Human Biomedical Research Act (HBRA)Update

Expected SAE Reporting (Transition Period) and DSMB report submission

Updated on 21 Nov 2017

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Expected SAE report submission

Background

Per requirement of Human Biomedical Research Regulation 2017, PI needs to submit following to Research Institution:

- All Expected Serious Adverse Events (SAE)- New
- All reports of any data and safety monitoring board established by the RI- Existing submission process

For site action:

1. Determine whether the study is HBR study.
2. Expected SAE is to be reported for HBR study via other study notification (OTH) in ROAM during transition period.
3. When and how to submit Expected SAE.
4. Submit all DSMB reports promptly via OTH (per existing process) instead of other supp forms.

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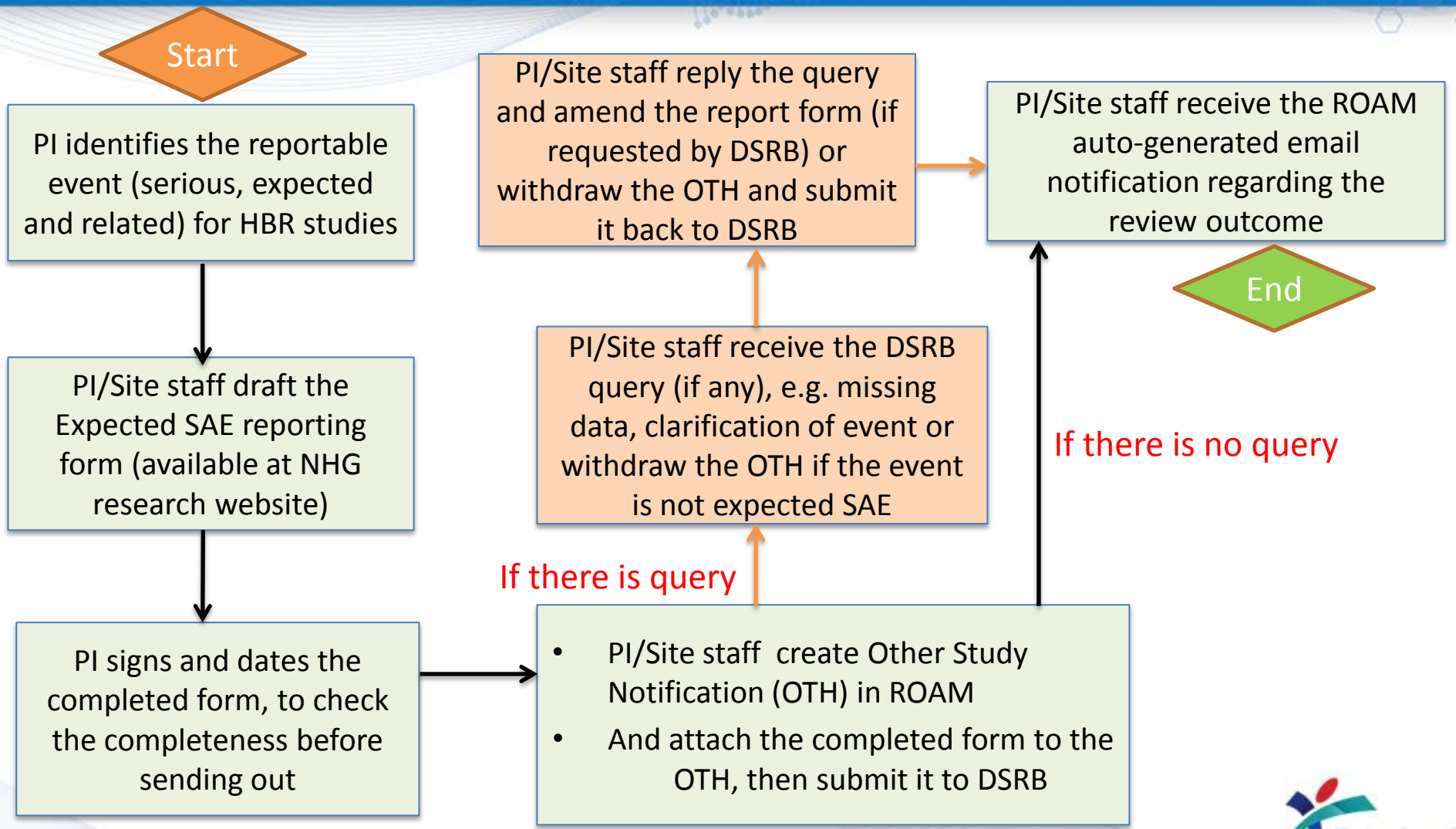
Expected SAE reporting process during transition period

