King's College London
Human Tissue Authority Licensed Laboratories

Standard Operating Procedure

Title: **Adverse Event / Incident Reporting Relating to Human Tissue for Research**

Purpose

The purpose of this SOP is to describe the process of identifying, reporting and taking action on Adverse Events/ Incidents associated with the acquisition, storage, use and disposal of human tissues for research purposes.

Scope

The scope of this SOP is to define what is classified as an Adverse Event / Incident in relation to human tissue research. It details the reporting mechanism for an AE/I, responsibility of the HTA Designated Individual and Person Designated and the escalation to KCL HTA Governance Group Chair and other appropriate College Officers.

Document Detail	
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Approved By	KCL HTA Governance Committee [30-Sep-2024]

Revision status

Each document has an individual record of amendments. The current amendments are listed below. The amendment history is available from the document control system

On issue of revised or new pages each controlled document should be updated by the copyholder.

Amendment Number: Date	Version no. Discarded	Insert Version no	Page	Section(s) involved	Amendment
1. 17/6/10	1.0	1.1	3 4 5	1.2 5 3.6 & 3.9	Inform HTA of AE/I in human application SAE/SAR graded as catastrophic Reporting to HTA
2. 28/5/13	Review Only				No changes
3. 8/6/15	1.1	2.0	3 5	1.2 & 2.3 1.3 & 4.4	Remove reference to human application AE/I. Reporting to KCL Audit and Compliance committee
4. 19/7/17	2.0	2.1	5	3.2 3.6 4.1	Added information about CAPA plans Removed the requirement to report serious AE/I to the HTA. AE/I reporting updated
5. 18/11/2019	2.1	2.2	5	3	Changed ‘College’ to KCL
6. 30/08/2022			4 5	2.3 3.4-3.8	Clarification on grading Update on reporting AE/I and communicating preventative actions
7. 30/09/2024	2.3	2.4	5	3.1 and 4.1	Major AE/I’s to be reported to HTAGG Chair immediately

Any minor amendment must be handwritten on the SOP without obscuring existing text. An asterisk should be placed in the adjacent margin to highlight the alteration. Alterations should be signed and dated by either the person designated or nominated individuals and then forwarded to the document controller. The SOP must be retyped, authorised and reissued as soon as possible. Amendments requiring immediate action should be dealt with in the same way but highlighted as high priority. Major changes must result in the immediate review of the procedure Document amendment does not replace the review process.

1 Responsibilities

1.1 User

It is the responsibility of the user to ensure that:

(i) They adhere to the AE / Incident reporting procedure outlined in this SOP.
(ii) They report any AE/ Incident to the Person Designated for their area or the Campus Designated Individual

1.2 Person Designated / Designated Individual

It is the responsibility of the PD/DI to ensure that:

(i) An AE/ Incident form has been completed by the user and reviewed for accuracy.
(ii) All reasonable enquiries or investigations relevant to the AE/Incident have been made
(iii) Steps have been taken to prevent a recurrence of an AE/Incident and information has been fed back to staff.
(iv) Information about AE/Incidents are reported to the KCL HTA Governance Group Chair in a timely manner.
(v) Other relevant KCL officers have been informed of the AE/Incident
(vi) To ensure an AE/Incident is followed up until completion
(vii) To monitor campus AE/Incident trends and take appropriate action to address system failures.

1.3 KCL HTA Governance Group

It is the responsibility of the HTA Governance Group to ensure that:

(i) An appropriate AE/Incident reporting procedure is in place
(ii) To liaise with Senior Management within both KCL and other King's Health Partners regarding AE/Incidents which have broader implications.
(iii) To provide regular updates on AE/Incidents to the KCL Audit, Risk and Compliance Committee

2 Definitions

2.1 Adverse Event (AE)

Any event that:

(i) Caused harm or had the potential to cause harm to staff or visitors
(ii) Led to or had the potential to lead to a breach of security of the premises and the contents contained therein
(iii) Caused harm or had the potential to cause harm to stored human tissue (including loss)
(iv) Gave rise to an internal inquiry

2.2 Incident

Any untoward event or sequence of events:

(i) That caused or has the potential to cause damage, harm, or a direct negative impact to an organisations business, security, reputation, facilities, personnel, safety, health and environment

(ii) Where an important policy, procedure or practice was not followed by staff leading to detrimental or the potential detriment of the above.

