when:	Task Status
a) There is a query for you to reply. Queries can be sent after: <ul style="list-style-type: none"> <li>• RI has reviewed the DNC/SAE/UPT submitted to IRB.</li> <li>• RI has reviewed the MOH report (SOC/Tiered SOC/SAE) submitted.</li> <li>• MOH requires clarification on MOH report submitted.</li> </ul>	<ul style="list-style-type: none"> <li>• Pending PI Response</li> <li>• MOH Report Pending PI Response</li> <li>• Pending Response to MOH</li> </ul>
b) There is a MOH Report for you to complete.	<ul style="list-style-type: none"> <li>• MOH Report Pending PI Response</li> </ul>
c) There is a MOH Report for you to endorse. <div data-bbox="282 1136 715 1210" style="background-color: #000080; color: white; border-radius: 15px; padding: 5px; display: inline-block; margin-top: 10px;">             Only for PI / Site-PI           </div>	<ul style="list-style-type: none"> <li>• MOH Report Pending Endorsement</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, and Report. The 'Dashboard' option under 'Homepage' is highlighted with a red box. The main content area displays three summary tiles: IRB (9 tasks), CRMS (1 task), and FCOI (0 tasks). Below these is a 'Compliance' tile with a total of 12 tasks. A red box highlights the 'Deviation/Non Compliance - Site' category with 8 tasks. The right sidebar shows 'My Notices' with a list of service disruption broadcast messages.

Category	Count
IRB	9
CRMS	1
FCOI	0
Compliance	12
Deviation/Non Compliance - Site	8
Serious Adverse Event - Site	4
PI Self-Assessment Form - Site	0
Study Closure Checklist - Site	0

**1B** The Compliance tile will display the total number of pending tasks assigned for your action.

Click on either "DNC – Site" or "SAE – Site" to view the tasks

## 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.

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

The screenshot shows the ECOS 'My Tasks' dashboard. The top navigation bar includes 'ECOS' and 'My Tasks'. The dashboard features four summary tiles: IRB (9), CRMS (1), FCOI (0), and Compliance (12). Below these tiles are filters for 'Deviation/Non Compliance - Site (8)', 'Serious Adverse Event - Site (4)', 'PI Self-Assessment Form - Site (0)', and 'Study Closure Checklist - Site (0)'. A table of tasks is displayed with columns for 'Latest Submission Date', 'Task Status', 'Form Type', 'Compliance Status', 'Form Ref/Task ID', 'Study Title', and 'Action'. The first row of the table has a 'View' icon circled in red. The sidebar on the left contains navigation options: Homepage, Dashboard, My Tasks, My Notices, IRB, CRMS, Compliance, FCOI, and Report.

Latest Submission Date	Task Status	Form Type	Compliance Status	Form Ref/Task ID	Study Title	Action
20-Aug-2024	Pending	SOC	Pending Response to MOH	2024-3262-DNC18-KK Women's and Children's Hospital-01D	Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR	View
20-Aug-2024	Pending	SOC	MOH Report Pending PI Response	2024-3262-DNC18-KK Women's and Children's Hospital-01B	Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR	View
20-Aug-2024	Pending	SOC	MOH Report Pending PI Response	2024-3262-DNC18-KK Women's and Children's Hospital-01A	Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR	View
13-Aug-2024	Pending	SOC	Pending Response to MOH	2024-3296-DNC1-KK Women's and Children's Hospital-01	FOR SINGHEALTH_Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR	View
17-Jul-2024	Pending	SOC	MOH Report Pending PI Response	2024-3315-DNC1-KK Women's and Children's Hospital-01	FOR SINGHEALTH_Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site Restricted HBR	View
17-Jul-2024	Pending	SOC	MOH Report Pending PI Response	2024-3296-DNC6-KK Women's and Children's	FOR SINGHEALTH_Compliance DNC/SAE UAT 1 – Multi-	View

Rows per page: 100 1-8 of 8

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

To find **ALL** pending tasks (i.e. including those not assigned for your action) **for your studies**:

### Example

In study with a large study team with many STMs added in the CRMS User Authorisation List (UAL), if only the main and backup STMs are assigned to a task, the other non-assigned STMs will not see this pending task on their personal dashboard or in 'My Tasks', i.e. it will show as "0" task for this non-assigned STM as nothing was assigned to this person.

However, the non-assigned STMs will still be able to view all the pending tasks for the study via the 'Site Task' page.

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

To find **ALL** pending tasks (i.e. including those not assigned for your action) **for your studies**:

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

**2** Click on the respective tab to select the type of task to view.

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

**4** Click 'View' to open the task. Note: For non-assigned personnels, only view access. You will not be able to edit and submit the form.