***Transition period: the period while the Expected SAE form is being implemented in NHG ROAM (Estimated from Nov 2017 to Apr 2018)**



1. Expected SAE reporting form can be downloaded at NHG research website: https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/ethics+forms+and+templates+
2. Site may maintain a SAE tracking log https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/resources/pcr+sops+and+templates

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How to determine HBR study

To refer to the final definition in the HBRA Fourth Schedule

Step 1: Determine if your study falls under 'Restricted Research'.

Does my study involve any of these?

- ☐ Human gametes or human embryos; or
- ☐ Cytoplasmic hybrid embryos; or
- ☐ The introduction of any human-animal combination embryo into an animal or human; or
- ☐ The introduction of human stem cells (Inc. induced pluripotent stem cells) or human neural cells into an animal at any stage of the development (including prenatal animal foetus or animal embryo)

If YES → This study falls under 'Restricted* Research' and is under the scope of HBR.

**Restricted research will be subjected to additional HBR requirements.*

If NO → Proceed to Step 2.

Step 2: Identify if your study objective falls within the scope of HBR.

Does the intent of my study involve:

- ☐ The prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body; or
- ☐ The restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques; or
- ☐ The performance or endurance of human individuals.

If NO → This study does not fall under the scope of HBR.

If YES → Proceed to Step 3.

Step 3: Identify if the methodology employed also falls under the scope of HBR.

Does my study methodology involve:

- ☐ Subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual; or
- ☐ The use of any individually-identifiable biological material obtained from the human body; or
- ☐ The use of any individually-identifiable health information.

If YES → This study falls under the scope of HBR.

**Please note that your study falls under HBR only if you have answered 'Yes' in both steps 2 and 3.*

If NO → This study is not HBR as it does not deploy the methodology as listed under step 3.

Web link to the checklist: https://www.research.nhg.com.sg/wps/wcm/connect/8ce77a8041efd1998c6ecd0e2456f3ee/QLT2017-61.pdf?MOD=AJPERES

Expected SAE submission

1. Scope

1) Only applicable for HBR studies.
2) Applicable for both local Singapore sites and overseas sites.

E.g. For multi-centred HBR involving collaborations from local and overseas research sites for the same research protocol, any SAE which occurs in a participant during the research at the overseas site must also be reported to RI.

2. 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.

3. When to submit

As HBRA took effect on 01 Nov 2017, all submissions should be made from **01 Nov 2017 onwards.**

4. How to submit

1) Via OTH during transition period (Estimated from Nov 2017 to Apr 2018). To refer to the General Guide book for Researchers version 1.0(section 4.5) in research website for creating OTH.
2) Expected SAE reporting form is aimed to be in ROAM by Apr 2018.
3) For HBR studies approved via mutual recognition, e.g. NHG studies approved by CIRB, please submit the reportable event as per CIRB requirements.

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Guide book to create OTH:
https://www.research.nhg.com.sg/wps/wcm/connect/9e8bb080475568a88460e499433b35ae/1+Researcher+Guidebook+v1.pdf?MOD=AJPERES

DSMB submission

1. Scope

Applicable to all types of studies. For HBR studies with established DSMB, to follow the guidelines below.

2. When to submit

Prompt reporting which means to submit the DSMB report whenever it is available.

3. How to submit

1) Via OTH (per existing process)- To refer to the General Guide book for Researchers version 1.0(section 4.5) in research website for creating OTH.

2) DSRB Analyst will query site to submit DSMB report via OTH if it is submitted via other Supp Forms, e.g. SRF

3) DSRB Analyst will query site during annual review for DSMB report if it is HBR study with DSMB.

Guide book to create OTH:
https://www.research.nhg.com.sg/wps/wcm/connect/9e8bb080475568a88460e499433b35ae/1+Researcher+Guidebook+v1.pdf?MOD=AJPERES

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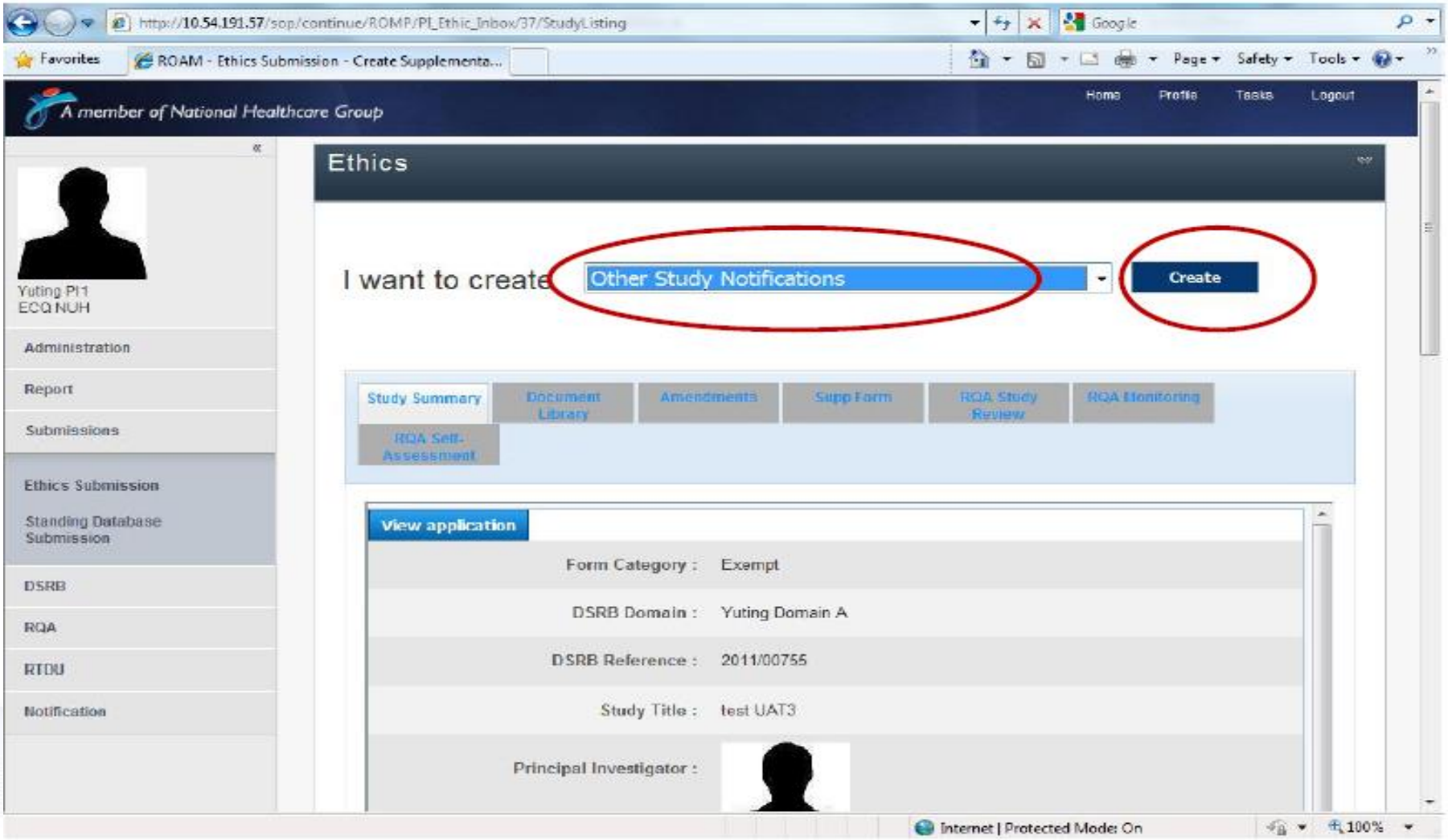
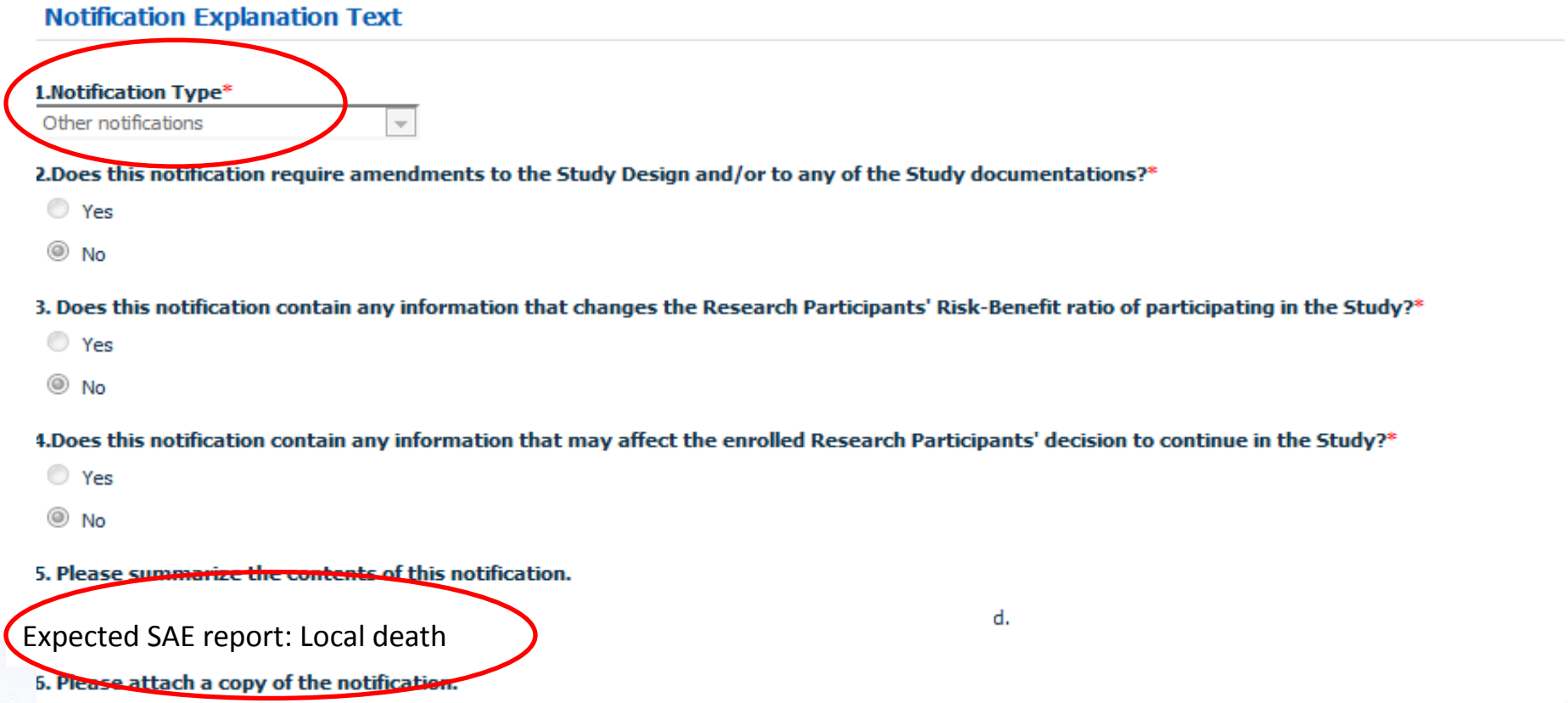
Guide to create OTH for Expected SAE (1)

