



Human Biomedical Research Act

Reporting Suspected Offence or Contravention (SOC)

- ❖ The Ministry of Health (MOH) 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 SOC to MOH within the timeframe stipulated in the HBRA.

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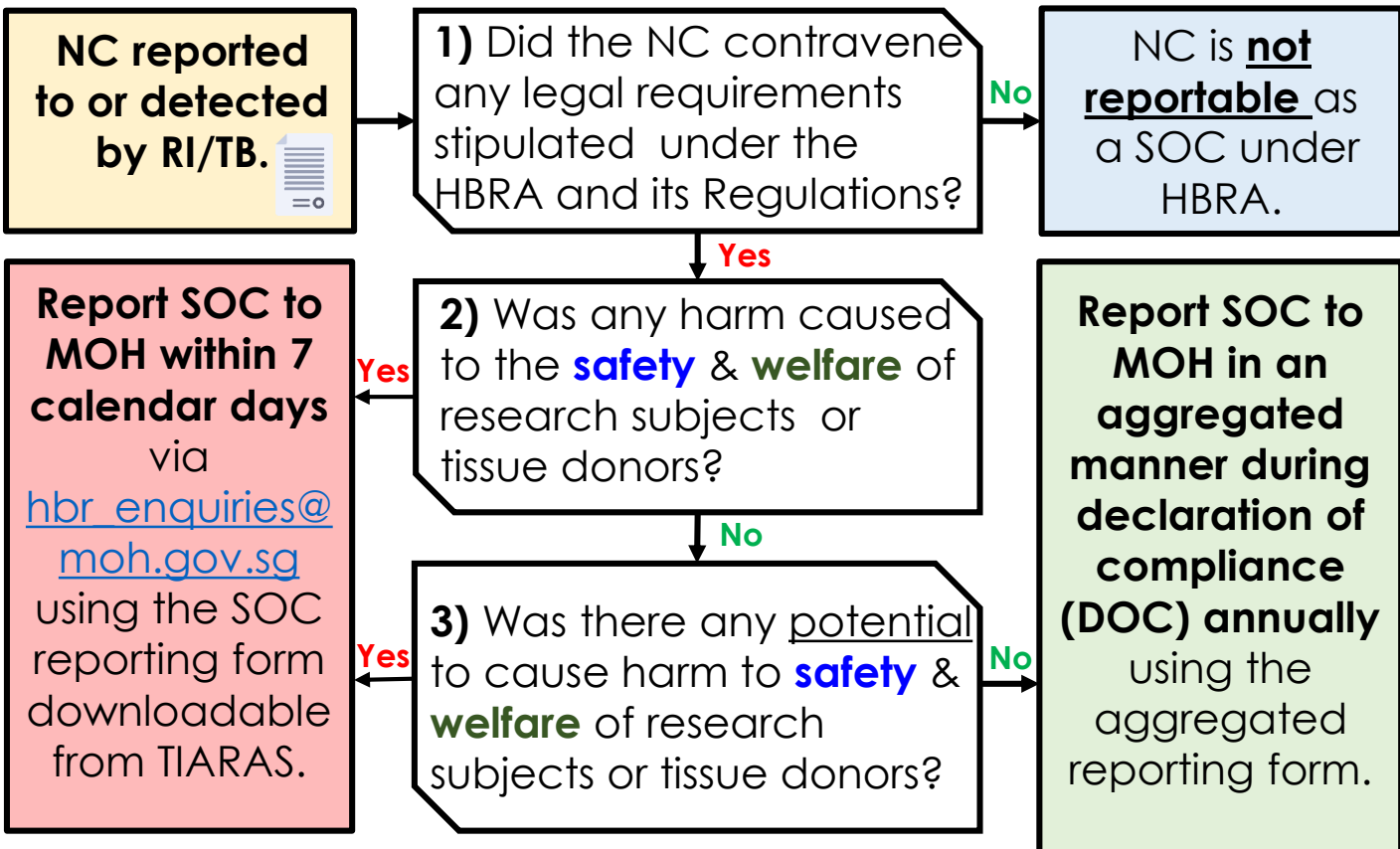
What constitutes an SOC under the HBRA?



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 SOC?





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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.



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

Social -
e.g. breach of confidentiality or the invasion of privacy.



Harm to Welfare

Financial -
e.g. incurring cost without consent.

Affecting one's autonomy.





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Types of SOC's and Reporting Timelines



Human Biomedical Research Framework (HBRF)



Human Tissue Framework (HTF)

a) Deviation from IRB-approved HBR protocol by the research subject.



Not considered SOC hence is not reportable.

Example:

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

b) SOC's that had not caused harm and have no potential to cause harm.



Reportable annually during DOC using aggregated Excel reporting form.

Aggregated Excel Reporting Form



Examples:

- i. **HBRF/HTF:** Administrative SOC's such as late notification to MOH;
- 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) SOC's that had caused harm or have the potential to cause harm.



Reportable 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 hbr_enquiries@moh.gov.sg