Version as of 1 November 2026

Human Biomedical Research Act

Reporting Suspected Offence or Contravention (SOC)

- **The Health Sciences Authority (HSA) is committed to protect the safety and welfare of research subjects and tissue donors, ensuring that their health and well-being are not compromised, and their privacy and autonomy respected.**
- **As part of the reporting requirements under the Human Biomedical Research Act (HBRA), Research Institutions (RI) and Tissue Banks (TB) are required to report all SOCs to HSA within the timeframe stipulated in the HBRA.**

1 What constitutes an SOC under the HBRA?



An SOC refers to any non-compliance (NC) to the legal provisions set out in the Human Biomedical Research Act and its Regulations.

2 How to report SOCs?

NC reported to or detected by RI/TB.

1) Did the NC contravene any legal requirements stipulated under the HBRA and its Regulations?

- **No** → NC is **not reportable** as a SOC under HBRA.
- **Yes** →

2) Was any harm caused to the **safety** & **welfare** of research subjects or tissue donors?

- **Yes** → **Report SOC to HSA within 7 calendar days** via HSA_HBR_Enquiries@hsa.gov.sg using the SOC reporting form downloadable from TIARAS.
- **No** →

3) Was there any potential to cause harm to **safety** & **welfare** of research subjects or tissue donors?

- **Yes** → **Report SOC to HSA within 7 calendar days** via HSA_HBR_Enquiries@hsa.gov.sg using the SOC reporting form downloadable from TIARAS.
- **No** → **Report SOC to HSA in an aggregated manner during declaration of compliance (DOC) annually** using the aggregated reporting form.

HSA
Health Sciences Authority

3 What is considered harm to the safety and welfare of research subjects / tissue donors?

Harm refers to injury, adverse effect, damage or danger.

Safety refers to freedom from danger, risk or injury.

Welfare refers to the physical, emotional and material well-being of a person.

Examples

Harm to Safety

Physiological -
e.g., physical hurt is caused

Harm to Welfare

Psychological –
e.g., mental and emotional distress such as feeling threatened or humiliated

Social –
e.g., breach of confidentiality or the invasion of privacy

Financial –
e.g., incurring cost without consent

Affecting one's autonomy

4 Types of SOCs and Reporting Timelines



Human Biomedical Research Framework (HBRF)



Human Tissue Framework (HTF)

a) Deviation from IRB-approved HBR protocol by the <u>research subject.</u>



✗ <u>Not considered SOC hence is not reportable.</u>

Example:

i. **HBRF:** Research subject missed a scheduled study visit despite reminders by the study team.

b) SOCs that had <u>not</u> caused harm and have <u>no</u> potential to cause harm.

✓ <u>Reportable</u> annually during DOC using aggregated Excel reporting form.

Aggregated Excel Reporting Form

Excel

Examples:

i. **HBRF/HTF:** Administrative SOCs such as late notification to HSA;

ii. **HBRF:** Missing out an intervention or performing an intervention that involves lower risk or no risk to subjects, as compared to the interventions approved by the IRB (e.g., drawing of 20ml of blood instead of 50ml).

c) SOCs that had caused harm or have the potential to cause harm.

✓ <u>Reportable</u> within 7 calendar days using SOC reporting form.

SOC Reporting Form



Examples:

i. **HBRF:** Recruiting or performing research interventions on research subjects who did not fulfill inclusion criteria;

ii. **HBRF/HTF:** Witness is absent when taking consent from vulnerable subject/donor;

iii. **HTF:** Storing, supplying or use of human tissue in ways which deviated from the consent conditions/ restrictions of tissue donor.



Questions?

Contact us at HSA_HBR_Enquiries@hsa.gov.sg