

[Update] Human Biomedical Research Act: Reporting of Expected Serious Adverse Events (SAE)

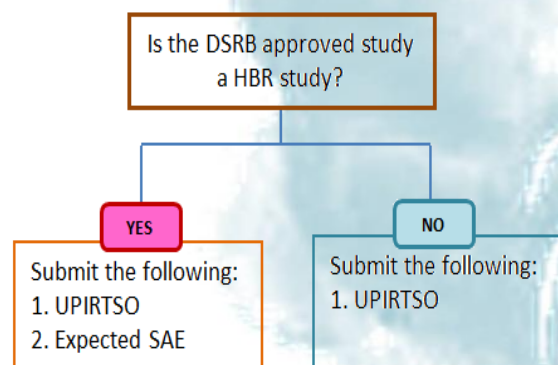
Background

The Human Biomedical Research Act (HBRA) requires all expected and unexpected serious adverse events (SAE) to be reported to the Research Institution.

Impact on Approved Human Biomedical Research (HBR) Studies

Effective 1 Nov 2017, apart from UPIRTSO reporting, Expected SAE is required to be submitted as well. This new requirement only applies to HBR studies reviewed by the NHG DSRB.

The following flow chart summarises the SAE reporting requirements:



Reportable Events

- Adverse Events that are expected, serious and related to the HBR study should be reported as soon as possible but no 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.

- Reportable events occurred in both local Singapore sites and overseas sites should be reported within the stipulated timeline above. E.g. For multi-centered HBR involving collaborations from local and overseas research sites for the same research protocol, any SAE which occurred in a participant during the research at the overseas site must also be reported.
- For the studies approved by other IRBs via mutual recognition arrangement, e.g. NHG study approved by CIRB, Expected SAE reporting should follow the requirements set by the approving IRB.

Submission Process / Instructions

The Expected SAE reporting form will be implemented in the NHG ROAM (*estimated effective date: April 2018*). Prior to that, investigator(s) would need to submit the signed and dated Expected SAE reporting form via “Other study notification” (OTH) in the NHG ROAM.

Expected SAE Reporting Forms and Guides

You may find the relevant forms and guidance for submission here.

- [Expected SAE reporting form with the user guide](#)
- [Expected SAE reporting process \(for site\)](#)
- [How to determine if your study is a HBR study](#)
- [NHG ROAM Guide book on how to create OTH: General Guidebook for Researchers, version 1, section 4.5](#)

Contact Details

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

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