2.3 Grading of Adverse Events/ Incidents associated with KCL HTA Research Sector Licensable Activities

5 Catastrophic	• Loss of unique relevant material that has a significant impact on a study or potential future studies • Loss of participant identification records in public area or during transportation
4 Major	• Loss of relevant material not classed as unique • Relevant material removed from a participant, stored or used without appropriate consent • Staff member seeking consent who has not been appropriately trained • Relevant material used for a research study which has not been approved by the appropriate Research Ethics Committee • Breach of Data protection/confidentiality • Incorrect type of specimen acquired or from wrong participant. • Specimen incorrectly labelled or in wrong format, making it unusable. • Freezer/ Nitrogen back-up and alarm failure resulting in destruction of material • Unauthorised removal of material from a storage facility • Relevant material placed with non-clinical or animal waste for disposal • Quality of unique relevant material significantly compromised during transportation
3 Moderate	• Relevant material transported to or from KCL without appropriate contract/ MTA in place • Not using a tracking system to record material acquisition, storage, use and disposal • Inappropriate transport of specimens
2 Minor	• Incorrect version of policy or SOP in use • Not registering new SOPs or updating existing ones on the SOP register • Labelling error that can be accurately rectified
1 Insignificant	• Incident occurred which resulted in no compromise of relevant material
0 Near Miss	• AE/ Incident could have happened if intervention had not been made.

3 Procedures

3.1 Any AE/I that occurs under the HTA licence must be reported to the PD and DI within 24 hours and accompanied by a completed AE/I form (appendix 1). The DI will give a preliminary grading to the AE/Incident. Any AE/Incident graded ‘catastrophic’

or ‘Major’ must be escalated to the KCL HTA Governance Group Chair immediately. When appropriate, the Chair will liaise with relevant KCL bodies, Senior Management and other King’s Health Partners establishments.

3.2 Remedial action must be taken immediately where staff, visitors, premises, relevant material, data and facilities are at risk. Each AE/I report should document clearly what corrective and preventative actions (CAPA) are required and the responsibility and timeframes for the completion of these.

3.3 Appropriate KCL officers must be informed where an AE/Incident falls into their jurisdiction.

3.4 A DI may re-grade the incident, according to the detailed report.

3.5 Although there is no requirement for establishments in the research sector to report AE/I to the HTA, if the DI has concerns about an AE/I they can contact the HTA for further advice.

3.6 Within 3 to 5 days of receipt of the initial AE/I form graded as catastrophic or major, the KCL HTA Governance Group Chair and DI will review the AE/I details, suitability of action taken and confirm appropriateness of further planned activities with the PD.

3.7 Details relating to all AE/Is must be circulated to all relevant members of the department. Evidence of communication should be retained.

3.8 New AE/Is and any unresolved preventative actions will be discussed at the KCL HTA Governance Group meeting. Catastrophic AE/Is or those which may impact on other groups, should be circulated to all DIs between meetings.

3.9 Where appropriate updates will be provided to the KCL HTA Governance Group and PD’s along with relevant KCL bodies until the final outcome is reported.

4 Reporting

4.1 A summary of all recent AE/Incidents must be included at HTAGG meetings and all catastrophic graded AE/Is reported to the Audit and Compliance committee. Major AE/Is must be reported at the KCL HTA Governance Group Chair.

4.2 Outcome reports of AE/Incidents must be disseminated to relevant staff working under the KCL HTA Licence.

4.3 DI’s must monitor and report to the KCL HTA Governance Group any trends in AE/Incidents occurring on their campus.

4.4 The HTA Governance Group must provide details of all new AE/Incidents to the KCL Audit and Compliance Committee upon request.

Appendix 1: KCL HTA Adverse Event/ Incident Reporting Form

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KCL HTA Adverse Event/ Incident Reporting

The completed form must be submitted to the HTA Campus Designated Individual within 24 hour s of being made aware of an adverse event/incident under a KCL HTA licence. Please provide as much relevant information as possible. Please ensure that other relevant KCL incident report forms are completed.

1. HTA Licence details

Designated Individual		HTA licence number and licensed premise(s)
Designated individual contact number		Email address and contact number
Person(s) Designated		Email address and contact number

2. Reporting

AE/incident reported to:	**By:**	**On:** (dd/mm/yyyy)
Designated Individual[1]		
KCL HTA Governance Group Chair		
Other personnel – KCL/internal (please list)		
Other personnel – External (please list)		

[1] *If reported by a Person Designated*

3. Adverse Event/Incident

Date AE/incident occurred
Date DI or PD informed of/made aware of AE/incident
Room number/ Premise/site of AE/incident
Summary of AE/incident
Severity/grade of AE/incident

4. Initial action taken by DI and/or PD(s) since being made aware of AE/incident

Initial action taken
Corrective
Preventative
Date of resolution, if applicable

5. Any other relevant information

Please provide any additional information relevant to the AE/incident

Report completed by:	Date report submitted: