Keele University
Institute for Science and Technology in Medicine

Standard Operating Procedure

SOP Number: HTA-36 **Version: 1.0**

Title: **Transportation of Human Tissue**

Purpose: To provide a standardised approach to the transportation of human samples to HTA-licensed buildings of Keele University.

Written By: Alan Harper Date: 24.09.16
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SOP History:

VERSION	AMENDMENT	CURRENT VERSION
1.0	None	

1. Introduction:

As part of the requirements of the Institute for Science and Technology in Medicine (ISTM) holding a Human Tissue license (#12349), we are required to utilise a quality management system to ensure that all research projects use appropriate procedures for the acquisition of human tissues. Acquisition of tissue often does not occur within our research sites and as such this necessitates the transport of human tissues either locally, nationally or internationally. The transport of human tissue introduces risks of damage to the tissue itself as well as risk of exposure to biological and chemical hazards to those transporting it as well as the general public if packaging should fail. Projects involving transportation of human tissue should also detail their specific process for transportation as part of their project standard operating procedures, as well as document a risk assessment of their transport processes as part of their project risk assessment (HTA-31).

This standard operating procedure sets out the processes that must be followed when transporting human tissue between research sites to help minimise the risk of any of damage to tissues or individuals who may come into contact with it during transportation.

2. Procedure:

Transportation can occur over a range of differences. This SOP will set out the regulations covering transportation from shortest to longest distances.

2.1 *Transfer of human tissues between laboratories within the Huxley or Guy Hilton Research Centre (GHRC)*

2.1.1 Prior to transportation between labs, researchers should know the location of materials for cleaning and decontaminating spillages, as well as the nearest appropriate clinical waste disposal route to ensure that spillages can be dealt with promptly, efficiently and safely.

2.1.2 Transportation of human material between laboratories must be performed using suitable breakproof and spillproof containers. Containers should be made of materials that can be easily disinfected in the case of spillage. These should have secure lids which can

be tightly sealed. Tissues should not be carried directly in gloved hands, pockets or loose inside bags.

2.1.3 Samples held in Eppendorfs, test tubes or other round bottomed containers should be placed in a rack to hold the samples in an upright position to help prevent them from being damaged upon transfer.

2.1.4 Researchers transferring samples between laboratories should be wearing full personal protective equipment as appropriate for the handling of these tissues. Researchers should ensure that when transferring samples fresh gloves are worn to reduce the chances of contaminating door handles, and the researcher should either have someone accompany them to open doors or they should leave one hand ungloved to do this for themselves. This ungloved hand must then be gloved immediately at the destination prior to further handling of the tissue samples.

2.2 Local transfer of tissues from UHNM to Huxley or GHRC, or between Keele licensed buildings.

2.2.1 Transfer of human tissues must only be performed after consultation of the Human Tissue Officer (a.g.s.harper@keele.ac.uk), the local Persons Designated (m.e.smith@keele.ac.uk (GHRC) or d.furness@keele.ac.uk (Huxley)) or the Designated Individual (n.r.forsyth@keele.ac.uk).

2.2.2 Prior to transfer, any researcher handling the samples should have read the project SOP and risk assessment to ensure that they have familiarised themselves with all the necessary procedures and risk associated prior to undertaking transportation. They should also have read all relevant regulations (including this SOP) to ensure that the correct procedures are followed.

2.2.3 Within the environment of the UHNM, Tissue samples must be transported by the UHNM courier service when transportation either requires vehicular transport on UHNM

roads or use of public roads.

2.2.4 Local transfer by staff using vehicles other than UHNM courier must only be performed if it is either inappropriate or impractical to use UHNS courier through the need for immediate transfer, transfer during unsociable hours or the lack of UHNM courier availability at the required time

2.2.5 Local transfer by staff using vehicles other than UHNM courier can only be performed when a risk assessment approved by senior staff (specified in 2.2.1) has demonstrated that there is limited risk of harm to tissue sample, to the staff member transporting the sample or the general public who could be exposed to the sample in the case of a crash. If the risk is deemed too high, the research team must use an appropriate courier for the transfer of the human tissue sample. Researchers should ensure that the courier's SOP for transport will ensure the integrity of the human tissue sample and will be compliant with the Human Tissue Act as well as the HTA's codes of practice.

2.2.6 Staff members transferring tissue using vehicles other than the UHNM courier should ensure that the sample are at no time either left unattended or in the care of anybody other than a member of the research team.

2.2.7 Local vehicular transfer must only be performed using approved crash-proof packaging and a properly insured vehicle.

2.2.8 If tissue is being held in containers with screwcaps these should be taped shut to prevent leakage.

2.2.9 Each Human Tissue sample should be labelled with a unique sample identification number to facilitate traceability of the tissue from sender to receiver, a date of collection of the tissue, the initials of the principal investigator, a description of the species and cell/tissue type, and any preservative or medium it is held within and the date of packaging. Samples should not be labelled with any donor information in an uncoded format.

