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.

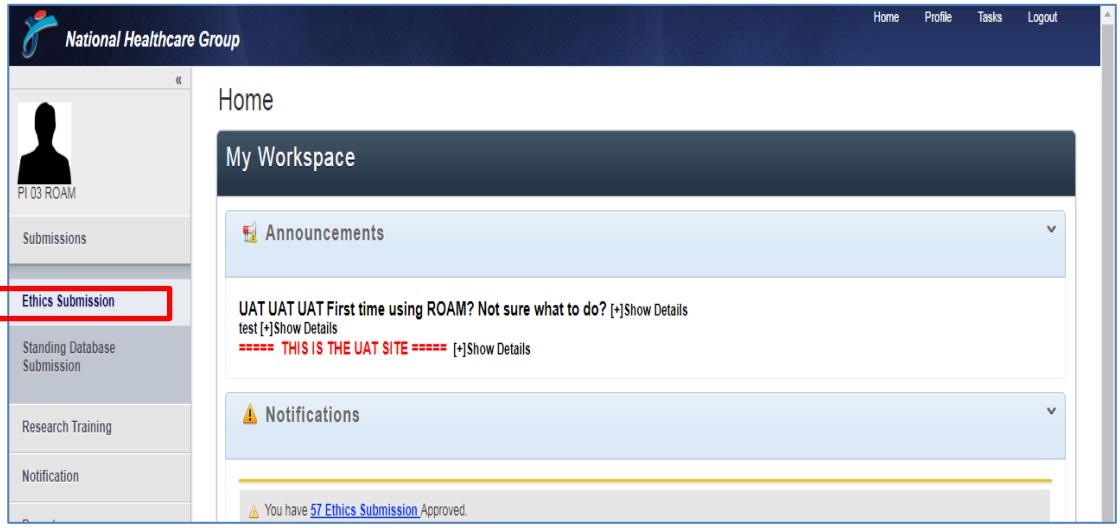
3. Reporting Timeline

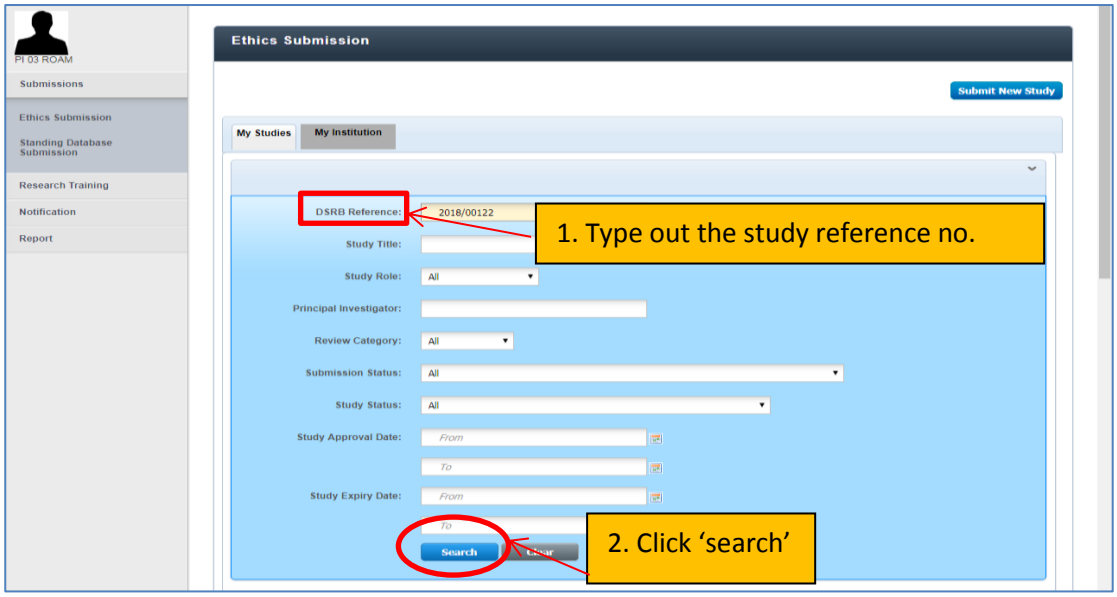
All Expected SAEs should be reported as soon as possible but not later than **7 calendar days** after first knowledge by the investigator, and any additional relevant information about the events should be reported within **8 calendar days** of making the initial report.

