South Eastern Health and Social Care Trust

Standard Operating Procedures (SOP) Research and Development Office

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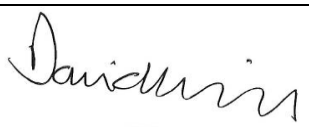
Signed:	
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Version History:

Version No.	Date	Author	Reason for Change
1.0	April 2009	Katrina Hughes	N/A
2.0	Aug 2011	Alison Murphy	Updated to new SOP layout. Appendices removed

Table of contents

1. INTRODUCTION

This SOP describes the SEHSCT Research Office approach to adverse event (AE)/incident reporting. It is committed to reducing potential AE/incidents and, to meeting the requirements of the Human Tissue Act (HT Act) and Human Tissue Authority (HTA). The SOP also describes how and when information should be passed internally to applicable SEHSCT staff and to external bodies.

The SEHSCT Research Office promotes an open, positive and non-punitive approach towards AE/incident reporting. This SOP must be used in conjunction with SEHSCT incident and accident reporting policies as well as other applicable central SEHSCT policies.

Reporting AE's/incidents are important as they help:

- Learn lessons and prevent recurrences
- Improve practice as a consequence of the findings
- Set priorities for e.g. training and/or other resources to prevent future mishaps

1.1 Definitions

An *adverse event* is 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
(iii) And the contents contained therin
(iv) Caused harm or had the potential to cause harm to human tissue (including loss)
(v) Gave rise to an internal inquiry
Source HTA guidance

An incident can be considered as an untoward event or sequence of events that has caused or has the potential to cause damage; harm; or a direct negative impact to an organisation's business, security, reputation, facilities, personnel, safety, health, environment; an event where an important policy, procedure, or practice was not followed by staff leading to detriment or the potential detriment of the above.

2. OBJECTIVE

To provide a generic SOP template and general instructions on the SEHSCT Research Office approach to adverse events and when information should be passed to SEHSCT staff and to external bodies.

3. SCOPE

This SOP applies to AE's/incidents that occur under the supervision of the SEHSCT DI and aims to provide staff with a centralised method of reporting AE/incidents.

Those undertaking activities relating to a license for the storage /use of human tissue cells for human application should follow the HTA's procedures for AE/'incident reporting:
http://www.hta.gov.uk/licensing/adverse_event_and _reaction_reporting.cfm

4. PROCEDURE

4.1 Reporting and Timescales

Any AE/incident that occurs under a license must be recorded and reported.

Initial reporting of an AE/incident under a SEHSCT HTA license must be made to the Research Office using the HTA AE/incident reporting form available from the Research Office (Appendix 1) or by ensuring the information requested in the form is provided in another format.

The DI/PD should discuss the AE/incident with staff and agree with them immediate medial/corrective action.

A full report/update of the AE/incident, action taken and further planned activities must be submitted to the Research Office within 3-5 working days of the AE/incident occurring or being known to the CI/PI.

Summary updates must be submitted as advised by the Research Office to inform them of progress being made.

4.2 Investigating AE/incidents

All AE/Incidents must be followed up until closure. The CI/PI is responsible for carrying out an immediate local investigation which should be communicated to the Research Office.

Depending on the severity of the AE/incident, there will be a number of actions which need to be taken in the subsequent hours and days after an AE/incident. These may include a preliminary meeting/discussion with the DI and other appropriate Senior Managers notifying external bodies as appropriate etc.

A root cause analysis (What happened? Why did it happen? What can be done to prevent/reduce it happening again?) and a review of the risk assessment is encouraged.

If the AE/incident is likely to result in immediate media interest, the Research Office will contact appropriate personnel at SEHSCT e.g. Medical Director, Press Office.

The outcome of a serious AE/incidents at HTA licensed premises will be reported the SEHSCT Research Governance Committee.

4.3 Complaints and Public Interest Disclosure

Where a complaint is made following an AE/incident e.g. from third parties, the CI/PI must notify the Research Office. Employees can also raise concerns related to AE/incidents through Whistleblowing policy.

4.4 Grading of an AE/Incident

This is an illustrative list only. In practice CIs/PIs are expected to exercise their professional judgement in identifying AE/incidents.

Catastrophic
Unexpected death of one or more persons on the licensed premise, national adverse publicity, potential litigation, major health and safety or AE/incident e.g. toxic gases, fire, catastrophic financial loss or loss of essential and unique “relevant material”, key departmental service/facility put into abeyance.

Major
Permanent injury, long term harm or sickness, involving one or more persons, potential litigation, extensive injuries, claims for negligence, closure of Department, facility, breach of security, breach of confidentiality and data protection relating to the possible identification of a donor, their relative or study participant by unauthorised individuals; health and safety AE/incident, some toxic release, fire, major financial loss. Mis-use of equipment/donated samples/body parts.

Moderate
Temporary injury, one or more persons, possible litigation, medical treatment required, health & safety incident, moderate financial loss.

Minor
Short term injury following incident, first aid treatment required, on-site toxic release immediately contained, minor financial loss.

Insignificant
Incident occurred but resulted in no injury, and no treatment required; no financial loss.

“Near miss”
Incident did not happen, but could have, if an intervention had not taken place; low financial loss

5. RESPONSIBILITIES

The CI/PI will inform the Research Office of any AE/serious incidents as they occur and will ensure that staff under their supervision know how to report AE/incidents. Systems must be implemented at HTA licensed premises that also incorporate the

recording of “non-serious” events that when taken together they could amount to an AE/incident.

If delegated to a PD(s), the DI is responsible for reviewing their PD(s) completed AE/incident report for accuracy.

The DI/PD should ensure that (i) all reasonable enquiries or investigations relevant to the AE/incident have been made (ii) steps have been taken to prevent a recurrence of an AE/incident. The DI is responsible for providing their staff with feedback on individual AE/incidents.

The SEHSCT Research Office is responsible for ensuring that an appropriate AE/incident reporting system is in place for reporting AE/incidents and monitoring trends.

The DI is responsible for reporting to and, liaising with other Trust staff to ensure that appropriate action is taken in relation to the reported AE/incident

6. REGULATIONS, GUIDELINES, REFERENCES, SOP LINKS ETC

The Human Tissue Act 2004 (Statutory Instrument 2005 No. 919)
Directions given under the Human Tissue Act 2004: 001/2006

7. APPENDICES

7.1 Appendix 1 SEHSCT HTA AE/incident reporting form

Appendix 1

Belfast Health and Social Care Trust

SEHSCT HTA AE/incident reporting form

The completed form must be submitted to the SEHSCT R&D Office within 24 hours of being made aware of an adverse event/incident under a SEHSCT DI's license. Please provide as much relevant information as possible. Please ensure that other relevant SEHSCT incident report forms are completed.

1. License details

Designated Individual		HTA license 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)
CI/PI		
SEHSCT R&D Office		
DI		
Licence Holder		

Other personnel – External		

3. Adverse event/incident

Date incident occurred
Date DI or staff under DI's supervision informed of/made aware of AE/incident
Location 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: