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Human Tissue Act
SOP - Change Control Systems

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Reviewed: Dr Georgios Giamas Designation: Designated Individual School of Life Sciences Reviewed: Dr Robert Fowler Designation: Persons Designate School of Life Sciences	Signature  	Date 11/09/2017 11/09/2017
Authorised By: UoS HTA Coordination Group - Chair	Authorisation not sought due to minimal changes	

Version	Date	Reason for Change
2.0	26/11/2012	Increased frequency of committee meetings requested by HTA inspector.
3.0	28/07/2014	To reflect merger of BSMS and SoLS practices for UoS
4.0	04/08/2017	Update to reflect change in DI

1.0 Purpose

This standard operating procedure outlines the management control of adverse events, patient complaints and new/altered operational procedures.

2.0 Introduction

To ensure that lessons are learned from adverse events, patient complaints and other issues raised in committee meetings, effective change control mechanisms are required.

3.0 Strategy and Operation

The School of Life Sciences HTA Governance Committee (HTAGC) and the BSMS HTA Governance Committee oversees:

- The strategic development and operational issues of human tissue storage.
- Project Issues, such as patient or staff feedback, new legislation or staff changes will be communicated via committee meetings (see reporting structure outlined in the Code of Practice) and by email.
- The Adverse events and complaints logs will be reviewed quarterly by the School HTA Committee and issues will be assessed to decide upon priorities, any necessary actions, assign a person responsible for ensuring actions are carried out and confirming completion.

Operational matters will be brought to the Life Sciences/ BSMS HTAGC as and when they arise. The committee will then decide if these require further consideration by higher level committees and will also decide and instruct on any changes required by assigning a person responsible. The effectiveness of implemented changes will then be assessed at the next committee meeting.

Staff will be notified of the changes during Management meetings and notification will be put on the website.

4.0 Documentation and version control

All documentation relating to the Quality Management System and standard operating procedures is revised and reissued as necessary, and all obsolete versions are to be removed from the point of use. The School website will contain the latest versions of Standard Operation Procedures and other documentation. Responsibility for the control of any local documentation lies with the relevant PD.

Such documentation may include:

Code of Practice
Standard Operating Procedures
Training and Reference Materials
Generic Forms

All changes to documents are reviewed by the person responsible for the original issue and, where appropriate, the nature of the change is indicated on the document. Master copies of the revised documents are retained as records of the changes and renewed as necessary to ensure clarity. Revisions to central

documents will be approved by both the HTAGC and the School Management committee for Life Sciences and the BSMS HTAGC.