



**University of Leicester Research Governance Office
Standard Operating Procedures**

SOP S-1042 UoL

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

Version 2.0, May 2024

Effective Date: July 2024

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used. For active studies there is no requirement to update appendices to the latest version.

1.0 Introduction and Scope

This Standard Operating Procedure (SOP) describes the process for sample management in research sponsored by the University of Leicester (UoL). This SOP is applicable to studies involving the handling, processing, receipt, storage or analysis of samples of human tissue for all UoL Sponsored studies. It relates to samples obtained from human participants and applies whilst the study/trial is under current ethical approval. Beyond ethical approval, where samples containing [HTA relevant material](#) are retained at the end of a study, the [HTA SOPs](#) will apply.

Samples collected as part of clinical research need to be managed appropriately to maintain their integrity and ensure that any analytical analyses produce results that are accurate, reliable and in line with the study protocol. Careful consideration needs to be given to the complete sample-management process, from collection, (including receipt where necessary), processing, storage and analysis, and including any transfer steps.

IMPORTANT FOR CTIMPs: Laboratories that perform storage, processing, analysis or evaluation of human biomaterial for CTIMPs must be set up and managed to the appropriate laboratory standard to ensure that patient safety is not compromised, that data is reliable and accurately reported, and in accordance with applicable law and the accepted principles of GCP.

The CI may wish to use laboratories external to the UoL, including academic and commercial institutions, to perform some or all of the sample analysis. As the responsibility for oversight of the trial ultimately resides with the sponsor, it is essential that the ability of the external laboratory to comply with the regulatory requirements of GCP in the laboratory standard, as described in the [European Medical Agency - Reflection paper for laboratories that perform the analyses or evaluation of clinical trial samples \(PDF - 136 KB\)](#) is assessed prior to analysis being initiated.

The Sponsor requires the CI to perform an assessment of any laboratory.

2.0 Consent

The CI (or delegate) must ensure that appropriate consent has been obtained for any given sample. The Informed Consent form and Participant Information Sheet must include information about the collection or obtaining of samples, their use, storage, transfer but also permissions relating to its use (now and in the future), storage, transfer and/or disposal (where applicable).

Where a study is using samples obtained under the ethical approval of another trial/study, the CI must ensure they obtain evidence that participants have provided prior agreement for the future use of these samples.

For further information on consent please refer to SOP S-1021.

3.0 General Requirements for Samples Collected as Part of a Research Study

The Principal Investigator (PI) must maintain oversight of samples collected for a study at their research site, however this can be delegated to a member of the study team. This must be clearly documented on the Delegation of Authority and Signature Log (see SOP S-1010 Appendix 2). Samples must only be collected and processed in accordance with the study protocol and individual 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 and should include relevant details relating to, but not limited to;

- Sample collection
- Sample labelling
- Sample storage
- Sample transfer
 - Sample shipping
 - Sample receipt
- Sample disposal or long-term storage
- Sample tracking

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

A sample analysis plan should be put in place prior to any samples being analysed.

3.1 Sample Labelling

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

- Study identification (e.g., Study Number or Study short name/Acronym)
- Participant ID number
- Date and time of collection or sampling visit time point
- Type of specimen

In the case of multiple aliquots of the same sample, each aliquot should have a unique ID (e.g. Visit 1_1, Visit 1_2 etc.).

Note: Under no circumstance should participant identifiable information including 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.

3.2 Sample Storage

A system for recording the storage conditions (e.g., within the fridge/freezer) 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/Haier
- Completion of a manual daily temperature log (template provided in Appendix 1a/1b) for recording min/max and current temperature.
- The level of Nitrogen in Nitrogen storage vessels (template provided in Appendix 1c) should be monitored and documented.

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

A copy of the temperature monitoring log should be filed in the Trial Master File (TMF) or Investigator Site File (ISF) as relevant 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, including when to notify the Sponsor of the temperature excursion.

3.2.1 Sample Transfer

Samples must only be transferred to and from the UoL in accordance with the protocol, participant consent and contracts.