2.2.10 All sample labels should be waterproof and legible. If handwritten, it must be written in permanent ink.

2.2.11 Samples being transported at different temperatures must be transported in separate packages.

2.2.12 Human Tissue samples should be packaged in line with the World Health Organisation's "*Guidelines for the safe transport of infectious substances and diagnostic specimens*". This specifies a triple packaging system consisting of:

- a primary, leakproof, watertight container holding the sample. This receptacle should be wrapped in enough absorbent material to absorb all liquids in case of breakage of the sample.
- a secondary, durable, leakproof, watertight container in which to enclose and protect the primary receptacle. Multiple primary containers may be placed inside a single secondary container. Details of all the samples contained within, the shipper and the receiver should be placed in a waterproof bag and taped to the outside of this container.
- Outer shipping packaging which should be waterproof and of sufficient strength to protect the sample from physical forces. If dry ice is being used, the packaging must allow the release of carbon dioxide gas as the dry ice sublimates to prevent rupture. The outer packaging should also be labelled with a human tissue hazard warning label (UN 3373), as well as any hazard warning labels relating to the medium or preservative it is transported in (e.g. formaldehyde or dry ice).

2.2.13 To ensure that the traceability of the tissue during transfer, a list of the number, and type of samples to be transported should be sent to the receiving institute. This list must be acknowledged prior to any samples being sent. The sending institute should then log the samples actually sent, and the receive institute should cross-check this against the list. These logs should be cross-referenced by both institutes upon arrival of the tissue at the destination to ensure that all samples have been safely received. Copies of these logs of both institutes should be stored securely for auditing purposes.

2.2.14 If samples are found to have been lost on transport, this should be logged as an adverse event and the instances surrounding this should be investigated by the human tissue officers of both institutes. Corrective and protective actions should be put in place before further samples can then be sent.

2.3 Import or export of human tissue samples to/from external locations within the UK or overseas.

2.3.1 Transportation of human tissues from non-commercial sources external to Keele University must only be performed after consultation of either the Human Tissue Officer (a.g.s.harper@keele.ac.uk), the local Persons Designated (m.e.smith@keele.ac.uk (GHRC) or d.furness@keele.ac.uk (Huxley)) or the Designated Individual (n.r.forsyth@keele.ac.uk). Staff planning projects involving the import and export of human tissue from outside of the UK must contact the Human tissue officer (Alan Harper; a.g.s.harper@keele.ac.uk) prior to sending or receiving tissue samples. Researchers should ensure that these activities are undertaken in accordance with HTA's code of practice on import and export of human tissues (see references). Export of human tissue may also require the additional approval of the relevant authorities (e.g. UK stem cell bank)

2.3.2 Acquisition of human tissue samples from non-commercial sources external to Keele University of UHNM must be conducted under a material transfer agreement.

2.3.3 All Material Transfer Agreements (MTA), Materials Use Licenses (MUL) or Memorandum of Understanding (MOU) must be undertaken through and with the guidance of the Directorate of Engagement & Partnerships at Keele University (https://www.keele.ac.uk/admin/directorateofengagementpartnerships/).
Staff should contact Clare Stevenson (Academic Legal Services Advisor, IC2, Keele University, Keele, ST5 5NH; 01782-734491; c.stevenson@keele.ac.uk) to discuss the requirements of their research project.

2.3.4 Prior to sending out or receiving human tissue samples, any researcher handling the samples should have read the project SOP and risk assessment to ensure that they have familiarised themselves with all the necessary procedures and risk associated prior to undertaking transportation. They should also have read all relevant regulations (including this SOP) to ensure that the correct procedures are followed.

2.3.5 Investigators should also make themselves aware of the regulations covering the transportation of hazardous materials by road, rail, air and sea, and these rules must also be followed in addition to those set out here.

2.3.6 If tissue samples are being imported for use at Keele University, the research team must obtain assurance that these samples have been obtained in an ethical manner under written informed consent. Researcher's should gain documentation that consent and ethical approvals has been obtained and is held by the supplier prior to the acquisition of tissue samples. This requirement should form part of any material transfer agreement.

2.3.7 The import and export of Human Samples defined as Relevant Material (Human Tissue Act 2004) must be through authorized shipping agents (Keele commonly uses DHL). Researchers should ensure that the courier's SOP for transport will ensure the integrity of the human tissue sample and will be compliant with the Human Tissue Act as well as the HTA's codes of practice.

2.3.8 Upon delivery a sample should be immediately checked for integrity of the packaging. If the packaging is leaking or damaged then the samples should only be opened in a biological safety cabinet by trained personnel wearing appropriate personal protective equipment. The handling of these parcels is covered in the HTA-4 SOP ("Handling Broken or Leaking Specimens"). An adverse event report should be submitted for any sample in which the integrity of the packaging has been compromised.

2.3.9 If after opening the integrity of the sample has been found to be compromised, these should be disposed of utilising the procedures outlined in the disposal SOP (HTA-

36). An adverse event report should be submitted for any occurrence in which the transportation of the human tissue has found to have damaged the tissue integrity.

2.3.10 The export of Human Samples must only occur if approvals to export are explicitly obtained during the Informed Consent process and have been subjected to ethical approval. The acquisition of these must be documented as part of the material transfer agreement.

2.3.11 Samples exported from Keele to other UK or overseas institutions should be labelled and packaged as set out in **2.2.8**, **2.2.9**, **2.2.10** and **2.2.11**.

2.3.12 A log of the release and receipt of the tissue should be held in both the original and final destinations of the tissue to ensure that each individual tissue sample can be traced throughout the import or export procedure as set out in **2.2.12** and **2.2.13**

3. References:

Guidelines for the safe transport of infectious substances and diagnostic specimens http://www.who.int/csr/emc97_3.pdf

HTA code of practice on import and export of human tissues https://www.hta.gov.uk/guidance-professionals/codes-practice/code-practice-8-import-and-export