
Expected Serious Adverse Events (SAE) ROAM Guide (For Site)

1. Administrative Instructions

- 1) Expected SAE reporting is only applicable to Human Biomedical Research (HBR) studies.
- 2) Please submit the Expected SAE via NHG ROAM from 09 Apr 2018 onwards.

2. Reporting Criteria

ALL of the following 3 criteria have to be met for reporting of Expected SAEs.

1) **SERIOUS**

These are events that meet one of the 6 categories of untoward medical occurrences as defined in the HBR Act.

- a. Results in or contributes to Death
- b. Is life-threatening
- c. Requires inpatient hospitalization or prolongation of existing hospitalization
- d. Results in or contributes to persistent or significant disability/incapacity
- e. Results in or contributes to a congenital anomaly /birth defect
- f. Any other events that may be prescribed, e.g. Medical event that may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above

2) **EXPECTED**

These are risks or events reported in the Investigator's Brochure and listed in the consent form or other study document.

3) **RELATED (including possibly related) to participation in the research**

Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

The following conditions might help to assess causality:

- a. The event has a reasonable temporal relationship to the intervention,
- b. The event could not have been produced by the underlying disease states,
- c. The event could not have been due to other non-study interventions,
- d. The event follows a known pattern of response to the intervention, or
- e. The event disappears with cessation of intervention.

3. Reporting Timeline

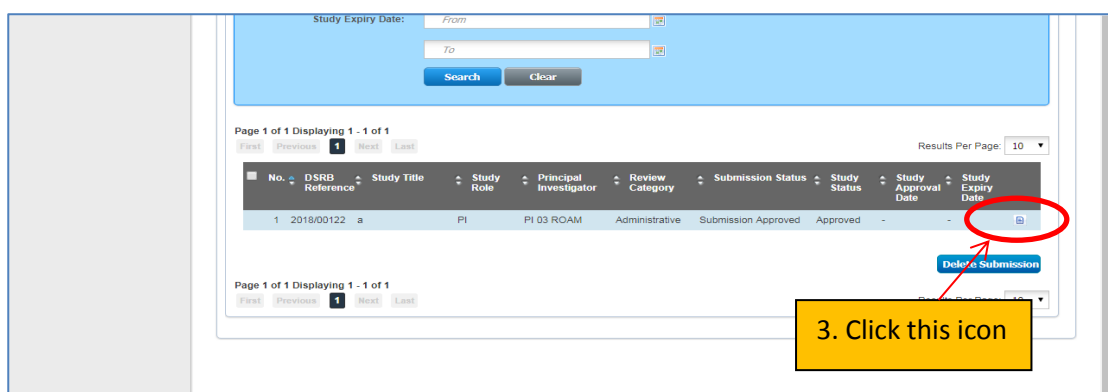
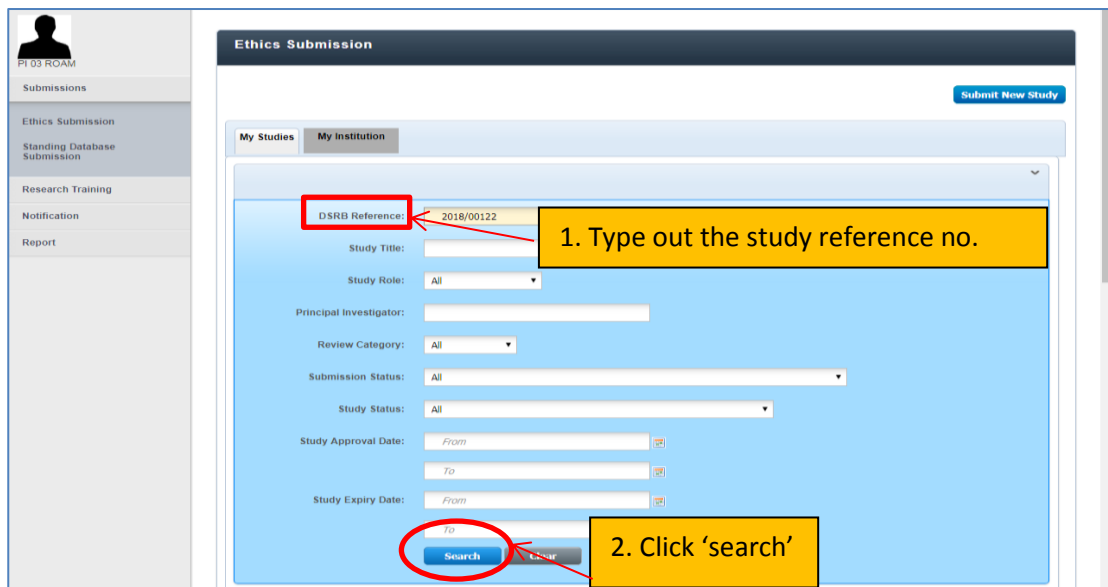
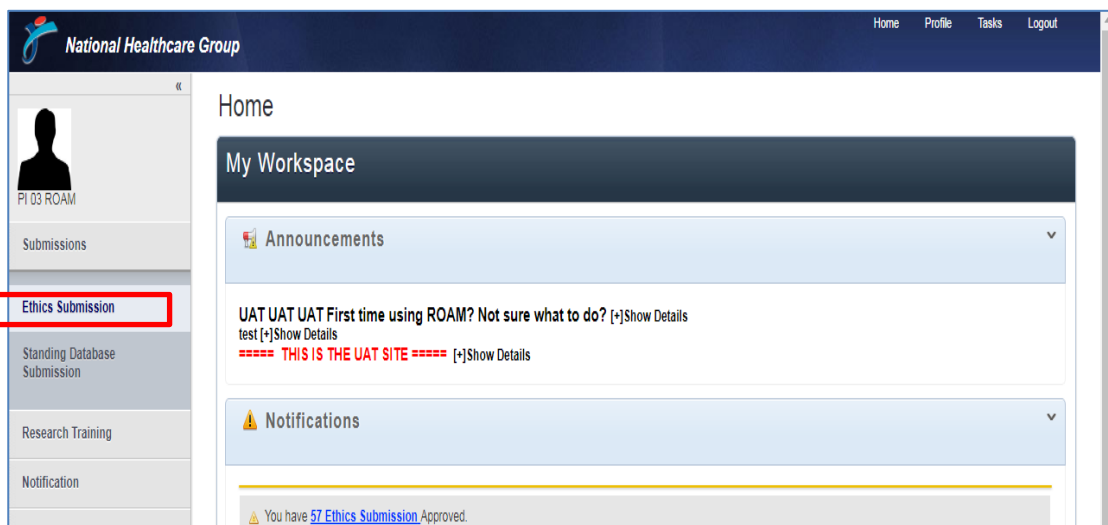
All Expected SAEs should be reported as soon as possible but not later than **7 calendar days** after first knowledge by the investigator, and any additional relevant information about the events should be reported within **8 calendar days** of making the initial report.

