



**UNIVERSITY OF LEICESTER
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

**University of Leicester (UoL) Research Governance Office
SOP S-1042 UoL**

Version 1.1, September 2021

**Process for Sample Management in Research Sponsored by the
University of Leicester**

OFFICE BASE

Research Governance Office
Academic Department, Ground Floor
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Effective Date: October 2021



1 Introduction

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

2 Scope

This SOP applies to all studies sponsored by UoL where samples are taken from human participants including archived and existing collections.

3 Procedure

3.1 General Requirement for Sample Management

The Chief Investigator (CI) should maintain oversight of samples 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 Log (see Appendix 1 to SOP S-1021). Samples must only be collected and processed in accordance with the trial protocol and consent. Instructions and processes for key activities relating to the management of samples should be detailed in either the protocol or a separate document such as a Laboratory Manual or study specific Sample Processing SOP.

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

The Research & Enterprise Division (RED) 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. This should also be checked where UHL is the host site.

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 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 GCP 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 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 an HTA licensed area and now require disposal, the HTA Disposal Form should be utilised (see Appendix 1 to SOP HTA-1001 UoL).

4 Responsibilities


	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)	RED 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 Monitoring and Audit Criteria

Key Performance Indicators	Method of Assessment	Frequency	Lead
All research sponsored by UoL has appropriate Risk Assessment	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	Research Governance Manager or their Delegate

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Development and approval Record for this document

Author/Lead Officer:	Cat Taylor
Job Title:	Head of Research Assurance
Reviewed by:	Research Sponsorship Management and Operations Group
Approved by:	Professor Nigel Brunskill 
Date Approved:	13/10/2021

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Sept 2021	1.1	Cat Taylor	Administrative changes