MINISTRY OF HEALTH
SINGAPORE

Human Biomedical Research Act

Reporting Serious Adverse Event (SAE) for Human Biomedical Research

- **The Ministry of Health (MOH) is committed to protect the safety and welfare of research subjects, ensuring that their health and well-being are not compromised, and their privacy and autonomy respected.**
- **As part of the reporting requirements under the HBRA, it is mandatory for researchers to report all SAEs which occurred as a result of the human biomedical research (HBR) to their Research Institutions (RIs). Where the SAEs are unexpected, RIs are required to report them to MOH.**

1 What constitutes a HBR SAE under the HBRA?

SAE in relation to HBR, refers to any untoward medical occurrence **as a result of any HBR** which includes events that :

2 What type of SAE should be reported by RI to MOH?

Untoward Medical Occurrence (UMO) occurs

UMO reported to and assessed by RI in 2 steps:

A Determining relatedness of SAE

Any possible causal relationship with HBR procedures?

If no: Not an SAE under the HBRA. For such cases, RIs are advised to check with HSA if necessary.

If yes: Proceed to B.

B Determining unexpectedness of SAE

Were the nature, frequency and severity of UMO consistent with either the :

i) Known or foreseeable risk of medical occurrence associated with the procedures involved in the HBR that are described in:

a) protocol-related documents (e.g. IRB-research protocol)

b) other relevant source of information (e.g. product labeling)

Or

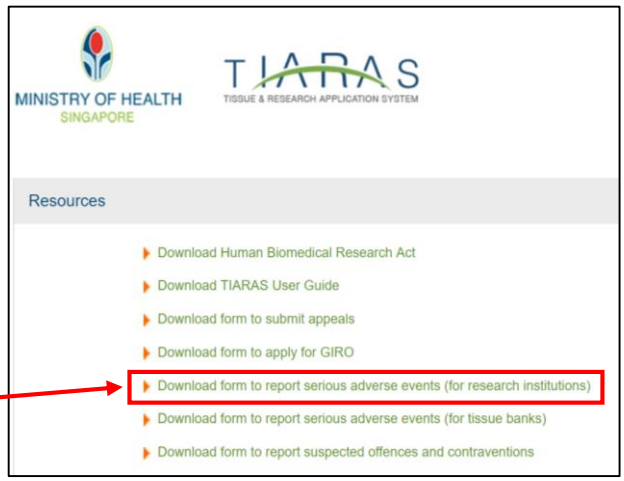
ii) Natural progression of underlying disease, disorder, medical condition or subject's predisposing risk factor

If no: It is an **unexpected SAE**. RIs are required to **report the incident to MOH within the stipulated timeline**.

If yes: It is an **expected SAE.** RIs to document SAE into RI's SAE log.

3 How to report unexpected SAE to MOH?

RIs can download the SAE reporting form from TIARAS and submit the completed form to MOH via **hbr_enquiries@moh.gov.sg**



4 What is the reporting timeline?

Did the SAE involve any death(s) or was it life-threatening?

YES

- RIs to report to MOH within **7 calendar days** after knowing the event.
- Additional relevant information should be submitted by RIs within **8 calendar days** of recording such information.

NO

- RIs to report to MOH **within 15 calendar days** after knowing the event.

5 Case studies

Case Study 1

a) HBR study aims to ascertain if switching of anti-platelet medication based on platelet reactivity assays (PRA) would make for better judgement.
b) Subject 1 died of intracranial hemorrhage while on the study.
c) Attending physician relied on the PRA rather than clinical assessment to guide the switch of drugs from Drug A to Drug B.
d) Intracranial hemorrhage is a known side effect of Drug B.

Assessment

The is an **"expected" SAE** as it occurred as a result of the HBR and is expected within the study. **Document in RI's SAE Log.**

Case Study 2

a) HBR study designed to ascertain the efficacy of using a newly developed harness as part of a stroke rehabilitation program.
b) Subject 2 suffered a fall due to the misapplication of the harness and died from intracranial haemorrhage while on the study.

Assessment

This is an **"unexpected SAE"** as it occurred as a result of the HBR but intracranial haemorrhage is not expected within the study. **Report to MOH within stipulated timeline.**

Questions?

Contact us at hbr_enquiries@moh.gov.sg

Brought to you by:
MOH Biomedical Research Regulation Branch
Regulatory Compliance & Enforcement Division