MINISTRY OF HEALTH
SINGAPORE

REPORTING SERIOUS ADVERSE EVENTS (SAE)

UNDER SECTION 23(3) OF THE HUMAN BIOMEDICAL RESEARCH ACT 2015 (HBRA)

Form A2 – HUMAN BIOMEDICAL RESEARCH (HBR)

Important note:

1) Did the SAE[1] occur in a participant during the HBR, or another research conducted outside Singapore but connected with the HBR?

☐ Yes (please proceed to Question 2)

☐ No (SAEs unrelated to HBR do not need to be reported under Section 23(3) of the HBRA. If the incident is related to any tissue banking activity, please use Form B2 to report such incident)

2) Was the SAE unexpected?

☐ Yes (please elaborate and fill up the form below)

Please elaborate:

Tap here to enter text.

☐ No (SAEs that are expected do not need to be reported under HBR Reg 10. If the incident is related to any tissue banking activity, please use Form B2 to report such incident)

Note: In the assessment of whether the SAE was unexpected, RIs may wish to consider inter alia if the nature, frequency and severity of the SAE was consistent with either the:
(1) Known or foreseeable risk of medical occurrence associated with the procedure(s) involved in the HBR that are described in:
a) protocol-related documents (e.g. Institutional Review Board ("IRB") approved research protocol); or
b) other relevant source of information (e.g. product labeling); or
(2) Natural progression of underlying disease, disorder, medical condition or subject's predisposing risk factor.

[1] In relation to human biomedical research, means any untoward medical occurrence as a result of any human biomedical research which (i) results in or contributes to death; (ii) is life-threatening; (iii) requires in-patient hospitalisation or prolongation of existing hospitalisation; (iv) results in or contributes to persistent or significant disability or incapacity; (v) results in or contributes to a congenital anomaly or birth defect; (vi) results in the transmission of a communicable disease; results in any misidentification or mix-up of any type of human biological material, gamete or embryo; or results in such other event as may be prescribed.

A) Name of Supervising RI

Tap here to enter text.

B) Summary of SAE

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

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

3) Date supervising RI first became aware of incident(s): Tap to enter a date.

4) No. of subjects affected by the incident(s): Tap here to enter text.

5) Category of SAE:

☐ Resulted in or contributed to death

☐ Was life-threatening

☐ Required in-patient hospitalisation or prolongation of existing hospitalisation

☐ Resulted in or contributed to persistent or significant disability or incapacity

☐ Resulted in or contributed to a congenital anomaly or birth defect

☐ Resulted in the transmission of a communicable disease

☐ Resulted in any misidentification or mix-up of any type of human biological material, gamete or embryo

6) Description of SAE:

Tap here to enter text.

7) Known or possible cause(s) of SAE:

(e.g. To elaborate on the link/relationship between SAE and HBR)

Tap here to enter text.

8) RI's assessment of the type and severity of harm caused to the research subjects:
Note: Harm caused to the safety[1] & welfare[2] of research subjects should be included as areas of consideration in the assessment.

Tap here to enter text.

[1]Examples of harm to safety:
(a) Physiological – physical hurt is caused.

[2]Examples 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 subject
(d) Affecting one's autonomy.

9) Assessment of SAE by appointed IRB and Principal Investigator ("PI"), if any

(a) <u>Appointed IRB:</u>

Whether the incident arose in relation to any HBR:

Tap here to enter text.

Whether the SAE was unexpected:

Tap here to enter text.

(b) <u>PI:</u>

Whether the incident arose in relation to any HBR:

Tap here to enter text.

Whether the SAE was unexpected:

Tap here to enter text.

10) Have there been other SAE that have occurred for the same HBR where the current SAE occurred?

☐ Yes ☐ No

If Yes, please provide details and the number of research subjects affected:

Tap here to enter text.

C) Chronology of SAE

(To include the dates the SAE was detected and reported to the RI by the study team)

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

1) IRB reference number: Tap here to enter text.

2) Date of IRB's approval: Tap here to enter text.

3) Name of PI: Tap here to enter text.

4) Status of HBR: ☐ On-going

☐ Suspended (a) **Date of suspension:** Tap to enter a date.

(b) **Reason for suspension:** Tap here to enter text.

(c) **Intention to resume the HBR?:** ☐ Yes ☐ No

☐ Terminated (a) **Date of termination:** Tap to enter a date.

