

1. Introduction

The aim of this Standard Operating Procedure (SOP) is to define the process for sample management in research sponsored by University Hospitals of Leicester NHS Trust (UHL).

2. Scope

This SOP applies to all research studies that are Sponsored by the UHL where samples / tissue that are originally from human participants. This includes newly acquired tissues / samples as well as those in archived and existing collections. For purposes of clarification, this refers to samples / tissues that are defined as either Relevant or Non-relevant material.

3. Procedure

3.1 General Requirement for Sample Management

The Chief Investigator (CI) should maintain oversight of samples / tissue collected for a trial; however this can be delegated to a member of the trial team. This must be clearly documented on the Delegation of Authority & Signature Log (see Appendix 1 to SOP S-1006 UHL) Samples / Tissue must only be collected and processed in accordance with the approved trial protocol, the approved consent process and have valid consent documented. Instructions and processes for key activities relating to the management of samples should ideally be detailed in the protocol. However, where deemed appropriate and agreed by the Sponsor a separate document such as a Laboratory Manual or study specific Sample Processing SOP may be used.

Documents necessary to record sample management should be ready for implementation prior to the collection of the samples.

The Research & Innovation contracts team should be consulted for advice on the legal requirements including material transfer agreements and service level agreements where samples are sent to an external organisation for storage or analysis.

Before analysis of clinical trial samples can be performed a laboratory protocol/analysis plan should be generated.

3.2 Sample Labelling

For the purpose of sample identification, samples should be labelled clearly with the following minimum information:

- Trial identification (e.g. Trial Number or Trial short name).
- Subject ID number or initials.
- Date and time of collection or sampling visit time point.
- Type of specimen.
- For aliquots of the sample a distinguishing sub factor (e.g. Visit 1_1, Visit 1_2 etc.).

Note: Under no circumstance should the patient name, hospital number, address or DOB be added to the sample label.

Sample labels can be pre-printed and generated locally with the required details, ensuring that the labels are freezer/nitrogen proof if required. If handwritten on the sample, a permanent freezer/nitrogen proof marker pen should be used.

3.3 Sample Storage

A system for recording the storage conditions within the fridge/freezer or other containment method must be in place to ensure storage conditions are kept within defined limits and meet protocol requirement such as:

- Utilisation of an automated system such as Tutela etc.
- Completion of a manual daily temperature log (template provided in Appendix [1a/1b](#)) recording min/max and current temperature.
- The level of Nitrogen in Nitrogen storage vessels (template provided in Appendix [1c](#)) should be monitored.

Where local procedures do not exist, the templates provided in Appendices 1a-1c can be utilised.

A copy of the temperature monitoring log should be filed in the Trial Master File at the end of the study.

Samples should be stored upright and in a labelled container suitable for the required storage condition.

A system should be in place to report any temperature excursions and record the actions taken.

3.4 Sample Tracking

Sample tracking is necessary to provide a chain of custody and audit trail of samples from collection to disposal. Sample tracking can be tracked on an automated system e.g. Openspecimen etc. or manually on a sample tracking log. Where local procedures do not exist the template provided in Appendix 2 can be utilised.

When completing a sample tracking log the following points should be considered:

- The tracking log should be completed in a timely and regulatory compliant manner.
- A new row/entry should be used for each time point.
- "Ditto" or brackets should not be used when booking in multiple samples.
- Storage locations must refer to room number and equipment ID in which samples are stored. Specific storage location within a fridge/freezer/nitrogen storage vessel must record the exact location e.g. column and row number within a box/tray/shelf/column/tray. Ensure that storage vessels are clearly labelled externally with a contact name and number.

3.5 Sample Shipping

If samples are shipped for storage or analysis the following points should be considered:

- Date of shipment and destination recorded on the sample tracking log.
- Samples should be packaged to the relevant IATA regulations and in accordance with details listed in Appendix 4.
- A copy of the sample tracking log listing the samples sent should accompany the samples shipped.
- If transported by courier then copies of the shipping documents should be filed in the lab section of the TMF.
- Confirmation of receipt should be requested from the receiving site.

3.6 Sample Receipt

When receiving samples the following points should be considered:

- The number of samples expected should match the number of samples received and be in accordance with shipping documents.
- Samples should be labelled appropriately and any participant identifiable information is removed and reported to the relevant sites accordingly.
- Samples should have arrived in an intact state and in the expected condition i.e. frozen, cold, room temperature. If this is not the case, then the shipping site must be informed.
- A receipt should be sent to the shipping site to confirm receipt.
- The samples should subsequently be stored in accordance with the requirements specified by the shipping site prior to sample receipt.
- A sample tracking log should be updated as appropriate to clearly document the chain of custody.

3.7 Sample Disposal or Long Term Storage

Once a trial end of study notification declaration has been submitted, it will be necessary for any remaining samples to be disposed of or transferred for long term storage in a relevant HTA licensed area in accordance with the IRAS form and dependant on the participants consent status. The study sample end of study notification form (Appendix 3) should be completed and returned to the Sponsor at the same time as the end of study declaration to REC.

Samples must be disposed of or transferred to long term storage within twelve (12) months of end of study notification.

If consent has been given for storage for future research, then any relevant samples must be transferred to suitable storage within a Human Tissue Authority (HTA) licensed premises. Consent forms must be retained for the duration of sample storage.

Sample disposal must be documented on the sample tracking log.

If samples have previously been moved to a relevant HTA licensed area and now require disposal, the HTA Disposal Form should be utilised (see S-1039 Appendix 5)

4. Responsibilities

1.	Responsibility	Undertaken by	Activity
1	Chief Investigator (CI)	CI or delegated study team member	Oversight of Sample Management
2	Chief Investigator (CI)	CI or delegated study team member	Sample labelling, storage, tracking, shipping, receipt and disposal.
3	Chief Investigator (CI)	R&I Contracts team	Drafting and review of any necessary contracts including Material Transfer Agreements and Service Level Agreements.
4	Chief Investigator (CI)	CI or delegated study team member	Completion of end of study sample notification form and return to Sponsor.

5. Supporting Documents and Key References

SOP S-1039 Appendix 1a, 1b, 1c, 2, 3, 4 & 5

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6. Key Words

Research, Innovation, Volunteers, Participants, CTIMPS, Trials, Sample, Human Tissue, Specimens

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