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

The screenshot shows the ECOS interface with the 'Site Task List' module selected. The main content area displays a table of tasks. The table has columns: Task ID, ECOS Ref, Status, Date of DNC reported, PI/Site PI, Study Site, and Action. A single task is listed with the following details:

Task ID	ECOS Ref	Status	Date of DNC reported	PI/Site PI	Study Site	Action
2024-3296-DNC7-KK Women's and Children's Hospital-01	2024-3296	Pending PI Response	16-Jul-2024	A/Prof KKH_PI 1	KK Women's and C Hospital	

At the bottom of the page, there is a pagination control showing 'Rows per page: 100' and '1-5 of 5'.

The 'Filter' dialog box on the right side of the screenshot contains the following fields:

- Task ID:
- ECOS Ref:
- Status:
- Date of DNC reported:  Start Date → End Date
- PI/Site PI:
- Study Site:
- Department:

Buttons:

# Navigating the Module – Where to find your tasks?

To see all tasks (pending and completed), clear all task status in the filter tool:

**6** Click 'Filter'.

f DNC reported	PI/Site PI	Action
2024	A/Prof KKH_PI 1	

Filter

**7** Clear the default selection of task status by hovering your mouse cursor over the 'v' until it changes to a 'x' and clicking on it.

Task ID:

ECOS Ref:

Status:

- MOH Report Pending PI Response x
- Pending PI Response x
- MOH Report Pending Endorsement x
- Pending Response to MOH x

Date of DNC reported:

PI/Site PI:

Reset Search

**8** Enter the Task ID or the ECOS Ref No.

Filter

Task ID:

ECOS Ref:

Status:

Date of DNC reported:

PI/Site PI:

Department:

Reset Search

**9** Click 'Search' to see all the tasks.

Click on 'Reset' to restore the default selection of task status to see only pending tasks again.

## 4) Navigating the Module: How to reply to a query?

Site Task Detail

2024-3296-DNC7-KK Women's and Children's Hospital-01 | KK Women's and Children's Hospital Pending PI Response

ECOS Ref: 2024-3296

Date of DNC reported: 16-Jul-2024

Current Editor: -

Study Title: FOR SINGHEALTH\_Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR

Quick Link: [Study Summary](#)

[DNC \(RI Query\)](#) Attachment

DNC (RI Query)

1. Which study site(s) did this/ these Study Deviation/ Non-Compliance occur at?

- KK Women's and Children's Hospital
- National Cancer Centre Singapore
- National University Hospital
- Tan Tock Seng Hospital

2. Date of Occurrence of Study Deviation/ Non-Compliance . ⓘ

16-Jul-2024

Guidance

**DNC Form**

Declaration

Query List

1

Click on 'Query List' to view the consolidate list of queries for the whole DNC /SAE report. A pop-up page will appear on the right.

The red dot will indicate that there are unanswered queries.

## 4) Navigating the Module: How to reply to a query?

Different types of queries can be found under their respective query list:

Type of queries	Task Tab	Refer to
RI queries on DNC/SAE/UPT report submitted to IRB	DNC/SAE/UPT (RI Query)	
RI queries on the completed MOH report	MOH report	
MOH queries on the submitted MOH report	MOH report	

### **Note**

The red dot will indicate that there are unanswered queries.

## 4) Navigating the Module: How to reply to a query?

The screenshot shows the 'Query List' interface. On the left, there's a sidebar with a 'DNC (RI Query)' section containing a list of study sites and a date field. The main area displays a list of queries, with the first one selected. The 'Pending Query' tab is active, showing a progress bar for 0/2 pending queries. Below the query details, there are two 'Reply Query' sections, each with a text input field and an attachment link labeled 'Attachment.docx'.

**2** Default view will be the 'Pending Query' tab.  
The 'All Query' tab will display completed and pending queries.  
There is a progress bar to indicate the number of pending queries you have replied.

**3** View attachments (if any) from the RI Secretariat by clicking on it.

**4** Reply to the query in the text box.

**5** Click on any space outside of the 'Query List' page to exit it. Drafted replies will be automatically saved.

## 4) Navigating the Module: How to reply to a query?

6

Site Task Detail

2024-3262-DNC12-KK Women's and Children's Hospital-01 | KK Women's and Children's Hospital Pending PI Response Reply Query

ECOS Ref: 2024-3262

Date of DNC reported: 16-Jul-2024

Current Editor: -

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

Quick Link: [Study Summary](#)

[DNC \(RI Query\)](#) Attachment

DNC (RI Query) Query List

**Guidance**  
This report form should be submitted once Principal Investigator is aware of the non-compliance/ study deviation according to the reviewing IRB's requirement. All sections must be completed. Principal Investigators are obliged to suspend their research immediately pending their report to the IRB if deviations are substantial or are likely to result in greater harm or greater likelihood of harm to the research participants.

**Definitions**  
Study Deviation: is an unplanned excursion from the study that is not implemented or intended as a systematic change.