4. ROAM submission

- 1) In filing an Expected SAE report, a maximum of 20 events can be reported in the same form.
- 2) Each individual event requires clicking on 'Add New Event' to add a new row of details.
- 3) For supporting documents, click on 'Attach' to upload related documents pertaining to the report.
- 4) The 'I agree' declaration check box must be ticked to allow the submission to proceed
- 5) The screenshots below show the steps of submission.

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• Step 1: Locate your study in ROAM



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- **Step 2: Select 'Expected SAE report' in the drop down list**

The screenshot shows the 'Ethics' section of the ROAM system. A dropdown menu is open under the heading 'I want to create', listing several report types: New Amendment, Study Status Report, Non Compliance/Study Deviation Report, UPIRTSO Report, Expected SAE Report (highlighted in blue), and Other Study Notifications. A red circle highlights the 'Create' button to the right of the dropdown. A yellow callout box with a red arrow pointing to the 'Expected SAE Report' option contains the text: 'Select 'Expected SAE Report' and click 'Create''. Below the dropdown, a 'View application' button is visible, and the form category is listed as 'Non Exempt'.

- **Step 3: Fill up all necessary fields**

The screenshot displays the 'Expected SAE Report' form. At the top, there are tabs for 'Supp Form', 'Attachments', and 'DSRB Attachments'. The form title is 'Expected SAE Report'. Below the title, it says 'Expected SAE Report (Single/Multiple Event/s)'. A note indicates that asterisks denote compulsory fields. The form contains several fields for metadata: Form Status (Submission Draft), Form ID ([DRAFT]), DSRB Reference Number (2018/00122), Study Title (a), Principal Investigator (PI 03 ROAM), Institution (ROAM-INST), and Department (ROAM-DEPT). Below this is a table for 'Events (Maximum 20)' with columns for No., Event Onset Date, Study Site, Death at Study Site Under The Oversight of NHG DSRB, Event Keywords, and Study's risk-benefit ratio has changed. A red circle highlights the 'Add New Event' button in the top-left corner of the table. A yellow callout box with a red arrow pointing to the 'Add New Event' button contains the text: 'Click 'Add new event' to start the report'. Below the table is a section for 'Attach any applicable document(s)' with a table for document details and an 'Attach New/Replace' button. At the bottom, there is a 'Principal Investigator's Declaration' section with a checkbox for 'I agree'.

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Expected SAE Report Form

Summary Page

Section A 1) all three options need be chosen.

Section A: SAE Classification Ensure the Event fulfills all three conditions.