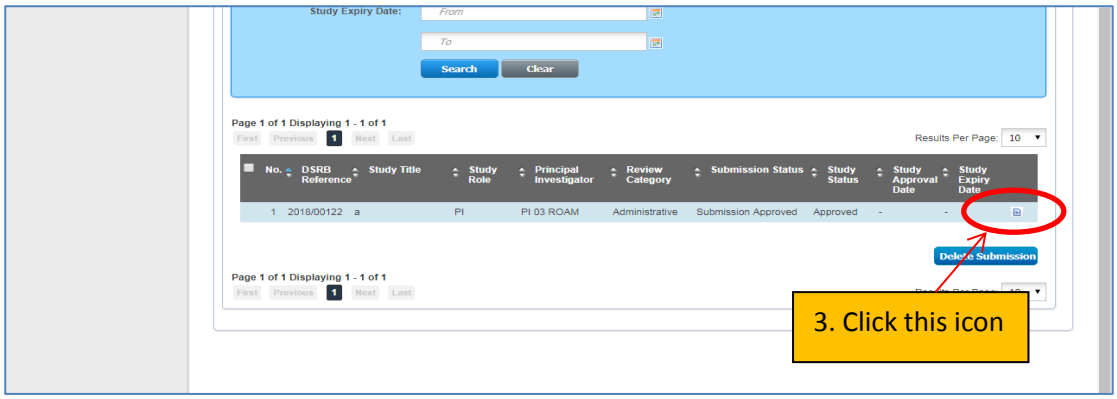
4. ROAM submission

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.