- A study deviation could be a limited prospective exception to the protocol (e.g. agreement between sponsor and investigator to enroll a single research participant who does not meet all inclusion/exclusion criteria). Like study amendments, deviations initiated by the investigator must be reviewed and approved by the IRB and the sponsor prior to implementation, unless the change is necessary to eliminate an immediate hazard to the research participants.
- Study deviation is also used to refer to any other, unplanned, instance(s) of study non-compliance. For example, situations in which the investigator failed to perform tests required by the protocol or failures on the part of the research participant(s) to complete scheduled visits as required by the protocol.

Guidance  
DNC Form  
Declaration

Click 'Reply Query' to submit.

**Note:** The system will only allow you to click on 'Reply Query' when ALL queries have a reply.

There is no red dot if all queries have a reply.

## 4) Navigating the Module: How to reply to a query?

Site Task Detail

2024-3262-DNC12-KK Women  
ECOS Ref: 2024-3262

Date of DNC reported: 16-Jul-2024  
Current Editor: -  
Study Title: Compliance DNC/SAE UAT 1 – M  
Quick Link: [Study Summary](#)

[DNC \(RI Query\)](#) Attachment

DNC (RI Query)

**Guidance**  
This report form should be submitted once Prin requirement. All sections must be completed. P deviations are substantial or are likely to result i

**Definitions**  
Study Deviation: is an unplanned excursion from  

- A study deviation could be a limited prospere research participant who does not meet all reviewed and approved by the IRB and the research participants.
- Study deviation is also used to refer to any other, unplanned, instance(s) or study non-compliance. For example, situations in which the investigator failed to perform tests required by the protocol or failures on the part of the research participant(s) to complete scheduled visits as required by the protocol.

Do you want to submit the following replies with the latest form?

Query Item: 4. Please describe in detail the nature of the Study Deviation/ Non-Compliance and chronology of events, including why or how the Study Deviation/ Non-Compliance occurred. For studies with multiple study locations, please specify the study location.

Please provide more details.  
[Attachment.docx](#)

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Maecenas porttitor congue massa. Fusce posuere, magna sed pulvinar ultricies, purus lectus malesuada libero, sit amet commodo magna eros quis urna. Nunc viverra imperdiet enim.

Query Item: 7. Please explain:

Please provide more details.  
[Attachment.docx](#)

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Maecenas porttitor congue massa.

Cancel Confirm

A pop-up will appear to prompt you to confirm your decision to submit your reply. Click on 'Confirm' to proceed.

All replies will be displayed here (read-only). To edit the reply again, click 'Cancel' to return.

## 4) Navigating the Module: How to complete the MOH report?

1

Click on 'SOC' / 'Tiered SOC' / 'SAE' tab.

The tab will appear only if the RI Secretariat has determined the event is reportable to MOH.

The MOH Report template will load with some pre-filled details auto-populated from the DNC / SAE report.

2

Click on 'Edit' to complete report.

## 4) Navigating the Module: How to complete the MOH report?

The screenshot shows the 'Site Task Detail' page for a specific site task. The header includes a home icon, a menu icon, and a 'Back to Site Task List' link. The main title is '2024-3262-DNC5-National Cancer Centre Singapore-01E | National Cancer Centre Singapore'. Below the title, there is a 'MOH Report Pending PI Response' status and a 'Submit' button. The page displays various details: ECOS Ref: 2024-3262, Date of DNC reported: 11-Jul-2024, Outcome: Reportable as SOC within 7 days, Current Editor: NCC\_BU, and Study Title: Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR. A 'Quick Link: Study Summary' is also present. The 'SOC' tab is selected, showing a form with two questions and radio button options. Two callouts are present: callout 3 points to the 'Save' button, and callout 4 points to the 'Track Changes' button.

Site Task Detail

2024-3262-DNC5-National Cancer Centre Singapore-01E | National Cancer Centre Singapore MOH Report Pending PI Response Submit

ECOS Ref: 2024-3262

Date of DNC reported: 11-Jul-2024 Outcome: Reportable as SOC within 7 days

Current Editor: NCC\_BU

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

Quick Link: [Study Summary](#)

DNC (RI Query) **SOC** Attachment

**SOC** Cancel Save Track Changes e-Form Query List

Reporting Suspected Off... Annex A

**Important note:**

\*1) Did the SOC arise in relation to a HBR study?

Yes

No

\*2) Did the SOC cause harm/death to or had the potential to cause harm to research subjects?

Yes

No

**3** Click on 'Save' to save a draft of the MOH report.

**4** 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 MOH report?

Review Task Detail

2024-3262-DNC14-National Cancer Centre Singapore-01 | National Cancer Centre

MOH Report PI Responded, Pending RI Review

Track Changes

5 Select the 2 different versions of the report to compare. By default, the system will compare between the latest version and the version immediately before that.