1) Does the event meet ALL the following criteria? [* Click here for definition of criteria](#)

- Related to the Human Biomedical Research
- Expected
- Serious

2) Classify the SAE into one of the following categories of untoward medical occurrences resulting from the human biomedical research:*

- Results in or contributes to Death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in or contributes to persistent or significant disability/incapacity
- Results in or contributes to a congenital anomaly /birth defect
- Others, e.g. Medical event that may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above

Note: If the event is UNEXPECTED, serious and related to the human biomedical research, [* Click here for determination of HBR study](#) please submit the report in the ROAM portal using the UPIRISO form.

[← Previous](#) [Next →](#) More than one option can be selected.
[Printer Friendly](#) [Cancel](#)

Section B: Basic Information

1. Event Onset Date *
01-Mar-2018

2. Date of First knowledge by NHG Site *
02-Mar-2018

3. Study Site*
Local (under the oversight of NHG DSRB)

If Local, please state which Study Site:
Tan Tock Seng Hospital

4. Type of Report*
Follow Up Report : The report to provide additional information(if available) about the particular SAE after making the initial report.

Please state the Initial Report Date *
01-Feb-2018

Report No (E.g. SAEXXXX) *
SAE0002

Fill up all sections in the Form.
Fields with *are compulsory.

- Step 4: Click 'I agree' and 'Save button

4. Any other Comments (Please attach additional pages if needed.)

Comment:

Section G: Supporting Documents

Please attach any supporting documents you may have regarding this event. (e.g. CIOMS report, MEDWATCH Report)

Document Title	Document Version Number	Document
discharge summary	-	screenshots for SAE Pre-U

Attach New/Replace

Section H: Submission Declaration

Principal Investigator's Declaration

I confirm that the information submitted in the above SAE report is true and accurate at the date of submission of

By checking the "I agree" box, you confirm that you have read, understood and accept the Principal Inv

I agree

← Previous

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- **Step 5: Click 'I agree' and 'Submit'.** The acknowledgement page will provide you with the Expected SAE no. Your report will be routed to DSRB for review.

ROAM - Supplementary Form - SAE Reporting Form (Single/Multiple Event/s) - Create - Google Chrome
10.242.16.61:10000/sop/process/ROMP/Ethics_Sub_Attachments?url=08&studyId=17404

Supp Form Attachments DSRB Attachments

Expected SAE Report (Single/Multiple Event/s)

*Denotes compulsory fields

Form Status: Submission Draft
Form ID: [DRAFT]
DSRB Reference Number: 2018/00122
Study Title: a
Principal Investigator: PI 03 ROAM
Institution: ROAM-INST
Department: ROAM-DEPT

Events (Maximum 20)

No.	Event Onset Date	Study Site	Death at Study Site Under The Oversight of NHG DSRB	Event Keywords	Study's risk-benefit ratio has changed	
1	01-Mar-2018	Local (under the oversight of NHG DSRB)	No	heart failure	No	Edit Delete

[Add New Event](#)

Attach any applicable document(s).

Document Title	Document Version Number	Document Name	Document Date
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[Attach New/Replace](#)

Principal Investigator's Declaration
I confirm that the information submitted in the above SAE report is true and accurate at the date of submission of the report.
By checking the "I agree" box, you confirm that you have read, understood and accept the Principal Investigator's Declaration.

I agree

[Submit](#) [Save Draft](#) [Printer Friendly](#) [Cancel](#)

ROAM - Ethics Submission x
10.242.16.61:10000/sop/continue/ROMP/PI_Ethic_Inbox/260/StudyListing

National Healthcare Group Home Profile Tasks Logout

PI 03 ROAM

Submissions

Ethics Submission

Standing Database Submission

Research Training

Notification

Report

Supp Form Acknowledgement

Your Expected SAE Report is 2018/00122.SAE0001

Your Expected SAE Report is sent to Anthony Chua(DSRBStaff) , NG HWEE HIAN(DSRBStaff) , DSRB Staff 01 ROAM(DSRBStaff) , Eling Ho(DSRBStaff) , DSRB Domain A1-1(DSRB Staff) , DSRB Domain A1-2(DSRB Staff) , GUO QIANPING(DSRB Staff) , Noorul Ameen S/O Abdul Jaleel(DSRB Staff) , DSRB ROAM 01(DSRB Staff) , ecq admin ecq admin(DSRB Staff) , ecqadmin(DSRB Staff) , Kian Wah Yeo(DSRB Staff) , Shijia Qiu(DSRB Staff) , Jun Hong Adam Koh(DSRB Staff) , Felicia Wong(DSRB Staff) , Lynnette Wang(DSRB Staff) , Fatimah Begum/NHG(DSRB Staff) , Siya Chen(DSRB Staff) , Jaslin Shen Fong Tan(DSRB Staff) for review.

Process Tracking

Supplementary Form Supplementary Form Review

Form submission DSRB Review DSRB Domain Member Review

Go to Ethics Submission Listing