King's College London
Human Tissue Authority Licensed Laboratories

Standard Operating Procedure

Title: Transfer of human material to other establishments for research purposes

Purpose
The purpose of this SOP is to describe the transfer of all human material used for a research purpose (as defined by the Human Tissue Act 2004) to other establishments.

Scope
The scope of this SOP is to describe the transfer of human material within King's and to other organisations using a variety of transport methods depending upon the format and end-user location.

Document Detail	
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Revision status

Each document has an individual record of amendments. The current amendments are listed below. The amendment history is available from the document control system

On issue of revised or new pages each controlled document should be updated by the copyholder.

Amendment Number: Date	Version no. Discarded	Insert Version no	Page	Section(s) involved	Amendment
1. 12/09/2022	1	2	4 9-11	3.1.4 5	Remove requirement for separate shipment record. Transfer related documents changed to examples
2. 30/09/2024	2	3	5 6 8	3.2.3 3.2.4 3.3.3 5.1 and 5.2	Added requirement to place igloo in cardboard box. Use of commercial leak-proof packaging Changes to use of Synnovis Pathology Transport Updated references
3.					
4.					
5.					
6.					

Any minor amendment must be handwritten on the SOP without obscuring existing text. An asterisk should be placed in the adjacent margin to highlight the alteration. Alterations should be signed and dated by either the person designated or nominated individuals and then forwarded to the document controller. The SOP must be retyped, authorised and reissued as soon as possible. Amendments requiring immediate action should be dealt with in the same way but highlighted as high priority. Major changes must result in the immediate review of the procedure Document amendment does not replace the review process.

1 Responsibilities

1.1 User

It is the responsibility of the user to ensure that:

(i) They adhere to the transportation of samples procedure as outlined in this SOP in addition to the KCL H&SS Biological safety responsibilities, management and arrangements guidelines (Appendix I).
(ii) They keep a record of all material transferred.
(iii) Transferred materials reach their destination within the planned timescale.
(iv) They adhere to transporters regulations.
(v) They use a method of transportation that maintains the integrity of the material and is appropriate to the size and stability of the material.
(vi) The mode of transport reflects the standards of KCL
(vii) They inform their HTA Person Designated immediately if samples are delayed or compromised in any way during transfer.

2 Materials

2.1 Equipment

Slide boxes
Plastic specimen bag
“Care - Pathological specimen” tape
Soft tissue paper
Parafilm
Bubble wrap
Jiffy bags
Cardboard boxes
Packing Tape
Polystyrene igloos (and outer carton if for dry ice shipment)

2.2 Reagents

Dry ice (solid CO_2)
Wet ice
Cold-pack

2.3 Documents

Example Materials Dispatch Form (Appendix A)
Example Confirmation of Receipt Form (Appendix B)
Courier request form
Example Proforma invoice (Appendix C)
Royal Mail special delivery label
Biohazard Labels

3 Procedures

3.1 Documentation

3.1.1 Complete a ‘Material Dispatch Form’ for all samples being transferred at any one time.

3.1.2 Enclose a copy of the completed Material Dispatch Form and Confirmation of Receipt Form with the samples.
3.1.3 If samples are to be sent outside of the EU, complete a proforma invoice (indicating the samples are being supplied free of charge).
3.1.4 Update the main study or sample database to indicate which samples have been shipped, where to and date of dispatch.
3.1.5 Ensure materials are receipted in a timely manner.

3.2. Packaging
All samples should be packaged to comply with H&S regulations, specifically UN Packing Instruction PI650, and ensure sample viability.

3.2.1 Microscope Slides

a) Place glass microscope slides in purpose made slide box/mailer.
b) Pack soft tissue paper between the slide edge and box to prevent slides from moving (poorly packed slides may be damaged even in a box). Place correct lid onto box, and secure with tape.
c) If necessary wrap the box in extra bubble wrap and then place in appropriate sized padded Jiffy bag or cardboard transit box.
d) Include in the package a copy of the “Material Dispatch” and “Confirmation of Receipt” forms.
e) Attach a complete recipient name and address label to the envelope or package.
f) Ensure that the name and address of the sender is attached on the reverse of the package.
g) Attach Pathological Specimen tape to outside of package.
h) Add details of slides sent, date of collection, time and person who collected to the sample shipment log.