Close Export

Current Version 25-Jul-2024 14:35:35 2024-3262-DNC14-National Cancer C... ▾

Previous Version 19-Jul-2024 17:25:27 2024-3262-DNC14-National Cancer C... ▾

Reporting Suspected Offence or Contravention (SOC)

Date

~~19-Jul-2024~~ 25-Jul-2024

Green highlight refers to text added.

Purple highlight with strikethrough refers to text deleted.

\*1) Did the SOC arise in relation to a HBR study?

Yes

No

## 4) Navigating the Module: How to complete the MOH report?

Site Task Detail

2024-3262-DNC12-KK Women's and Children's Hospital-01 | KK Women's and Children's Hospital Pending PI Response Reply Query

ECOS Ref: 2024-3262

DNC (RI Query) Attachment

Attachment + Upload Attachment

Document	Document Description	Uploaded by	Upload Date	Action
No Record				

**6** To attach supporting document(s) required for any of your replies, click on the 'Attachment' tab.

**7** Click on 'Upload Attachment' button and a pop-up page will appear on the right.

Click 'Upload' and select the file to upload. Provide a description to the document. For a query related attachment, you can indicate which query it is for.

Click 'Save' to complete the upload.

**Note:** Only the user who uploaded the documents can delete them.

Upload Attachment Save

Document Description:

\* Document:

Upload

Examples of attachments for the SOC & SAE report: Study Protocol, IRB Application Form, Informed Consent Form, etc.

## 4) Navigating the Module: How to complete the MOH report?

Site Task Detail

2024-3262-DNC5-National Cancer Centre Singapore-01E | National Cancer Centre Singapore

ECOS Ref: 2024-3262

Date of DNC reported: 11-Jul-2024 Outcome: Reportable as SOC within 7 days

Current Editor: -

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

Quick Link: [Study Summary](#)

DNC (RI Query) SOC Attachment

SOC

Important note:

\*1) Did the SOC arise in relation to a HBR study?

Yes

No

\*2) Did the SOC cause harm/death to or had the potential to cause harm to research subjects?

Yes

No

MOH Report Pending PI Response

Submit

Export Edit Track Changes e-Form Query List

Reporting Suspected Off...

Annex A

9B

Always check the task status before exporting as you may not be viewing the version that is submitted to MOH.

9A

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

8

Click on 'Submit' to submit the MOH report for RI Secretariat review.

If the mandatory fields are not completed, the report cannot be submitted.

## 4) Navigating the Module: How to complete the MOH report?

Information required on the MOH report is exactly the same as the hard copy version.

### Sample SOC Reporting Template



MINISTRY OF HEALTH  
SINGAPORE

**REPORTING SUSPECTED OFFENCE OR CONTRAVENTION (SOC)  
UNDER SECTION 23(3) OF THE HUMAN BIOMEDICAL RESEARCH ACT (HBRA)**

**Form A1 – HUMAN BIOMEDICAL RESEARCH (HBR)**

**Important note:**

**1) Did the SOC arise in relation to a HBR study?**

Yes (please fill up the form below)

No (incident is not reportable under the HBR framework. Please use Form B\* to report SOCs related to tissue banks and tissue banking activities)

**2) Did the SOC cause harm/death to or had the potential to cause harm to research subjects?**

Yes (please fill up the form)

No (please report the SOC using the form on TIARAS during annual declaration of compliance)

Note: Incidents involving consent obtained in the absence of a witness do not need to be reported if the incidents fulfilled the exemption criteria specified in Regulation 2 of the Human Biomedical Research (Requirements for Appropriate Consent – Exemption) Regulations 2019.

**A) Name of Supervising Research Institution (RI)**

Tap here to enter text.

**B) Summary of Suspected Offence or Contravention**

**Date of incident(s):** Tap here to enter text.

**Date supervising RI first becomes aware of incident:** Tap to enter a date.

**No. of subjects affected:** Tap here to enter text.

**Brief description of SOC:**

Tap here to enter text.

**RI's assessment of harm caused / potential harm to the safety<sup>1</sup> & welfare<sup>2</sup> of research subjects (i.e. Type of harm and the corresponding severity):**

Note: Harm caused to the safety<sup>1</sup> & welfare<sup>2</sup> of research subjects should be included as an area of consideration in the assessment.

Tap here to enter text.

## 4) Navigating the Module: How to complete the MOH report?

### Sample SAE Reporting Template



MINISTRY OF HEALTH  
SINGAPORE

**REPORTING SERIOUS ADVERSE EVENTS (SAE)  
UNDER SECTION 23(3) OF THE HUMAN BIOMEDICAL RESEARCH ACT 2015 (HBRA)**

**Form A2 – HUMAN BIOMEDICAL RESEARCH (HBR)**

**Important note:**

**1) Did the SAE<sup>1</sup> occur in a participant during the HBR, or another research conducted outside Singapore but connected with the HBR?**

Yes (please proceed to Question 2)

No (SAEs unrelated to HBR do not need to be reported under Section 23(3) of the HBRA. If the incident is related to any tissue banking activity, please use Form B2 to report such incident)

**2) Was the SAE unexpected?**

Yes (please elaborate and fill up the form below)

**Please elaborate:**

Tap here to enter text.