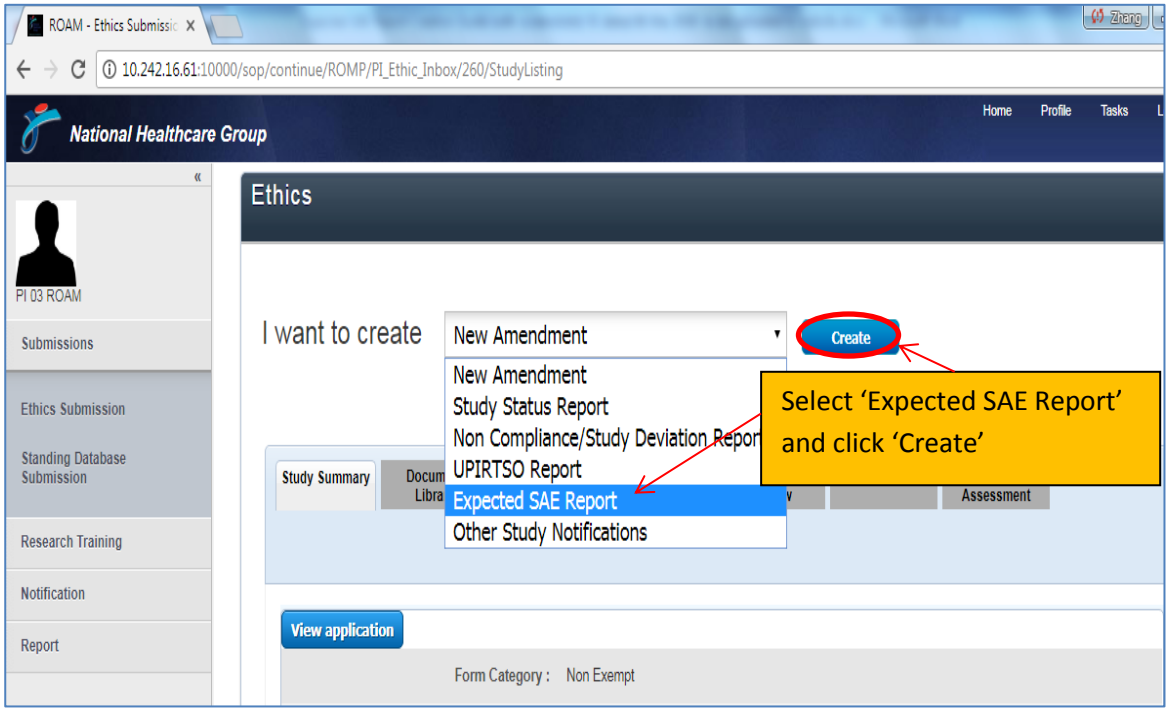
- **Step 1: Locate your study in ROAM**



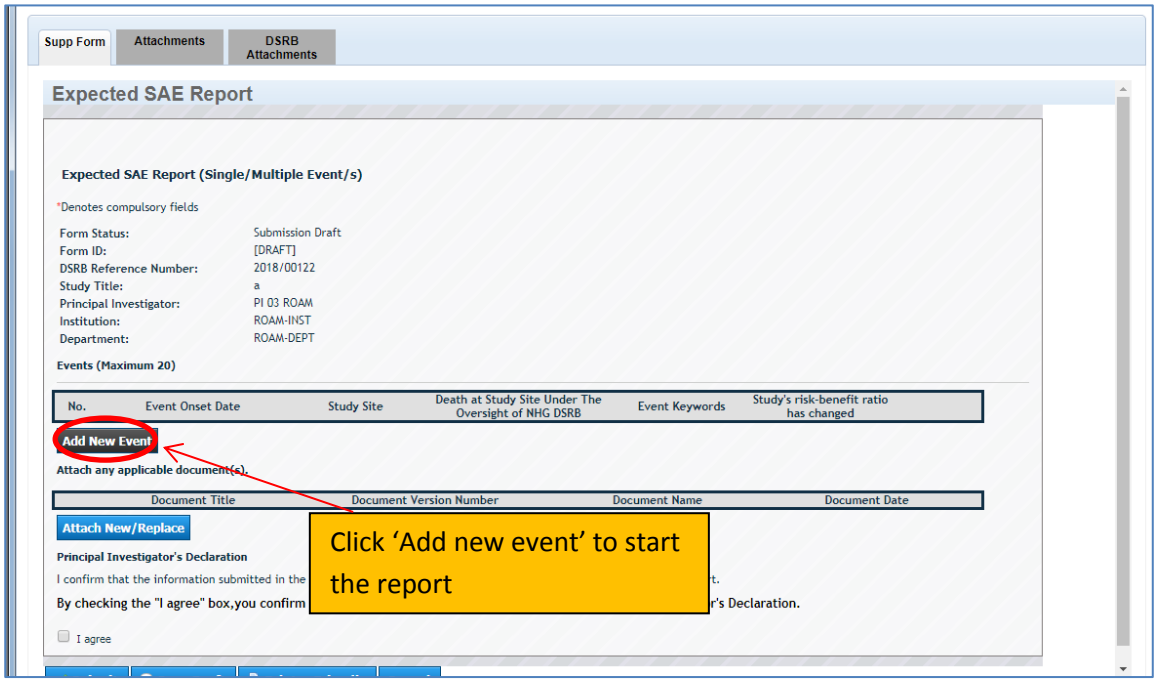