(b) **Reason for termination:** Tap here to enter text.

5) Number of subjects recruited for the HBR till date: Tap here to enter text.

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

☐ Yes ☐ No

If Yes, was the research 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

Brief description of research Intervention(s):

Tap here to enter text.

E) Key Details of Affected Subject (s)

(Please submit details for multiple subjects as a separate attachment)

1) Subject ID / code: Tap here to enter text.

2) Age (based on birthdate): Tap here to enter text.

3) Current health status of affected subject (i.e. physiological, physical):

Date of assessment: Tap to enter a date.

Health status: Tap here to enter text.

4) Subject's underlying medical condition(s) and concomitant medication(s) (if any):

Tap here to enter text.

F) For SAE Involving Death or Hospitalisation

☐ Not applicable

1) Cause(s) of death or hospitalisation:

(a) Medical cause of death / hospitalisation:

Tap here to enter text.

(b) Possible contributing factors resulting in the medical cause (please indicate if death / hospitalisation was due to underlying health conditions):

Tap here to enter text.

2) Duration of hospitalisation: ☐ Not applicable

☐ Subject had been hospitalised since Tap to enter a date.

☐ Tap to enter a date. to Tap to enter a date.

G) For SAE Involving the Transmission of Any Communicable Disease

☐ Not applicable

1) Name of communicable disease

Tap here to enter text.

2) Possible source of communicable disease (e.g. equipment used, blood samples etc.)

Tap here to enter text.

- **Please answer 2a) – 2b) if the communicable disease originated from any <u>human biological material (Affected HBM)</u>** ☐ Not applicable

2a) Has the Affected HBM been destroyed or quarantined?

☐ Quarantined ☐ Destroyed ☐ No

Date Affected HBM was destroyed or quarantined: Tap to enter a date.
Reason for not destroying or quarantining the Affected HBM: Tap here to enter text.

2b) Possible cause of Affected HBM contamination

Tap here to enter text.

- **Please answer 2c) – 2d) if the communicable disease originated from <u>equipment</u> used in the HBR where the SAE occurred ("Affected Equipment").** ☐ Not applicable

2c) Has the Affected Equipment been quarantined or sterilised?

☐ Quarantined ☐ Sterilised ☐ No

Date Affected Equipment was quarantined / sterilised: Tap to enter a date.

Reason for not quarantining or sterilizing the Affected Equipment: Tap here to enter text.

2d) Possible cause of Affected Equipment contamination: Tap here to enter text.

3) Had any institutional measure(s) been put in place to prevent or control the spread of communicable diseases?

☐ Yes ☐ No

Brief description of institutional measure(s):

Tap here to enter text.

4) Did the study team members comply with the institutional measure(s) mentioned in 3), if any?

☐ Yes ☐ No

Reason for not complying with institutional measure(s):

Tap here to enter text.

H) 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.

I) Declaration by Reporter of the SAE

- 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 SAE	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.

ANNEX A

A) Corrective Actions Taken to Mitigate Any Impact (e.g. Relating to Autonomy, Safety or Welfare of Participants) of SAE:

S/N	Measures	Implementation progress	Target completion or Implementation date	How would effectiveness of measure be monitored?
E.g.	Appropriate medical assistance had been rendered to subject.	Implemented	1-Feb-19	Subject will be visited daily for checks on said subject's recovery. Subject will be contacted every two weeks for a period of two months post discharge.
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 by the PI Within the HBR and by the RI to Prevent Recurrence of SAE:

S/N	Measures	Implementation progress	Target completion or Implementation date	How would effectiveness of measure be monitored?
Preventive actions within the HBR (For PI's inputs)				
e.g.	HBR has been temporarily suspended to evaluate the process of administering interventions and determine possible cause of the SAE. Based on the evaluation, appropriate safety measures will be introduced to minimise the recurrence of similar SAE.	Implemented	1-Apr-19	valuation report will be submitted to the research office and the HBR will only be resumed after the RI is satisfied with the safety measures put in place. Non-compliance by the study team will be flagged out to PI on a weekly basis.
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.

Institutional-wide preventive actions by the RI (For RI's inputs)				
e.g.	Incident and safety measures would be shared with other researchers as a case study for learning purposes and compliance.	To be implemented	30-Apr-19	RI will conduct audits on two similar HBR over the next 6 months to ensure relevant safety measures are put in place.
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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