University of Sussex

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Human Tissue Act
SOP - Reporting of Adverse Events

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Authorised By: UoS HTA Coordination Group - Chair	Authorisation not sought due to minimal changes	

Version	Date	Reason for Change
2.0	28/7/2014	To reflect merger of BSMS and SoLS practices for UoS
3.0	04/08/2017	Changes to reflect changes to DI

1.0 Purpose

This SOP outlines the procedure for recognising and reporting an adverse event related to the procurement, transport, storage, processing and disposal of human tissue for the purposes of research.

2.0 Procedure

The School of Life Sciences and BSMS Codes of Practice outline the policy relating to the management of adverse events and an extensive, though not comprehensive, list of the types of adverse events encountered is shown below as well as in the CoP.

If an untoward event or near miss occurs, it must be reported to the Person Designate (PD) immediately.

- The PD will decide whether to report the event to the Designated Individual (DI)
- The Designated Individual will complete the relevant paperwork recording the event in the 'Adverse events log'.
- The Designated Individual will follow up any incident until closure is achieved. Appropriate action will be taken by the Designated Individual through local structures, which may include the School Management Committee
- The report will be brought before the relevant School's HTA committee for appropriate action.

Examples of incidents that require reporting

Consent	• Human tissue removed from a patient without appropriate consent • Human tissue stored without appropriate consent • Human tissue used without appropriate consent • Human tissue used for a research study that has not been approved by a NHS REC • Staff member seeking consent is not appropriately trained
Governance and quality	• Wrong version of SOP in use/ failure of change control mechanism • Breach of Data protection/ confidentiality. • Research material sent off site without appropriate review/authorisation/material transfer agreement
Specimen acquisition/ research request forms	• Wrong type of specimen • Incorrectly labelled specimen • Specimen in wrong format • Specimen from wrong patient
Tracking	• Labelling error • Stored research material not on Research database • Discrepancy between Research database and storage location • Incomplete audit trail resulting in failure to trace a specimen
Storage	• Cold storage breakdown with alarm failure - discovered in time – near miss • Cold storage failure – alarm failure • Unauthorised access to storage facilities/ breach of security • Human Tissue Stored in an inappropriate facility.
Disposal	• Human tissue disposed of with general clinical waste • Incorrect or failure to label Human tissue waste • Reason for disposal of stored research material not documented
Transportation	• Material transferred without appropriate agreements and authorisation • Material lost during transportation • Material quality compromised during transport

• In the case of a 'serious adverse event', the DI will immediately inform the license holder. A separate reporting structure involving direct liaison with the HTA

is required which will be undertaken by the DI. A ‘serious adverse event’ means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that

- might lead to the transmission of a communicable disease,
- might lead to death or life-threatening, disabling or incapacitating conditions for patients
- might result in, or prolong, hospitalisation or morbidity.