Where appropriate consent is in place to do so, a copy of the consent form should be transferred alongside the sample to be held by the new sample custodian in the TMF. Where this is not possible, we recommend that a copy of a blank consent form, a participant information sheet and the REC reference is transferred alongside the samples. There should also be some form of due diligence check which documents the relevant participant IDs and the permissions that have been agreed (e.g., a sample consent audit).

Sample shipping (From UoL to another organisation)

When transferring samples from UoL to another organisation, you must ensure:

- The date of shipment and destination is recorded on the sample tracking log.
- The samples are packaged in accordance with the relevant [IATA regulations](#) and details listed in Appendix 4.
- A copy of the sample tracking log listing the samples being sent is included.
- Confirmation of receipt of all transferred samples is obtained from the receiving site and retained at UoL.
- If the samples are transported by courier, copies of the shipping documents (consignment notes) should be filed in the relevant section of the TMF/ISF.

Sample Receipt (From another organisation to UoL)

When receiving samples from another organisation into UoL, you must ensure:

- The number of samples expected matches the number of samples received.
- Samples are labelled appropriately and any participant identifiable information has been removed by the sending organisation (any breaches of this must be reported to the sender).
- Samples have arrived in the expected condition (i.e., frozen, cold, room temperature). Any breaches of this must be reported to the sender.
- The samples are subsequently stored in accordance with the requirements of the protocol and/or sender.
- Confirmation of receipt is issued to the sender.
- A sample tracking log is updated as appropriate to clearly document the chain of custody.

3.3 Sample Tracking

Sample tracking is necessary to provide a chain of custody and audit trail of samples from collection to disposal. Samples can be tracked on an automated system (e.g., Open specimen) or manually on a sample tracking log. Where local procedures do not exist, the template provided in HTA SOP 1013 Appendix 1 'Sample Tracking Log' should 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 both the room number and equipment ID (e.g., fridge or freezer number) 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. Ensure that storage vessels are clearly labelled externally with a contact name and number and appropriate freezer maps.

Sample tracking logs should be updated at every point where a change is made to the sample (e.g., if it is brought out of a fridge/freezer for analysis), when it is returned, if its storage location changes (e.g., just a building change or an organisation change), when it is disposed of.

3.4 Sample Disposal or Long-Term Storage

Once the relevant regulatory authorities have been notified of the end of a study/trial, it is necessary for any remaining samples to either be disposed of, or transferred for long term storage. This must occur within 12 months of end of study notification. Within that 12-month period, samples can only be used for data verification purposes. No new or future research should be conducted with them.

The required action will depend on what was approved as part of the initial application (or subsequent amendments) and in accordance with a participants consent status.

The ‘Sample end of study notification’ form should be completed and returned to the Sponsor at the same time as the end of study declaration to REC. This is available as part of the Human Tissue Act suite of [SOPs](#). Please refer to HTA-A1001 – Appendix 2.

3.4.1 Sample Disposal

Sample disposal must be documented on the sample tracking log. Disposal should have the date, method and reason for disposal added to the logs.

If samples have previously been moved to an HTA licensed area and now require disposal, the HTA Disposal Form should be utilised (HTA-A1004 - Appendix 1).

3.4.2 Long-term storage

If consent has been given for storage for future research, then any relevant samples must be transferred to suitable storage location. Any samples containing relevant material must be transferred to the UoL HTA research license ref 12384 and be housed within a Human Tissue Authority (HTA) licensed area. Consent forms must be retained for the duration of sample storage.


Samples that have been rendered acellular will not require transferring to the license however they must be stored within an appropriate storage location to ensure the samples integrity is maintained and as per the terms of participant consent. The storage can be outside of the HTA research licenced area.

4.0 Responsibilities

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

5.0 Development and approval Record for this document

This table is used to track the development and approval of the document

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Management and Operations Group (RSMOG)	Professor Nigel Brunskill 	14/06/2024

6.0 Review Record

This table is used to track any changes made on revised/reviewed versions

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Sept 2021	1.1	Cat Taylor	Administrative changes
May 2024	2.0	Cat Taylor	Formatting and administrative changes Major updates to wording to provide clarity Removal of office address. Minor formatting and administrative changes to Appendix 1 and 4. Removal of Appendix 2 'Sample Tracking Log' and Appendix 3 'Sample End of Study Form' and instead link to relevant Appendices within the HTA suite of SOPs.