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Human Tissue Act

SOP – Receiving/Sending Human Tissue Life Science Stores

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Authorised By: UoS HTA Coordination Group - Chair		

Version	Date	Reason for Change
V2.0	17/04/2018	Clarifying what documentation needed for incoming material

1. Purpose

This standard operating procedure outlines the procedure to be followed in the Storeroom when sending or receiving Human Tissue samples from and to the University of Sussex under the HTA Act. It is aimed to help inform Storeroom staff about the requirements and regulations for incoming and outgoing Human Tissue samples.

Receiving/Sending Human Tissue

Life Sciences Stores

Why the transport of Human Tissue is Important

The removal, storage and use of human tissue is governed by the Human Tissue Act 2004 (the HT Act). Human tissue is defined by the HT Act as material that has come from a human body and consists of, or includes, human cells. It is referred to in the HT Act and below in this document as 'relevant material' (full list in Appendix I).

The Human Tissue Authority (HTA) regulates activities related to the HT Act and issues codes of practice and practical guidance for the storage and use of human tissue. It acts as the licensing authority and carries out inspections to ensure that licence conditions are met.

There are 3 licenses held at the University of Sussex;

- HTA Research Licence: BSMS
  Designated Individual: Prof Chris Pepper (8644)
- HTA Anatomy Licence: BSMS
  Designated Individual: Dr Claire Smith (7579)
- HTA Research Licence: University of Sussex premises other than BSMS premises
  Designated Individual: Dr Georgios Giamas (3163)

What to do when you receive a package with Human Tissue

1) A Material Transfer Agreement (MTA) (or an alternative agreement e.g. Declaration of Compliance) should be in place for all Human Tissue movement between institutions. The person receiving the human tissue should have let the DI know, and they or the DI should have let Stores know**. If a MTA is not present and you have not been told of the delivery, contact the DI immediately.**

2) A record of all incoming deliveries of human material to anyone working under research licence numbers 12119 (Life Sci) and 12561 (BSMS) must be kept. A record book for each site must be kept where the details of each shipment are documented. The details to record include;
   - Contact names
   - Journey start point
   - Destination
   - Air-Way-Bill information

3) Contact the DI and addressee and inform them of the arrival of the samples. The member of staff should have prior knowledge of the expected shipments so that material can be promptly collected and stored.

Important! 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 DI, Safety Coordinator and Addressee for whom the parcel is intended should be notified immediately.

What to do when Sending Human Tissue to another institution

1) A Material Transfer Agreement (MTA) should be in place for all Human Tissue movement between institutions. The person sending the human tissue should have let the DI know, and the DI should have let Stores know. If a MTA is not present and you have not been told of the out-going package, contact the DI.
2) Record all outgoing material.
    - Contact name of sender(s)
    - Destination
    - Air-Way-Bill information
3) The packaging of the samples should comply with HTA rules. The total packaging must include:

- A watertight, leak-proof primary receptacle
- Watertight, leak-proof secondary packaging
- Outer packaging of sufficient strength for its capacity, mass and intended use.

(Both of which must be able to maintain their integrity at the temperature of transport paying special attention to packages that require shipment on dry ice (-79ºC, -109ºF).)

Appendix I – full list of Relevant Materials for the purposes of the Human Tissue Act 2004

Material Description	Relevant Materials for the purposes of the Human Tissue Act 2004?
Antibodies	No
Artificially created stem cells*	No
Bile	Yes
Blood	Yes
Bone marrow	Yes
Bones/skeletons	Yes
Brain	Yes
Breast Milk***	Yes
Breath condensates and exhaled gases	No
Buffy coat layer (interface layer between plasma and blood cells when blood is separated)	Yes
Cell lines**	No
Cells that have divided in culture	No
CSF (Cerebrospinal fluid)	Yes
Cystic fluid	Yes
DNA	No
Eggs*	No

Embryonic stem cells (cells derived from an embryo)**	No
Embryos (outside the body)*	No
Extracted material from cells, e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids.	No
Faeces	Yes
Fetal tissue	Yes
Fluid from cystic lesions	Yes
Gametes*	No
Hair (from deceased person)	Yes
Hair (from living person)	No
Joint aspirates	Yes
Lysed cells	No
Mucus	Yes
Nail (from deceased person)	Yes
Nail (from living person)	No
Nasal and bronchial lavage	Yes
Non blood derived stem cells (i.e. derived from the body.)	Yes
Non fetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes)	Yes
Organs	Yes
Pericardial fluid	Yes
Plasma (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and other blood cells. If any of these cells are present then the plasma must be regarded as relevant material.)	No
Platelets	Yes
Pleural fluid	Yes

Primary cell cultures (whole explant/biopsy present)	Yes
Pus	Yes
RNA	No
Saliva	Yes
Serum	No
Skin	Yes
Sperm*	No
Sputum (or phlegm)	Yes
Stomach contents	Yes
Teeth	Yes
Tumour tissue samples	Yes
Umbilical cord blood stem cells	Yes
Urine	Yes

* While outside the definition of relevant material for the purposes of the HT Act, these materials fall under the remit of the Human Fertilisation and Embryology Act 1990, and are regulated by the Human Fertilisation and Embryology Authority (HFEA).

** Cell lines and embryonic stem cell lines fall within the regulatory remit of the HTA by virtue of the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which regulates the processing, storage and distribution of stem cell lines for human application. Both the HFEA and the Medicines and Healthcare products Regulatory Agency (MHRA) also have a regulatory remit in respect of cell lines and embryonic stem cell lines. A joint position statement issued by the HTA, HFEA and MHRA provides guidance on the relevant regulatory remits.

*** Breast milk does not constitute tissue or cells for human application under the (Quality and Safety for Human Application) Regulations 2007, but is classified as relevant material for the purposes of the Human Tissue Act 2004 where stored or used for a scheduled purposes.

http://www.hta.gov.uk/_db/_documents/Supplementary_list_of_materials_200811252407.pdf