Document Title: Handling of Biological Samples

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Summary of Amendments

Version Number	Modification:
1.0	**New SOP created**
2.0	**Section 4.4.5.c amended to action change request in IQM**
3.0	**Risk Assessment in Appendix removed.** **Reference to RAC/RD/TBR/004 added to key related documents**

Key related documents:	DN180 - Needlestick Sharp and Splash Incidents involving blood or body fluids, Procedure DN115 - Control of Substances Hazardous to Health DN375-Waste Management Policy Risk Assessment RAC/RD/TBR/004 Fresh Samples SOP029 Management of R&D Freezers SOP097 Sample Transport SOP095 Laboratory Biological Safety Cabinet SOP098 Pipetting SOP096 centrifuges

	GD034 CRF User Guidelines GD044 R&D Laboratory User Manual FRM038 Protocol Non-Compliance Form FRM083 Samples Disposal Form

Key Points of this Document

1 Purpose and Contents

a. The Human Tissue Authority (HTA) ensures that human tissue is used safely and ethically, and with proper consent. It regulates organisations that remove, store and use tissue for research. The handling of human tissues must comply with the regulations set by HTA.

b. To ensure that all biological samples obtained for research use are correctly stored and are traceable through a complete audit trail. Samples are processed safely according to ethically approved protocols.

2 Roles & Responsibilities

a. Only competent trained personnel should handle human tissue. Depending on their role within the study, personnel must be trained and competent in the following: receiving, processing, storing, transport and disposal of human tissue.

b. Sample tracking of samples must be from when they are received to when samples are transferred to a researcher.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

4 Procedure

4.1 Health and safety of Handling Human Samples

Before handling samples, staff members should read all COSHH forms and associated risk assessments related to:

- Chemicals used to clean after handling fresh samples include: Tristel Duo Jet (foam) and Tristel Fuse, biohazard cleaning kit Haz -Tab- chlorine releasing disinfectant granules and tablets, Clinell wipes and 70% alcohol.
- Dry ice and or liquid nitrogen.
- Fixative such as formalin/ or media if required.

All COSHH forms and risk assessments should be saved in the 'H&S related folder' in the S: shared >R&D>Pathology.

4.2 Receiving samples

a. Samples can be received directly from Papworth or externally from another Institute.

b. A consent form should be viewed before processing a sample; make sure the consent form has been completed correctly, and the date of the consent is not after the date the samples were taken (unless the study protocol allows).

c. Good practice is to receive samples with 3 points of identification; for example, NHS or hospital number, patient name and date of birth. However, research samples may not include these details, instead other forms of identification such as study number, will be used. Be aware in some cases a barcode, or patient's details could be inside a closed sample bag.

d. Check that the details on the paperwork match with details on the sample/blood tube. If details are not correct you must contact the person who took the samples and ask them to clarify and correct the details before the sample is processed.

4.2.1 Receiving samples from outside Royal Papworth Hospital

a. There must be a materials transfer agreement (MTA) in place.

b. Samples must be tracked and have a contact in case samples do not arrive within a specified time (especially if samples are temperature sensitive and are sent in dry ice.)

c. When a sample arrives make the following checks:

1. Identify samples in accordance with the study protocol (e.g. barcode, lab number).
2. Samples received need to match the manifest, if not contact the sender about any discrepancies.
3. Record the state of the samples when received.
4. Frozen samples may include temperature sensors which will need to be stopped before unpacking.

4.3 Appropriate PPE

Proper PPE must be worn when handling biological samples, especially if the samples are fresh as there is a risk of infection.

a. Gloves must be worn throughout the entire process.

b. Ideally lab coats should be worn but are required when processing blood samples on the bench. Uniforms with aprons may be used during sample processing and storing samples in fridge/ freezer.

c. Goggles or visors must also be worn when processing samples on the bench.

d. Freezer gloves should be worn when handling samples that have been frozen in -80 or liquid nitrogen.

e. Lab coats are recommended to be worn when retrieving samples from -80 freezer to avoid skin touching metal racks as they can cause freezer burns.

4.4 Sample Spillage/ Leaked samples

a. Deal with all spills immediately. Once the initial spillage is resolved then other parties can be informed where necessary (especially for larger spills).

b. If fresh samples have leaked when unpacked handle the item in a Biological Safety Cabinet.

c. If samples have been stored in media or fixative, you will also need to refer to the relevant COSHH risk assessment and follow handling/disposal procedure.

d. If blood and/or any other bodily fluids have spread to surfaces in the laboratory, make sure you wear full PPE. This includes a visor or goggles, lab coat, and gloves. Make sure you do not have exposed areas of skin.

e. If sample is fresh (not fixed) neutralise the biological hazard. See sections 4.4.1 & 4.4.2.

f. Remove any glass and/or needles by lifting them carefully with forceps. Place the glass/sharps directly into a sharps container.

g. Gloves must be worn when handling any form of sample. If the spillage is very large double glove (i.e. 2 pairs of gloves). After disposing most of the biological waste remove the first pair of gloves and finish the cleaning with the gloves underneath.

h. Where there has been skin contact with a biological spillage or sharps injury follow the Needlestick, Sharp and Body Fluid Splash Incident Procedure DN180 (located on intranet policies and procedures pages).