3.2.2 Tissue Blocks

a) Individually wrap fixed, paraffin-embedded tissue blocks in soft tissue paper and place together in a secure plastic specimen bag.
b) If necessary wrap in extra bubble wrap and then place in appropriate sized, padded Jiffy bag or cardboard transit box.
c) Include in the package a copy of the “dispatch” form.
d) Include in the package a copy of the “Material Dispatch” and “Confirmation of Receipt” forms.
e) Attach a complete recipient name and address label to the envelope or package.
f) Ensure that the name and address of the sender is attached on the reverse of the package.
g) Attach Pathological Specimen tape to outside of package.
h) Add details of blocks sent, date of collection, time and person who collected to the sample shipment log.

3.2.3 Frozen/Cold Tissue

a) Select an igloo that can be filled with sufficient dry ice or cold blocks to ensure samples are kept at the correct temperature for longer than the estimated journey time.
b) Weigh the igloo and samples if using dry ice.

c) Partially fill the polystyrene igloo with dry ice allowing room for sample containers and extra ice. Alternatively, place cold blocks in the base of the igloo.
d) Wrap sample containers in absorbent material and place in sealable plastic bags.
e) Place sample containers in dry ice or on the cold block, avoiding the walls of the igloo, as these may not be in contact with the ice/block so may be warm. Bagged samples may be placed in an additional sealed plastic bag or plastic box to aid cataloguing.
f) Fill the igloo with sufficient dry ice to cover the samples and re-weigh to calculate the mass of dry ice.
g) Place “Material Dispatch” and “Confirmation of Receipt” forms in a sealed plastic specimen bag and place in the igloo.
h) Place lid on igloo and close the cardboard box . If using dry ice, do not seal the lid to ensure sublimed gas can vent.
i) To the package attach a complete recipient name and address label, the sender’s address label and pathological specimen and very low temperature hazard labels. If using dry ice, state the mass in kg.
j) Add details of samples sent, date of collection, time and person who collected to the sample shipment log.

3.2.4 Liquid Samples

a) Check that each tube is tightly closed but do not over-tighten. It is recommended that the lid is additionally secured with parafilm or equivalent.
b) Either wrap each tube in paper towel and place into a sealable plastic bag or place tubes into commercially supplied leak-proof packaging that is suitable for the sized tube being used.
c) Seal either bag or container shut
d) If the samples are to be transferred frozen or cold, place in an igloo and follow the procedure for frozen/cold tissue.
e) For samples being transported at ambient temperature, place the bag/container into a bubble wrap sleeve and seal closed.
f) Place the wrapped samples into a rigid box with “Material Dispatch” and “Confirmation of Receipt” forms in a sealed plastic specimen bag.
g) Seal the box.
h) Attach a complete recipient name and address label, the sender’s address label and pathological specimen.
i) Add details of samples sent, date of collection, time and person who collected to the sample shipment log.

3.3. Methods of Transport

It is the responsibility of the provider to ensure that samples are transported in a way that is compliant with the current regulations relating to human tissue, health and safety and transportation.

NOTE: Transport for London specifically bans the transport of any Dangerous Goods, which includes biological samples [5.2]. Likewise, King’s Health Partners’ inter-hospital shuttle bus also bans transport of biological samples.

3.3.1 Collection by or delivery to Requestor/ Representative

a) All sample types can be collected from or delivered by the provider if appropriately packaged, will not be taken on public transport and control measures are in place to minimise risk of sample deterioration.

Before arranging either collection or delivery, the risk of a sample not reaching or being delayed in reaching its destination must be considered. Use of motor vehicles, cycling and walking all have associated risks where any impact on sample delivery needs to be minimised.

b) When a requestor makes arrangements to collect or have materials delivered, the date and time of pick-up should be confirmed prior to packing any samples.
c) When collected, the confirmation of receipt form should be completed and left with the sender.