No (SAEs that are expected do not need to be reported under HBR Reg 10. If the incident is related to any tissue banking activity, please use Form B2 to report such incident)

Note: In the assessment of whether the SAE was unexpected, RIs may wish to consider inter alia if the nature, frequency and severity of the SAE was consistent with either the:

(1) Known or foreseeable risk of medical occurrence associated with the procedure(s) involved in the HBR that are described in:

- a) protocol-related documents (e.g. Institutional Review Board ("IRB") approved research protocol); or
- b) other relevant source of information (e.g. product labeling); or

(2) Natural progression of underlying disease, disorder, medical condition or subject's predisposing risk factor.

---

<sup>1</sup> In relation to human biomedical research, means any untoward medical occurrence as a result of any human biomedical research which (i) results in or contributes to death; (ii) is life-threatening; (iii) requires in-patient hospitalisation or prolongation of existing hospitalisation; (iv) results in or contributes to persistent or significant disability or incapacity; (v) results in or contributes to a congenital anomaly or birth defect; (vi) results in the transmission of a communicable disease; results in any misidentification or mix-up of any type of human biological material, gamete or embryo; or results in such other event as may be prescribed.

1

## 4) Navigating the Module: How to complete the MOH report?

### Sample Tiered SOC Reporting Template

The screenshot displays the Microsoft Excel interface for a 'SOC Tiered Reporting Form for SOC's (RI).xlsx'. The ribbon is set to 'Home', and the window title is 'Chee Kok Keong (SHHQ) CK'. The form content is as follows:

**Section 23(3)(a) of the Human Biomedical Research Act  
Regulation 8(3) of the Human Biomedical Research Regulations**  
Reporting Suspected Offences or Contraventions (SOC) that **did not cause harm to** and had **no potential to cause harm to** research subjects

**Name of Research Institution:** Singapore Health Service Pte Ltd

**Reporting Period:** 01 Jan 2024 to 31 Dec 2024

S/N	SOC Category	HBRA Section(s) / Regulation(s) Contravened	IRB Reference Number	Date of SOC Occurrence	Site(s) of SOC Occurrence	Person(s) Who Contravened the HBRA	No. of Subject(s) Affected	Research Interventions Involved	Brief Summary of SOC (Please provide key details of SOC, including details of how the incident occurred)	Rationale by RI for Classifying SOC as No Harm & No Potential for Harm to Safety & Welfare of Research Subject(s)	Date Corrective Action Implemented	Date Preventive Action Implemented
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
16												
17												
18												
19												

The bottom of the screenshot shows the 'Sheet1' tab selected, and the status bar indicates 'Ready' and 'Accessibility: Investigate'.

## 4) Navigating the Module: How to complete the MOH report?

### Q1

Can the Study Team Member (STM) complete the MOH Report on behalf of the PI / Site-PI?

Yes, the STM can either:

1. Complete and submit the report directly for SingHealth RI review. The system will automatically reflect the STM's details as the submitter on the report. After review, the RI will seek PI / Site-PI endorsement of the finalised report, which will change the submitter's details to reflect the PI / Site-PI's information; OR
2. Draft, save the report and inform the PI / Site-PI to submit. Since the PI / Site-PI's details will be reflected as the submitter, subsequent step of endorsement will not be required.

Note that any steps for additional queries/endorsement will take up time. Please bear in mind the timeline for submission to MOH (especially for 7-day or 15-day reporting timeline).

### Q2

Can the STM respond to the queries on behalf of the PI / Site-PI?

Yes. But if the STM has responded to queries, and **at the same time edited and submitted the MOH report**, the STM's details will be reflected as the submitter on the report. The RI will then need to seek PI / Site-PI endorsement, so that the PI / Site-PI's details are reflected as the submitter.

Note: If the edit button is clicked and report saved, it will mean that the report has been edited.

## 4) Navigating the Module: How to complete the MOH report?

Q3

If the DNC/SAE/UPT is not reportable to MOH, what will the site team see in ECOS?

In the manual process, the RI will not contact the site team (PI / Site-PI, Co-I & STM) if there is no reporting required. Similarly, in ECOS, the site team will not see any pending tasks generated in the Compliance Module, if no reporting is required. The tab for SOC, Tiered SOC or SAE containing the MOH report details will also not appear.

If reporting is required, a pending task will show up in the Compliance Module. Notifications (email & system) will also be sent to the site team.