1. Go to ROAM and search for the study which needs Expected SAE reporting
2. From the study page, select ‘Other Study Notifications’ from the drop down list



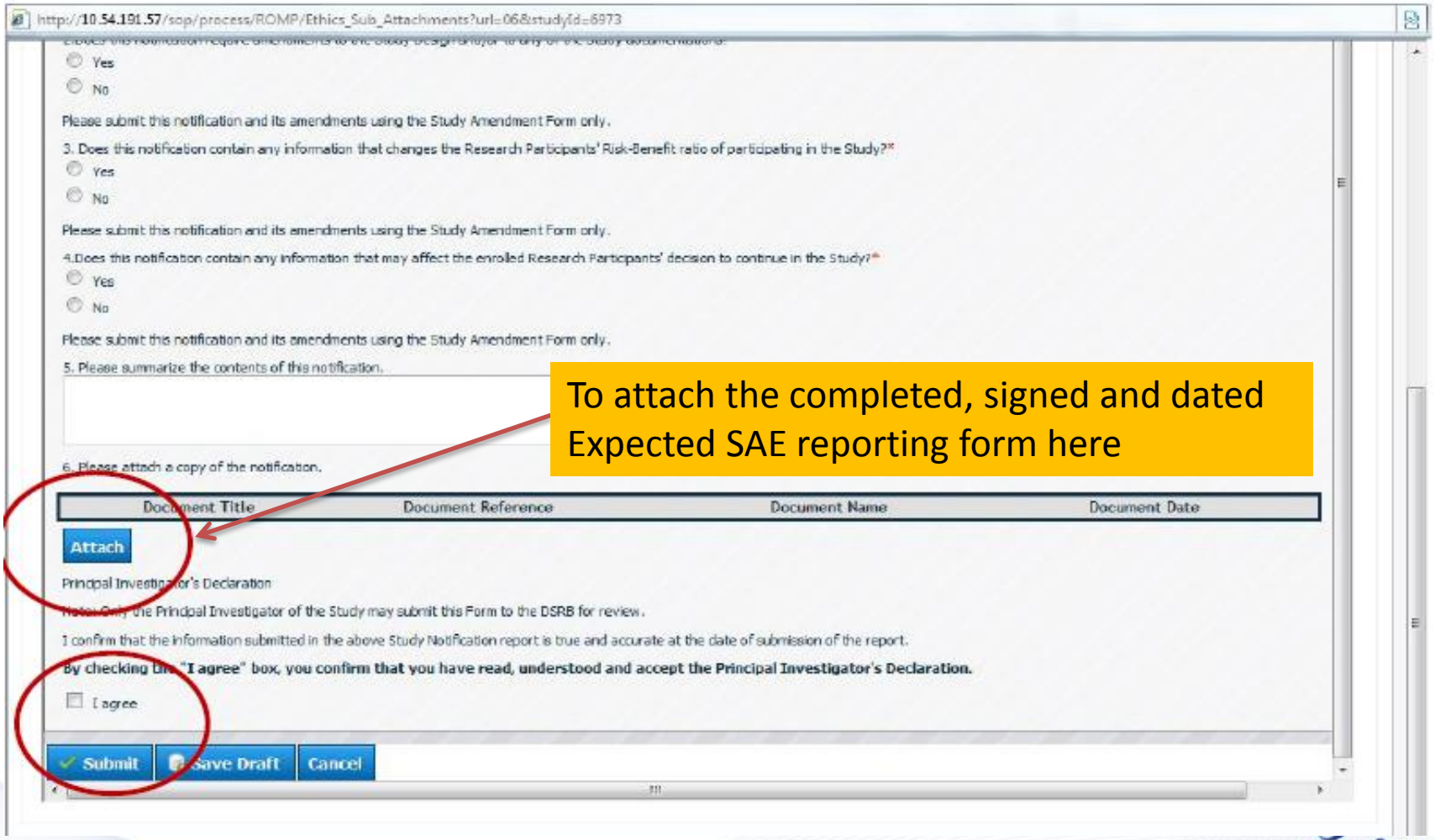
Guide to create OTH for Expected SAE(2)

3. Select ‘Other notifications’ under section 1
4. Select Yes/No if applicable for your submission under section 2 to 4
5. Summarize the content of the report under section 5. E.g. Expected SAE report: local death



Guide to create OTH for Expected SAE(3)

6. Attach the signed and dated Expected SAE reporting form under section 6



Contact information

If you have any feedback or enquiries on Expected SAE reporting, please contact us at OHRPP@nhg.com.sg or respective Domain Analyst.

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