3.3.2 Internal Mailing System

a) Internal mail use should be limited to microscope slides and processed paraffin-wax embedded tissue blocks.
b) All samples must be appropriately packaged and contain a 'Material Dispatch' and 'Confirmation of Receipt' Form as outlined in Section 3.2.
c) Post Rooms for delivery and collection are located at:
    i. Denmark Hill (East): Ground Floor Main IOP Building (ext 80113)
    ii. Denmark Hill (West): Ground Floor James Black Centre (ext 85465)
    iii. Guy's (KCL): Doyle's House (ext 86890)
    iv. Guy's (Hospital): Ground Floor, Tower Wing (02071885158/9)
    v. St Thomas' (KCL): Security at Gate 3 (02071883395)
    vi. St Thomas' (Hospital): Ground Floor South Wing (02071885157)
    vii. Waterloo (FWB): Ground Floor (ext 83805)
d) Log date, time and method of transportation on a copy of the dispatch form and place in the sample shipment records folder.
e) Inform the recipient that package has been sent.
f) Place completed 'Confirmation of Receipt Form' in the Tissue Shipment Records folder with the original Material Dispatch Form.

3.3.3 Synnovis Pathology Transport

a) This service is run by Synnovis and by arrangement may transport samples between Central Specimen Reception (CSR) on each hospital site.
Note: There is no direct service between Guy's and KCH, samples must be transported via St Thomas CSR. This may result in next day delivery – contact CSR for more information.
b) All samples must be appropriately packaged and contain a 'Material Dispatch' and 'Confirmation of Receipt' Form as outlined in Section 3.2.
c) Confirm if the Pathology Transport can be used.
d) Take package to CSR located at:
    i. Guy's Hospital: 4th Floor Southwark Wing (02071881168)
    ii. King's College Hospital: Bessemer Wing (02032994109)
    iii. St Thomas' Hospital: 5th Floor North Wing (02071881167)
e) Hand the packaged sample to reception staff.
f) Log date, time and method of transportation on a copy of the dispatch form and place in the sample shipment records folder.

g) Inform the recipient that package has been sent.
h) Place completed 'Confirmation of Receipt Form' in the Tissue Shipment Records folder with the original Material Dispatch Form.

3.3.4 Royal Mail Special Delivery

a) This is intended for non-hazardous material such as tissue sections or processed paraffin embedded tissue blocks that are to be delivered within the United Kingdom only. Next day delivery is guaranteed.
b) All samples must be appropriately packaged and contain a 'Material Dispatch' and 'Confirmation of Receipt' Form as outlined in Section 3.2
c) Complete a Royal Mail Special Delivery label, filling in both parts (Name and address of destination and Senders name and address). Package should be valued according to material cost of goods.
d) Take package and completed label to a Post Office where it will be weighed to determine the price of postage.
e) Obtain a receipt for subsequent reimbursement.
f) Log date, time and method of transportation on a copy of the dispatch form and place in the sample shipment records folder.
g) Inform the recipient that package has been sent.
h) To monitor delivery, the package may be tracked on the Royal Mail website www.royalmail.com, using the parcels individual reference number.
i) Place completed 'Confirmation of Receipt Form' in the Tissue Shipment Records folder with the original Material Dispatch Form.

3.3.5 Courier Service

a) This is intended for all potentially hazardous materials within and outside of UK and also use for non-hazardous materials to be sent outside of the UK. It is advisable to use a medical courier for additional transport benefits.
b) Before arranging a courier ensure all packing material including ice/dry ice are available or will be delivered with the courier. Also check the recipient will be able to receive the package at predicted delivery time.
c) To book the KCL preferred courier service, City Sprint either phone on 0844 888 4115 or email KCL@citysprint.co.uk. Quote your account number and Purchase Requisition number.
d) Other courier companies may be used and provide a service better suited to specific transport needs.
e) Complete an Proforma invoice for collection with the package if sending outside the EU (Appendix C).
f) Additional documentation may be required by other courier companies.
g) All samples must be appropriately packaged and contain a 'Material Dispatch' and 'Confirmation of Receipt' Form as outlined in Section 3.2
h) Log date, time and method of transportation on a copy of the dispatch form and place in the sample shipment records folder.
i) Inform the recipient that package has been sent.