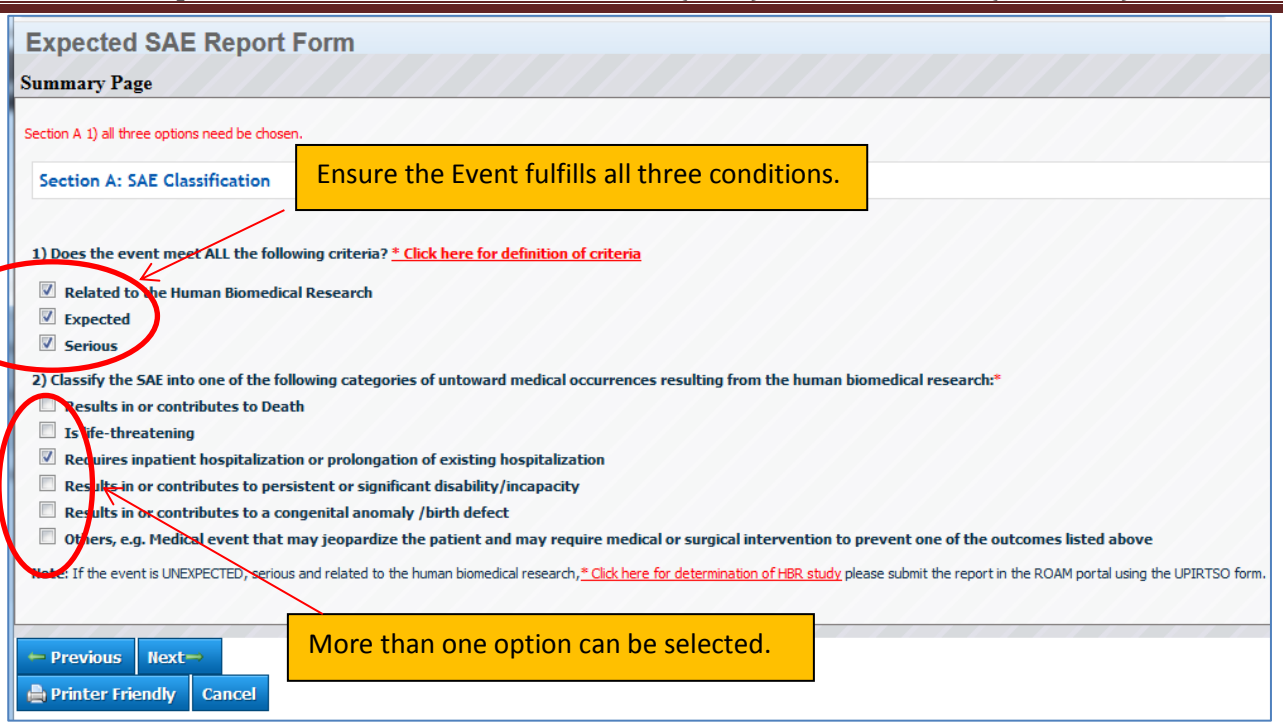


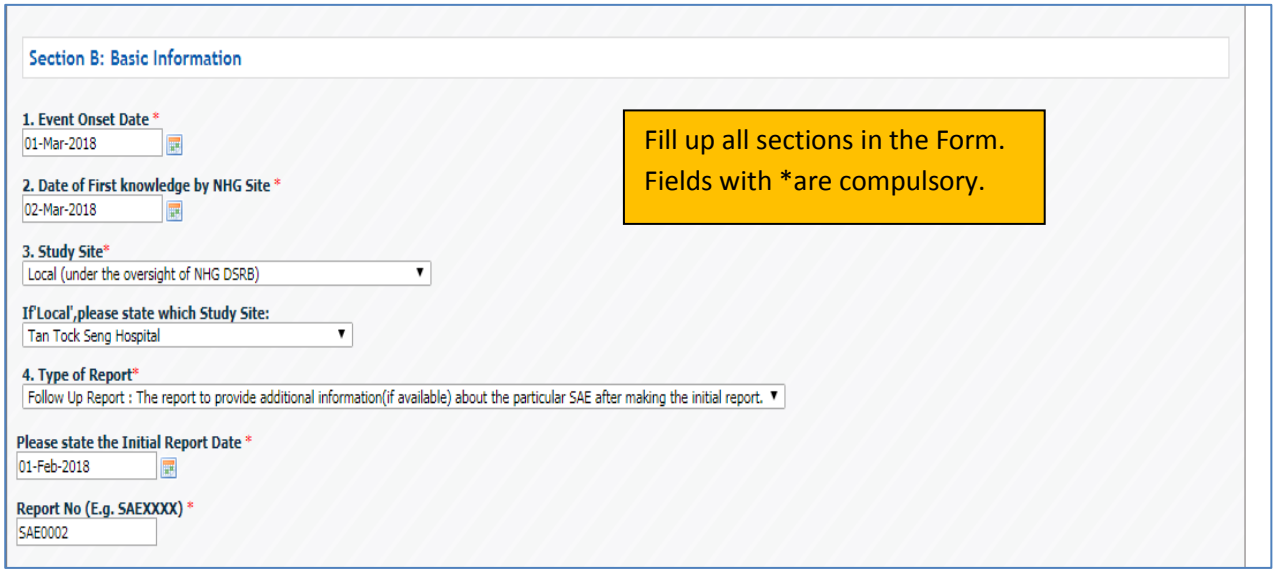
- **Step 2: Select 'Expected SAE report' in the drop down list**



