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Human Tissue Act
SOP – Record Keeping

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Authorised By: UoS HTA Coordination Group	Signatures 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	Change to reflect the update to DI

1.0 Purpose

This standard operating procedure outlines good record keeping processes in place to capture and manage its records on the removal, storage, use and destruction of human tissue.

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2.0 Introduction

One of the requirements of the Human Tissue Authority is that an auditable trail is maintained and documented for the storage and movement of all material from receipt to end use, disposal or distribution.

3.0 Procedures

Life Sciences

Principal investigators and custodians of human tissue collections must ensure that their holdings are fully documented. The system for recording this information should be proportionate to the activity being carried out. However, as a minimum, the following information on each sample should be kept in a record keeping system.

- Sample ID reference. This should be unique and coded so that it links to the donor. It should **not** include donor personal details.
- Tissue type (if more than one stored/used)
- Date of receipt and details of where it came from
- Date sample labelled
- Consent details (if required)
- Storage location
- Name of Principal Investigator
- Research project title (and if relevant clinical trial id.)
- Details and dates of processes applied to the sample
- If relevant, details and dates of any transfers out to and back from other locations on a temporary basis.
- Date and method of disposal. This could be transfer to another location or destruction using approved procedures.
- Reason for disposal.

Brighton & Sussex Medical School (BSMS)

3.1 Record capture

Other records

Principal investigators and custodians of human tissue collections must ensure that the following records are captured/created and maintained where required:

- records of consent (where required), recording who gave consent; what the consent related to; whether consent is related to a specific project or for wider use in research; any restrictions on use stipulated during the consent. If the consent records are in the custody of another organisation, the Principal Investigator or custodian of human tissue collections must

ensure that they have documentation that contains assurances of compliance with Human Tissue Act requirements;

- records of ethics approval
- records of human tissue use and movement, e.g. receipts; transfer documentation; laboratory log books;
- maintenance, cleaning and calibration of equipment records
- risk assessment records
- records of tissue destruction: receipts; laboratory log books;
- records of adverse and serious adverse events, including 'near misses';
- local Standard Operating Procedures and quality management documentation
- staff training records
- system for labelling human tissue

This list is indicative and not exhaustive.

3.2 Records Security and Maintenance

Records containing confidential and/or protected personal information must be kept secure at all times. Any paper records must be stored in a locked facility when not under the direct supervision of a member of the research team. Records relating to human tissue should only be accessible to authorised personnel. Access to records stored on a computer should be controlled by passwords and, where appropriate, access to individual files/databases should also be password protected. Passwords should be known only to authorised individuals and changed at regular intervals. PCs should be locked when left unattended.

Electronic records containing protected personal information if transferred or stored off site using removable media (including laptops, memory sticks, smart phones, CDs and portable hard drives) must be encrypted. The transferred material on the removable media should be deleted as soon as transfer is successfully effected. Where samples are part of a clinical trial, the PI of the study should retain only anonymised data, with the NHS clinical care team retaining the key to the identifiable data. If, at the conclusion of the study, the samples are accepted by the BSMS Tissue Bank, the DI will become the custodian of any associated identifiable data Electronic records and records management systems should be backed up regularly and ideally kept in a secure area on the University's shared drive which is backed up nightly.

3.3 Retention of Records

If the human tissue is to be used for further research purposes after the project has completed the records need to be retained for as long as the human tissue is held and as long as required to support the output of those research projects.

Once the research project has finished paper and electronic records should be archived in such a way as to ensure that they remain reliable and accurate throughout the retention period.

Records of consent, human tissue transfer and destruction
These records must be kept for 7 years after the transfer or destruction of the human tissue as an audit trail to demonstrate that the transfer or destruction complied with Human Tissue Act, 2004 and with the conditions of consent given by the donor.

Records of staff training
Logs of staff training relating to the use and storage of human tissue must be kept for 3 years, after person has left the University.

Record Destruction
At the end of the retention period records should be destroyed in a confidential manner either through the University's confidential waste service or using local shredding facilities. Any electronic equipment used should be wiped before disposal or reuse in compliance with Governance and Compliance Division's guidelines.