## 4) Navigating the Module: How to endorse the MOH Report?

Applicable to PI / Site-PI only

Review Task Detail

2024-3374-UPT2-SingHealth Polyclinic - Tampines North-01 |  
SingHealth Polyclinic - Tampines North

ECOS Ref: 2024-3374

Date of SAE reported: 15-Jul-2024 Outcome: Reportable as SAE within 7 days

Current Editor: DKNUS\_IR

Study Title: TM\_hqq20240715\_1

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

SAE (MOH) Attachment

Export Edit Track Changes e-Form Query List

Reporting Serious Adver...  
Annex A

**1** Click on 'SOC' / 'Tiered SOC' / 'SAE' tab.

**2** If required, the PI/Site-PI is still able to click on 'Edit' to make amendments to the MOH report at this stage.

**Important note:**

\*1) Did the SAE occur in a participant during the HBR, or another research conducted outside Site?

Yes  
 No

\*2) Was the SAE unexpected?

Yes  
 No

## 4) Navigating the Module: How to endorse the MOH Report?

Applicable to PI / Site-PI only

**Review Task Detail**

2024-3374-UPT2-SingHealth Polyclinic - Tampines North-01 |  
SingHealth Polyclinic - Tampines North

ECOS Ref: 2024-3374

Date of SAE reported: 15-Jul-2024 Outcome: Reportable as SAE within 7 days

Current Editor: DKNUS\_IR

Study Title: TM\_hqq20240715\_1

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

UPT (RI Query) **SAE (MOH)** Attachment

SAE (MOH) Export Edit Track Changes e-Form Query List

**Important note:**

\*1) Did the SAE occur in a participant during the H...

Yes  
 No

\*2) Was the SAE unexpected?

Yes  
 No

ECOS

Do you want to reject the endorsement of the MOH Report?

\* Comment:

Reject

MOH Report Pending Endorsement Copy X Reject ✓ Endorse

3

Click 'Endorse' to submit the MOH Report, if PI / Site PI approves the content of the report.

OR

Click 'Reject' to return the MOH report to the Study Team Member to amend.

A pop-up will appear for the PI / Site-PI to provide comments and to click 'Reject' to proceed with the rejection.

## 4) Navigating the Module: How to endorse the MOH Report?

### Q1

Will PI / Site-PI endorsement be required for every SOC/Tiered SOC/SAE report completed?

The details of the submitter will be auto-populated on the SOC/Tiered SOC/SAE report. If the PI / Site-PI has submitted the SOC/Tiered SOC/SAE report, the report (e.g., Section F of the SOC form) will display them as the Reporting Officer. No further endorsement by the PI / Site-PI is needed. If the details of Reporting Officer are the STM's, the RI will seek endorsement from the PI / Site-PI before submission to MOH.

F) Declaration by Reporter of the Suspected Offence or Contravention			
<ul style="list-style-type: none"> <li>I confirm that all information provided herein is accurate and factually correct at the time of the submission.</li> <li>I confirm that the principal person in charge of my research institution has been informed of and has assessed the harm/potential harm that may be caused to any person through this incident.</li> <li>By submitting this form, I confirm that the research institution allows the Government of the Republic of Singapore to collect, share and use the information contained herein for the purposes of data analysis, evaluation and policy formulation and review. This consent is given on behalf of the research institution and it shall be governed by and construed in accordance with the laws of the Republic of Singapore.</li> </ul>			
Name of Officer Reporting SOC	KKH_PI 1	Contact No.	67890003
Occupation/ Designation	Senior Consultant	Email Address	KKH_PI 1@abc.com
Signature		Date	11-Jul-2024

This form is generated from the Ethics and Compliance Online System (ECOS). No signature is required.

## 4) Navigating the Module: How to endorse the MOH Report?

### Q2 How do I know if the SOC/SAE report has been submitted to MOH?

Submission of SOC/SAE to MOH will be done by the SingHeath RI.

For a 7-day or 15-day submission of the SAE or 7-day submission of the SOC, when the SOC/SAE report has been submitted to MOH, the task status of 'Reported as SOC' or 'Reported as SAE' will be reflected. Tasks with these statuses can be found under the 'Site Task List' by filtering for them. They will not be shown automatically as only pending tasks are shown by default and tasks with the status of 'Reported as SOC' and 'Reported as SAE' are considered completed tasks.

2024-3262-DNC5-National Cancer Centre Singapore-01C | National Cancer Centre Singapore **Reported as SOC** [Copy](#)

ECOS Ref: 2024-3262 [📄](#)

Date of DNC reported: 09-Jul-2024 Outcome: Reportable as SOC within 7 days [🔗](#) Submission Date: 11-Jul-2024 [🔗](#)

Current Editor: IMB\_ROC1

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

Last Submitted by: Mr IMB\_ROC1

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

DNC (RI Query) **SOC** Reviewer Worksheet Attachment

**SOC** [📄 Export](#) [Track Changes](#) [📄 e-Form Query List](#) [📄 MOH Query List](#)

2024-3262-SAE1-National Cancer Centre Singapore-01B | National Cancer Centre Singapore **Reported as SAE** [Copy](#)

