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# Human Tissue Act
# SOP - Sample Storage and Security

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| **SOP Reference:** | **SOP/HTA/06** |
| **Version Number V 3.0** | **Date: 17/07/2017** |
| **Effective Date: 30/07/2017** | **Review by: 30/7/2018** |

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| **Authorised By:**<br>UoS HTA Coordination Group | Signatures not sought as minimal changes | |

| Version | Date | Reason for Change |
|---|---|---|
| 2.0 | 28/7/2014 | To reflect merger of BSMS and SoLS practices for UoS |
| 3.0 | 17/07/2017 | Change to reflect the update to DI |

## 1.0 Purpose
This standard operating procedure outlines the storage and security of human tissue samples.

## 2.0 Introduction
The giving or withholding of consent to the storage of tissue taken from the living or the dead are decisions that deserve respect. Human tissue taken from a living person can be stored provided that consent is obtained from an appropriate person, unless storage is bound up with the provision of clinical and diagnostic services.

Consent must be sought where tissue is taken from the living for research, unless the research is ethically approved and the material is anonymised.

Human tissue cannot be stored after death without consent unless for coroner's or criminal justice purposes. It is an offence to hold tissue for the analysis of DNA without consent, subject to exceptions.
Human tissue must be stored securely, in line with health and safety guidelines, and appropriate records kept. Any threat to their integrity, in particular where material is stored frozen – the possibility of thawing must be minimised as far as possible.

Access to all human material and related personal information is closely controlled

Long-term storage is acceptable where appropriate and if consent has been granted.

## 3.0 Storage of material

### 3.1 Existing holdings

It is lawful to store and use, without consent, relevant material and the body of a deceased person that is already held in storage on 1 September 2006. However, where the views of the deceased person or of their relatives or friends are known, those views must be respected. Records must be kept of existing holdings together with the records of material donated after 2006.

### 3.2 Storage of relevant material taken from the living

Storage of relevant material taken from a living person is allowed provided consent from an 'appropriate person' is obtained. Material taken from the living for any reason may also be stored (and used) without consent for the following purposes:

- clinical audit
- education or training relating to human health
- performance assessment
- public health monitoring and
- quality assurance

Consent is required to store tissue taken from the living for:

- obtaining scientific or medical information about a person which may be relevant to any other person (now or in the future)
- public display
- research into disorders, or the functioning, of the human body and
- transplantation.

Consent should be obtained for the use of tissue removed from the living for research. Where this is not possible, it is lawful for material taken from a living person to be stored for research purposes only if:

- the research is ethically approved
- the material is anonymised, and the researcher takes all necessary steps not to identify the person from whose body the material has come.

### 3.3 Unlinked Samples

Obtaining consent is ordinarily considered best practice, negating the need for complex systems for keeping samples unlinked.

Where consent has not been obtained samples should be unlinked, although the linking of samples can be made through a third party where necessary. When research involves clinicians who may have access to databases making identification possible, the sample will still be regarded as non-identifiable provided the researcher does not attempt to link the tissue with the patient. Research in this context is permissible without consent if approved by a research ethics committee.

### 3.4 Storage of relevant material taken after death

It is an offence under the Human Tissue Act to store relevant material taken after death without consent, apart from material stored for coroners' or criminal justice purposes.

### 3.5 Non-consensual analysis of DNA

It is an offence to have human tissue (including hair, nail and gametes in this context) with the intention of analysing its DNA without consent, subject to exceptions. Medical diagnosis and treatment, and criminal investigations are excluded from the offence.

### 4.0 Methods of storage

Tissue should be stored in line with current good practice on:

- security
- traceability, records should detail the location of the materials
- health and safety, including appropriate containment levels for the storage, transportation and handling of materials that may pose a risk to others.

Guidelines to be observed for the storing of Human Tissue:

- Human Tissue must be stored using recognised methods as per standard practice and guidance and labelled accordingly
- The label must convey what the specimen is (see SOP 8 Record Keeping)
- Human tissue must be stored in a licensed area that must be locked at all times when not in use.

### 4.1 Appropriate storage period

There is no time limit on the storage or organs and tissue, thus preventing the potential for the premature loss of useful material. Long-term storage in tissue banks may be acceptable to many donors or their relatives who have given consent for such storage and has added security benefits.

The Designated Individual is responsible for ensuring that records are maintained in the area covered by the licence.

## 5.0 Receipt, Security and monitoring measures
## Life Sciences

Records of delivery of human material to or from anyone working under licence number 12119must be kept. A record book for each site must be kept where the details of each shipment are documented. These details should include contact names, journey start point, destination, and AirWayBill information.

- JMS stores have a record book where these details should be recorded and stores staff should be informed of expected shipments (in and out) so that information can be recorded and collection signed for.
- The Genome Centre has a logging in book where these details are recorded and the porter is made aware of any expected shipments (in and out) so that information can be recorded and collection signed for.

There should never be an instance where human material is in transit and unaccounted for.

If the package appears to be leaking or damaged, it should only be opened in a biological safety cabinet by personnel who are trained in spill clean-up procedures and are wearing appropriate personal protective equipment. The person for whom the parcel is intended should be notified immediately.

- The areas that used for human tissue storage in the Genome Centre and Psychology are accessed through secure key-cards or by key code. Only staff or students who have been approved can enter this area.
- Sample security is maintained as follows:
    a. In JMS and Pevensey are stored in locked freezers/fridges/cabinets. Keys are stored securely with the PD in each area.
    b. GDSC building is secure, access gained via key pads controlled doors so only authorized individuals can enter the areas where the freezers are located.
- All individual freezers and fridges used for HTA storage are continuously monitored for temperature. Low temperature alarms will immediately alert the relevant person through an automatic dial-up system.
- The relevant person will immediately attend to the alarm; rectify the problem or, if not possible, follow SOP/HTA/10 for freezer failure. Details of back up freezer space are also attached to each freezer. In the event of a liquid nitrogen freezer failure the Genome Centre contingency plan comes into effect.

## BSMS

Records of delivery of human material to or from anyone working under licence number 12561 must be kept. A record book or folder for each study/trial must be kept where the details of each shipment are documented. These details should include contact names, journey start point, destination, and AirWayBill information.

There should never be an instance where human material is in transit and unaccounted for.

If the package appears to be leaking or damaged, it should only be opened in a biological safety cabinet by personnel who are trained in spill clean-up procedures and are wearing appropriate personal protective equipment. The person for whom the parcel is intended should be notified immediately.

- The areas that used for human tissue storage in the Trafford Centre and Medical Research Building (MRB) are accessed through secure key-cards. Only staff or students who have been approved can enter this area.
- Sample security is maintained as follows:
    a. In the Trafford and MRB, samples are stored in locked freezers/fridges/cabinets. Keys are stored securely with the PD in each area.
- All individual freezers and fridges used for HTA storage are continuously monitored for temperature. Low temperature alarms will immediately alert the relevant person through an automatic dial-up system.
- The relevant person will immediately attend to the alarm; rectify the problem or, if not possible, follow SOP/HTA/10 for freezer failure. Details of back up freezer space are also attached to each freezer. In the event of a liquid nitrogen freezer failure the relevant contingency plan comes into effect.

**4.0 Access to material**

Access to any stored material will be through the PD who will log the use and return of relevant material on the database.

**5.0 Audit of Use**

Once a year the database will undergo an audit procedure see SOP/HTA/13 to ensure that access is being correctly controlled