4.4.1 Biological Spillage (25mls or less)

a. For small spills on the bench, a Clinell wipe, or 70% alcohol can be used.

b. For small spills slightly bigger than a few drops use Tristel Duo Jet (foam). Press the pump to release the activated solution and repeat until the spillage is covered. Leave the Tristel Duo Jet solution in place for 1 minute to neutralise the spillage.

c. Clear up the spillage with paper towel and dispose of into a yellow clinical waste bag.

d. For cleaning vertical surfaces use Clinell wipes or Tristel pump. Remember to mop up any liquid collected on the floor.

4.4.2 Large biological spillage (more than 25ml)

a. Deal with all spills immediately. Once the initial spillage is resolved then, if required, the necessary parties can be informed.

b. For large samples spillage use either Tristel Fuse OR the Biohazard safety kit (do not use both):

1. Tristel Fuse, (follow instructions on packaging and use within 24 hours)

OR

2. Biohazard Spill Kit contains Haz-Tab Granules. This can be used to absorb any biological sample blood/ urine. Follow instructions in the kit and leave for at least 2 mins.

c. Use scoop and scraper to collect all the spillage waste and put into a clinical waste yellow bag. Close the yellow bag and put into clinical waste.

d. Discard remaining bleach solution by flushing down sink with plenty of cold water.

e. If the spillage is large and the room needs to be closed, or assistance from Trust cleaners is required, **inform the person in charge of the area on that day, including the duty nurse for Outpatients if working in the mini-laboratory or if working in the CRF follow GD034 User guidelines; further details in Appendix 2 of the R&D Laboratory Operations Manual (GD044)**. An all users email should be sent out to R&D to inform other laboratory users.

f. If the area has to be closed, complete a Datix incident form via the link on the hospital intranet. Inform your manager of the incident.

g. Replace contents of spill kit if required.

4.4.3 Samples that have dried onto equipment

See relevant SOPs for decontamination of specific equipment, but in general:

a. If there is dried blood in centrifuge buckets or on biological hood tray, use Tristel Fuse.

b. For centrifuge buckets pour Tristel in bucket. For flat surfaces it is best to use Tristel duo foam. Leave the Tristel on for 2 mins before rinsing with water.

c. If the stain has not been removed, do not soak with Tristel overnight. Decontaminate for 3 min and wash off as Tristel is corrosive, then soak in water overnight.

4.5 Processing samples: Follow study protocol.

a. Refer to SOP095 Laboratory Biological Safety Cabinet, SOP098 Pipetting, and SOP096 centrifuges if protocol requires using this equipment.

b. If a sample needs to be transferred to another container, make sure you label the container pot clearly before making the transfer.

c. Due care must be taken when centrifuging samples from more than one patient. If patient samples have been transferred to another tube make sure labelling is on the top and on the side of the tubes, with patient details or study number.

d. Any deviations to protocol must be recorded, for example: samples were not spun within 2-hour time frame. The sponsor will require a protocol non-compliance form to be completed (FRM038) or request the appropriate form from your study sponsor. In more severe incidences e.g. patient samples were mixed up, a DATIX may also be necessary.

e. Record any observations which may alter results, for example if blood is haemolysed.

f. After processing wipe down area and equipment with Clinell wipes or 70% ethanol and put a sticker to say that it has been clean or fill in clean schedule form for lab area.

g. Gloves used to process samples must be thrown straight away in clinical waste.

4.6 Sample storage

a. Correct sample storage is a requirement for HTA.

b. Once processed, samples need to be appropriately stored according to the protocol. Location of samples must be noted on study sample log spreadsheet.

c. If samples are to be frozen in -80, the freezer map must be updated to indicate the location of the new samples. See Management of R&D Freezers SOP029 for more details.

4.7 Sample transport

a. Refer to Sample Transport SOP097 for details on how to transport the various types of samples using the correct mode of transport. Be aware of any study specific protocol requirements.

4.8 Tracking

a. When samples are removed from storage, the date and destination must be entered into the study tracking log/ sample storage log. Sponsors may also require their logs or database to be used to track samples.

b. All movements must be dated to maintain a complete audit trail of samples.

4.9 Sample Disposal

a. Once a sample has been identified for disposal sample details must be verified. Depending on the study this may be barcode, sample type and sample location.

b. Use a Sample Disposal Form FRM083. If there are multiple samples an Excel spreadsheet may be used which has details of sample to be disposed, reason(s) why samples were disposed, date of sample disposal and initial and date samples were disposed.

c. For accuracy two members of the study team should compare the details on the samples with the details on the paperwork.

d. Paperwork to be signed and dated by both members of staff. Documentation of sample disposal must be scanned and stored in the electronic file.

e. Fresh/frozen samples are disposed of in clinical waste following DN375 Waste Management Policy.

f. If the sample is in a solution such as formalin or ethanol, the solution should be removed before disposing of tissue in clinical waste. The chemical solution must then be disposed of following COSHH.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments.

	UK Policy Framework for Health and Social Care Research (2023) Human Tissue Act (2004)

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Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

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