ECOS Ref: 2024-3262 [📄](#)

Date of SAE reported: 12-Jul-2024 Outcome: Reportable as SAE within 7 days [🔗](#) Submission Date: 23-Jul-2024 [🔗](#)

Current Editor: IMB\_ROC1

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

Last Submitted by: Mr IMB\_ROC1

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

SAE (RI Query) **SAE (MOH)** Reviewer Worksheet Attachment

**SAE (MOH)** [📄 Export](#) [Track Changes](#) [📄 e-Form Query List](#) [📄 MOH Query List](#)

## 4) Navigating the Module: How to endorse the MOH Report?

### Q3 How do I know if the Tiered SOC report has been submitted to MOH?

Tiered SOC are to be submitted annually to MOH by the SingHealth RI. If the Tiered SOC report has been or will be submitted to MOH, the task status of 'Reported as DOC' will be reflected. Tasks with these status can be found under the 'Site Task List' by filtering for them. They will not be shown automatically as only pending tasks are shown by default and tasks with the status of 'Reported as DOC' are considered completed tasks.

The screenshot displays the 'Site Task Detail' page for a task titled '2024-3262-DNC10-KK Women's and Children's Hospital-01 | KK Women's and Children's Hospital'. The task status is 'Reported as DOC', and the submission date is '07-Apr-2025'. The page includes navigation links, a back button, and a 'Back to Site Task List' link. The task details include the ECOS Ref, Date of DNC reported, Outcome, Current Editor, Study Title, and Quick Link. The task is categorized as 'Tiered SOC' under the 'DNC (RI Query)' section. The page also features an 'Export' button, a 'Track Changes' button, and an 'e-Form' button.

**Note:** As all Tiered SOC reports will be submitted to MOH during the annual Declaration of Compliance (DOC) exercise, the submission date may be a future date of the next planned annual DOC exercise.



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

### Q1

Will the PI / Site-PI receive an email notification for the endorsement of the SOC/Tiered SOC/SAE report?

Yes, if endorsement is required. Endorsement is a site-specific and will be done by the site level PI. A sample email is below.

**Task ID: 2024-3262-DNC5-National Cancer Centre Singapore-011 –  
Endorsement Required**

    [New meeting](#)  
07/22/2024 15:26:04

Dear Asst Prof NCC\_PI 2,

Task ID: 2024-3262-DNC5-National Cancer Centre Singapore-011

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

PI/Site-PI: Asst Prof NCC\_PI 2

Site of Occurrence: National Cancer Centre Singapore

This is to notify you that the above mentioned DNC/ SAE requires your action.

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

Q2

As a STM, what kind of email notifications will I receive? Will the PI / Site-PI or Co-I receive the same email notifications?

Only personnel assigned to the tasks will receive the notifications. By default, everyone in the site team (PI / Site-PI, Co-I & STM) will be assigned to tasks and will receive the notifications. The STM(s) must be added in the CRMS UAL, in order for the RI to assign them to the task.

If the site has a large team, it is important to update the 'Contact Personnel' section in the 'Site Information' page in CRMS, to indicate the main and back up STMs which will be assigned the tasks. **Otherwise, the whole team will be assigned to the tasks.**

Assigned personnels will receive email notifications for the following tasks:

- a) Reply to RI queries on the DNC/SAE/UPT form
- b) Complete the MOH (SOC/Tiered SOC/SAE) report
- c) Reply to RI queries on the MOH report
- d) Reply to MOH queries relating to MOH report
- e) For PI / Site-PI only - Endorsement of the MOH report

## Activation Date

Activation of completion of SOC/Tiered SOC/SAE report via ECOS on **2 Sep 2024**.

- A** New SOC/Tiered SOC/SAE reports to be completed will be sent through ECOS.
- B** Ongoing Tiered SOC reports will continue to be completed manually, where ORIC will continue to communicate via email with the site team.

This means that the site team will receive queries and tasks (i.e., completing the MOH report) via a mixture of email and ECOS up to the next Annual Declaration of Compliance to MOH in April 2025.

For all ongoing Tiered SOC reports that are to be completed manually, please complete them by end of 2024.

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

3 Click on the respective tab to select the type of task to view.

1 Click on the 'Compliance' module.

2 Click on 'Task Management'.

The screenshot shows the ECOS Task Management interface. The left sidebar contains navigation options: Homepage, IRB, CRMS, Compliance, Task Management (highlighted), FCOI, and Report. The main content area displays a table of tasks. At the top of the table, there are two tabs: 'Deviation/Non Compliance' and 'Serious Adverse Event', both highlighted with red boxes. The table has columns for Task ID, ECOS Ref, Status, Date of DNC reported, PI/Site PI, Study Site, and Action. The 'Filter' button is also highlighted with a red box. The table contains several rows of task data, including details like '2024-3315-DNC1-KK Women's and Children's Hospital-01' and '2024-3316-DNC1-KK Women's and Children's Hospital-01'.

