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.

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:

- Results in or contributes to death
- Is life threatening
- Results in or contributes to persistent disability or incapacity
- Requires in-patient hospitalisation or prolongation of existing hospitalisation
- Results in the transmission of a communicable disease
- Results in or contributes to congenital anomaly or birth defects
- Results in any misidentification or mix-up of any type of tissue, gametes or embryo

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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:

**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.

**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.
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

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.
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
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