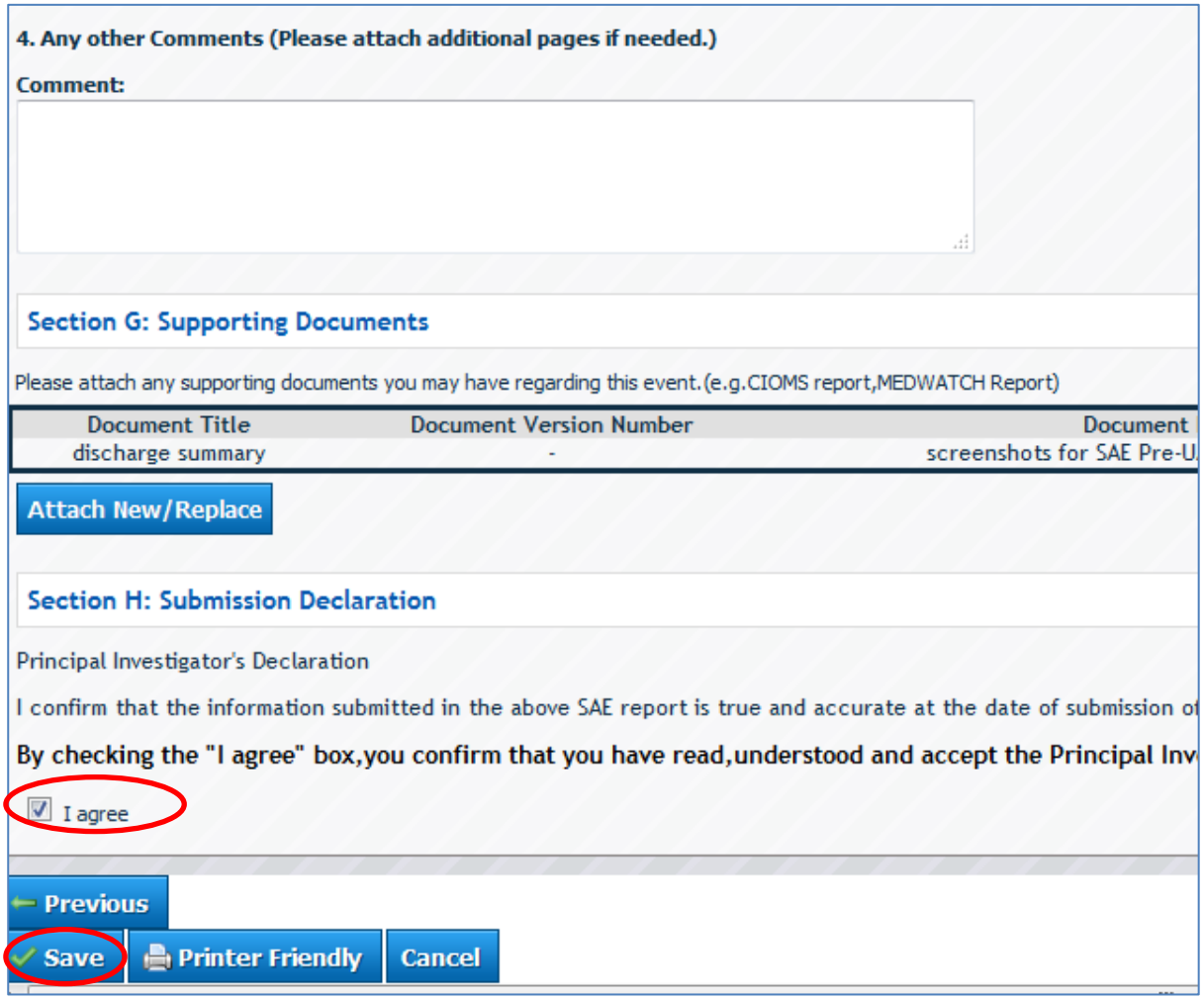
- **Step 3: Fill up all necessary fields**




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 UPIRTSO form.
More than one option can be selected.
Previous
Next
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**



- **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.**