



REPORTING SUSPECTED OFFENCE OR CONTRAVENTION (SOC)

UNDER SECTION 23(3) OF THE HUMAN BIOMEDICAL RESEARCH ACT (HBRA)

Form A1 – HUMAN BIOMEDICAL RESEARCH (HBR)

Important note:

1) Did the SOC arise in relation to a HBR study?

- Yes (please fill up the form below)
- No (incident is not reportable under the HBR framework. Please use Form B* to report SOCs related to tissue banks and tissue banking activities)

*More details on Form B would be released after the activation of the Tissue Banking Regulations

2) Did the SOC cause harm/death to or had the potential to cause harm to research subjects?

- Yes (please fill up the form)
- No (please report the SOC using the form on TIARAS during annual declaration of compliance)

A) Name of Supervising Research Institution (RI)

Tap here to enter text.

B) Summary of Suspected Offence or Contravention

Date of incident(s): Tap here to enter text.

Date supervising RI first becomes aware of incident: Tap to enter a date.

No. of subjects affected: Tap here to enter text.

Brief description of SOC:

Tap here to enter text.

RI's assessment of harm caused / potential harm to the safety¹ & welfare² of research subjects (i.e. Type of harm and the corresponding severity):

Note: Harm caused to the safety¹ & welfare² of research subjects should be included as an area of consideration in the assessment.

Tap here to enter text.

²Examples of Harm to safety:

- (a) Physiological – physical hurt is caused.

³Examples of Harm to welfare:

- (a) Psychological – mental and emotional distress e.g. feeling threatened or humiliated.
- (b) Social – breach of confidentiality or the invasion of privacy.
- (c) Financial – incurring cost without consent of the tissue donor/ recipient
- (d) Affecting one’s autonomy.

HBRA legal provision(s) contravened: (Please indicate HBRA Sections or Regulations)

1. Tap here to enter text.
2. Tap here to enter text.
3. Tap here to enter text.

C) Chronology of Suspected Offence or Contravention

(To include date detected by PI & date reported to RI)

Date	Event
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.

D) Key Details of Affected HBR Study**IRB reference number:** Tap here to enter text.**Date of IRB’s approval:** Tap here to enter text.**Name of principal investigator:** Tap here to enter text.**Date of 1st recruitment / identifiable HI was accessed (data studies):** Tap to enter a date.

- Status of study:** In-progress
 Completed
 Suspended

Target completion date: Tap to enter a date.**Date of completion:** Tap to enter a date.a) **Date of suspension:** Tap to enter a date.b) **Please indicate if study would be resumed:** Yes No

Did the HBR involve subjecting an individual to any research intervention that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual?

Yes No

If yes, was the intervention invasive? (note: procedures that are incisional [i.e. Penetrates the skin] would be considered invasive. E.g. Finger prick tests, venipuncture and skin punch biopsies) Invasive Non-invasive Not applicable

Brief description of intervention: Not applicable

Tap here to enter text.

**E) Study Protocol, IRB Application Form & Other Supporting Documents
(Documents to be Sent by Email to MOH)**

Document type	Document name
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.
Tap here to enter text.	Tap here to enter text.

F) Declaration by Reporter of the Suspected Offence or Contravention

- I confirm that all information provided herein is accurate and factually correct at the time of the submission.
- **I confirm that the principal person in charge of my research institution has been informed of and has assessed the harm/potential harm that may be caused to any person through this incident.**
- By submitting this form, I confirm that the research institution allows the Government of the Republic of Singapore to collect, share and use the information contained herein for the purposes of data analysis, evaluation and policy formulation and review. This consent is given on behalf of the research institution and it shall be governed by and construed in accordance with the laws of the Republic of Singapore.

Name of Officer Reporting SOC	Tap here to enter text.	Contact No.	Tap here to enter text.
Occupation/ Designation	Tap here to enter text.	Email Address	Tap here to enter text.
Signature		Date	Tap to enter a date.

Note: Please submit this form to MOH via hbr_enquiries@moh.gov.sg.

A) Corrective Actions Taken to Mitigate the Impact (e.g. Physical Harm, Harm to Patient Welfare & Autonomy) of SOC:

S/N	Measures	Implementation progress	Target completion or Implementation date	How would effectiveness of measure be monitored?
E.g.	Affected patients would be informed of the unauthorised access to their health information in the EMR and assured of the safeguards put in place to prevent recurrence of similar incident.	Implemented	1-Feb-19	Call logs would be submitted to research office on a weekly basis till all affected patients have been contacted and concerns addressed.
1	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.
2	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.
3	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.
4	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.

B) Preventive Actions Implemented/To Be Implemented to Prevent Recurrence of SOC within the 1) [HBR Study](#) and 2) [Research Institution](#):

S/N	Measures	Implementation progress	Target completion or Implementation date	How would effectiveness of measure be monitored?
Preventive actions for affected study team members (For PI's inputs)				
e.g.	A consent process checklist would be introduced for consent taking. This would help remind CRC on the need to obtain parental consent for minors.	Implemented	1-Apr-19	Consent forms would be crossed checked by CRCs involved in consent taking on a weekly basis to ensure adherence to the consent process checklist. Non adherence would be flagged out to PI weekly.
1.	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.
2.	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.
3.	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.
4.	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.

Preventive actions for all researchers In the RI (For RI's inputs)

e.g.	Researchers in the RI would be reminded on RI's policy on obtaining parental consent in the next HBR newsletter and relevant consequences of non-compliance.	To be implemented	30-Apr-19	RI would be conducting checks on 4 HBR studies involving minors over the next 12 months to monitor PI's compliance to RI's policy on obtaining parental consent.
1.	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.
2.	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.
3.	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.
4.	Tap here to enter text.	Choose an item.	Tap to enter a date.	Tap here to enter text.

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