4 Health & Safety

FROSTBITE – When handling dry ice always wear insulated gauntlets. Disposable gloves over cotton gloves may be used when handling the cryovials on dry ice or from -80 °C freezers.

BIOHAZARD – Some tissues may be unfixed and are a potential biological hazard. Personal protective equipment, including disposable gloves and laboratory coats MUST be worn throughout the procedure

5 Reference:

5.1 KCL H&SS safety procedure, "SPR040, Biological Safety responsibilities, management and arrangements."
https://emckclac.sharepoint.com/teams/HSS/SMS/KCL%20SMS/SPR040-Biological%20Safety%20Arrangements.pdf

5.2 KCL H&SS Guidance Note: Transportation and importation of biological agents
https://emckclac.sharepoint.com/teams/HSS/SMS/KCL%20SMS/GN073-HSS%20Transport%20and%20importation%20of%20biological%20agents.pdf

5.3 Transport for London Conditions of Carriage for Bus, Tube, Tram, DLR, London Overground and Elizabeth line Services (24 May 2022). Section 9: Taking personal possessions, luggage, bicycles, scotters and animals with you.
http://content.tfl.gov.uk/tfl-conditions-of-carriage.pdf

5.4 National Rail Conditions of Travel (6th February 2022). Section 23: Taking luggage and other articles with you on your journey.
http://www.nationalrail.co.uk/National%20Rail%20Conditions%20of%20Travel.pdf

Appendix A: Example Material Dispatch Form Template

King's College London

Material Dispatch Form

Please complete all sections of this form either electronically or by hand before despatching **ANY** material.
Attach a copy of;

- Confirmation of Receipt.
- Any other relevant documentation.

Title of Study	
Investigator	
Prepared By (Including date of preparation)	
Details of Material Sent i.e. blocks/slides/blood	

Dispatch/Collection Details	
Method of Transfer	
Address	
Signature of collector	
Date of collection	

Appendix B: Example Confirmation of Receipt Template

King's College London

<Sender Address>
<Sender E-mail>
<Sender Telephone>
<Sender Fax>

Please confirm receipt of the material listed below via

Phone (XXXXX) or Email (XXXX)

Project:	
Investigator:	
Material Sent	See Material Dispatch Form Attached
Date Received	

I the undersigned confirm that I have received the above material in its entirety

Signed: Date:

Comments:

Please return any unused material as soon as possible following use to the address below:

For the attention of XXXXXX
<Address>

CONFIDENTIALITY

The information contained in these documents is confidential and intended for the exclusive use of the addressee. If you are not the addressee and have received this transmission in error, please contact us immediately by telephone so that we can arrange for its return.

Appendix C: Example Customs Proforma Invoice

King's College London

<Sender Address>
<Sender E-mail>
<Sender Telephone>
<Sender Fax>

Pro-Forma Invoice

Shipper: <Sender Department Name>
<Sender Department Address>

Contact: <Name of Responsible Person (Sender)>

Receiver: <Receiver Department Name>
<Receiver Department Address>

Contact: <Name of Responsible Person (Receiver)>

Reference Number:

Description: The attached consignment contains Human biological samples
<Description including weight, number etc>

UN3373 Biological Substance Category B
This material is not known or suspected to contain an etiological agent, host, or vector of human disease.

Reason for export: Specific analysis in accordance with clinical studies required by central laboratory.

Value: No commercial value, however for customs purposes a value of $10 may be applied.

Declaration: I hereby certify that the information on this invoice is true and correct and that the contents of this invoice are as stated above.

_____ _____

Signature and Job Title **Date**