Task ID	ECOS Ref	Status	Date of DNC reported	PI/Site PI	Study Site	Action
Hospital-01					Hospital	
2024-3315-DNC1-KK Women's and Children's Hospital-01	2024-3315	MOH Report Pending PI Response	12-Jul-2024	A/Prof KKH_PI 1	KK Women's and Children's Hospital	
2024-3316-DNC1-KK Women's and Children's Hospital-01	2024-3316	Reported as SOC	12-Jul-2024	A/Prof KKH_PI 1	KK Women's and Children's Hospital	
2024-3296-DNC6-KK Women's and Children's Hospital-01	2024-3296	MOH Report Pending PI Response	12-Jul-2024	A/Prof KKH_PI 1	KK Women's and Children's Hospital	
2024-3296-DNC1-KK Women's and Children's Hospital-01	2024-3296	Pending Response to MOH	12-Jul-2024	A/Prof KKH_PI 1	KK Women's and Children's Hospital	
2024-3262-DNC10-KK Women's and Children's Hospital-01B	2024-3262	MOH Report Pending RI Review	12-Jul-2024	A/Prof KKH_PI 1	KK Women's and Children's Hospital	
2024-3262-DNC10-KK Women's and Children's Hospital-01A	2024-3262	Pending RI Assessment	11-Jul-2024	A/Prof KKH_PI 1	KK Women's and Children's Hospital	
2024-3262-DNC10-KK Women's and Children's Hospital-01	2024-3262	MOH Report Pending RI	11-Jul-2024	A/Prof KKH_PI 1	KK Women's and Children's Hospital	

4 By default, all tasks will be displayed.

Click on 'Filter' to search for a specific study, tasks with SOCs submitted to MOH and etc.

4

# Navigating the Module: How to generate the Tiered SOC Report?

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

**2** Click on 'Compliance Institution Report'.

**3** Click on 'SingHealth - Tiered SOC 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.

**Other Report Templates. Do not use for now.**

ECOS Ref No.	Study Title	Name of PI	PI's Department	PI's Institution	Date of Form
2024-3262	Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR	A/Prof KKH_PI 1	Family Medicine Service	KK Women's and Children's Hospital	22-Jul-2024
2024-3262	Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR	A/Prof KKH_PI 1	Family Medicine Service	KK Women's and Children's Hospital	11-Jul-2024
2024-3262	Compliance DNC/SAE UAT 1 – Multi-Cluster, Multi-Site HBR	A/Prof KKH_PI 1	Family Medicine Service	KK Women's and Children's Hospital	11-Jul-2024

Rows per page: 100 1-3 of 3

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



# Need help?

- SingHealth Users

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

- For Non-PHI Users

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

# Highlights of the Q & A session

**Q1** How can we assign a specific Study Team Member (STM) to a task?

The SingHealth RI reviewer will refer to the Contact Personnel section on the Site Information page in CRMS module and assign the task to the listed Primary and Backup Site Coordinator, in addition to the site PI and Co-I. Hence it is important that the study team indicates the Primary and Backup Site Coordinator on the Site Information page in CRMS. This is particularly so for a study with a large team. If there are no Primary and Backup Site Coordinator indicated, RI will assign the task to the entire team of STMs based on the User Authorisation List.

**Q2** How many back-up coordinators can be added to receive the notifications?

Under the Site Information page in CRMS, only 1 personnel can be selected as the Primary Site Coordinator. As for the Backup Site Coordinator, there is no limit set in the system. All listed Backup Site Coordinators will receive the notifications for the tasks assigned, along with the Primary Site Coordinator.

## Highlights of the Q & A session

**Q3** Will I get any notifications if the DNC/SAE is deemed non-reportable to MOH?

Notifications will not be sent to the study team if a DNC/SAE is deemed non-reportable to MOH. However, users can view the DNC/SAE that are non-reportable under 'Review Task' by clearing the Filter and select 'Non-Reportable' under the 'Outcome' filter.

**Q4** I am currently a Study Administrator (SA) for a HBR study, can I assist the PI in replying queries or submitting the SOC form?

**There is no functional role for the Study Administrator in the Compliance Module.** Only STM(s) is/are able to respond to the queries and submit the MOH forms. STM can be broadly defined as site personnel directly involved in the research conduct e.g. CRCs, Study Nurses, Pharmacists, etc., whereas SA refers to site personnel not directly involved in the research but provides administrative support such as Executives involved in the Start-Up Activities of a research. **A SA should not be added as a STM for the sole purpose of answering queries or submitting MOH forms.** In the event where a study does not have a STM, PI/Site-PI or Co-I will have to respond to the tasks as needed.

Please carefully evaluate the role of the research personnel in the study before adding the personnel on the User Authorisation List (UAL).