Standard Operating Procedure CCTU/SOP044

Research sample management for CTIMPs

(labelling, storage, tracking, shipment and receipt)

1. Scope

For use within designated sample handling areas where research samples obtained from participants taking part in Cambridge Sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs) are handled.

This procedure can also be followed for samples collected for other clinical research projects managed by the CCTU.

It does not apply to the Trust pathology laboratories processing patient samples.

2. Purpose

To ensure and demonstrate that samples are handled in accordance with GCP for laboratories in the CTIMP regulated setting, the protocol, the Human Tissue Act, and if applicable the sampling area's internal quality standards and/or SOPs.

To document the chain of custody from the time of collection to storage, processing or analysis, long-term storage or disposal to provide a complete audit trail.

3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

3.1. Definitions

Term	Definition
Cambridge Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH); or the University of Cambridge (UoC); or jointly by CUH and UoC OR Sponsored by: Cambridge University Hospitals NHS Foundation Trust (CUH) or CUH jointly with the University of Cambridge or Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge
Samples	Any biological sample e.g. Blood, Tissue, Urine, Hair, Skin, collected from participants
Relevant material	Cellular material refer to the HTA website https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004

Fridge/Freezer map	Plan of freezer to record exact location, i.e. shelf/cassette/box. This could also apply to other storage locations, e.g. cold room, liquid nitrogen
Chain of Custody	A record describing all pertinent information specific to each sample, including signatures of persons handling the sample
Laboratory Manual	Stand-alone document which covers all the sample handling activities supplementing the protocol, can be known as a sample handling manual, could also be a procedural document
Cryo pen	Pen where ink can withstand freezing and thawing when used to label samples

3.2. Abbreviations

Abbreviation	Meaning
R&D	Research and Development
ID	Identification
CI	Chief Investigator

4. Undertaken by

Members of research, trial and/or sample handling teams delegated to process samples and trained to this SOP

5. Items Required

Protocol, sample handling manuals, laboratory manual or other instructions related to the trial samples

IRAS form

Fridge/freezer Map and/or other sample location documentation

CCTU/TPL031 Sample Tracking and Processing Template, this can be adapted to create a trial specific document

Storage containers, labels, cryo pen

CCTU/SOP016 Transport of Biological Samples

6. Summary of Significant Changes

Trial initials can only be used as a sample identifier if it specifically written in the protocol. The use of initials is discouraged.

Record of disposal in the TMF

Patient's consent for the use of their samples management

Use of alternative templates

7. Method

The following sections provide a description of the processes to be followed when implementing this document’s procedures.

7.1. General requirements for research sample management

- Instructions and processes for key activities pertinent to the management of samples should be detailed in either the protocol or a standalone document such as a Laboratory Manual
- Where samples are sent to an external organisation for storage or analyses the R&D Department should be consulted for advice on legal requirements including material transfer agreement, service level agreement, technical agreement
- Any analysis or evaluation of clinical trial samples must be detailed in the protocol or laboratory manual
- Tracking documents for each sample must be kept
- Patient consent for the use of their samples must be managed by the trial team (e.g. email to the laboratory with the list of patients that have given consent)
- Samples must be stored and transferred in the required condition
- The CI is responsible for oversight of samples collected for a trial, this can be delegated to a member of the trial team
- The CI should review the integrity of the samples
- If any samples do not meet the required standard, and CI must consider if the samples or results obtained from the samples should be used
- Key sample management activities include but are not limited to:
    - Sample labelling
    - Sample processing
    - Sample storage
    - Sample tracking, shipping and receipt
    - Sample analyses and reporting
    - Disposal
- If a trial-specific Laboratory Manual is produced, this must be written in accordance with the protocol and the conditions stated in the IRAS form and any subsequent amendments that apply
- Documents required to record sample management, such as a sample tracking log, should be:
    - Ready for implementation prior to the collection of samples
    - Generated or adapted based on the CCTU template (CCTU/TPL031), consideration must be given to the nature of the samples collected storage and processing requirements. This must be printed and stored in the TMF

7.2. Sample Labelling

- For the purpose of identification, samples are labeled either with:
- Labels provided by CI/Sponsor
- Labels generated locally with required details
- Handwritten onto container with permanent freezer proof marker pen (e.g. cryo pen)

There must be no participant identifiable information on the samples or labels unless specifically agreed by the regulatory body

- Where labels are generated locally or information is hand written, samples should be identified minimally using the following:
    - Trial identification
    - Subject ID (anonymised)
    - Initials can only be used where there is specific instruction in the protocol
    - Date & time of collection or sampling time point
    - Type of specimen
    - For aliquots of the same sample a distinguishing sub factor

7.3. Sample Storage

- Samples must be stored as specified in the protocol to protect their integrity:
    - Containers used must be suitable for the required storage condition
    - Samples should be kept upright until frozen or as specified in the lab manual
- The storage location within the fridge/freezer or other must be recorded on the sample tracking log according to a freezer/fridge map; e.g. box/tray/shelf/column/row
- 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 requirements, either as:
    - Temperature log, recording minimum, maximum and current temperature
    - Automated temperature recording systems
- Specific instructions should be included to record any deviation from the protocol regarding temperature outage or storage conditions. When samples are removed from storage for transfer/shipment, the date and destination must be entered onto the tracking log

7.4. Sample Tracking

Sample tracking documents the chain of custody from the time of collection to storage, processing or analysis, long-term storage or disposal to provide a complete audit trail.

- The log must be completed in a timely and GCP compliant manner
- Use a new row on the form for each time point for clarity
- Do not use ditto or when booking in multiple samples brackets can be used where appropriate

7.5. Shipment

- When shipping samples externally samples must be packed according to IATA regulations as detailed in CCTU/SOP016 Transport of Biological Samples

- The date of shipment and destination must be filled out on the sample tracking log
- A copy of the sample tracking log must accompany the samples shipped
- If transported by courier or post then a signature must be obtained and the shipping documents filed in the lab sample section of the TMF
- If sent by any other method then The receiving site should be sent an email to expect the delivery
- Confirmation of receipt should be requested from the receiving site

7.6. Receipt

- The receiving site must check that:
- The number of samples expected should match the samples received and in accordance with the accompanying documents
- Labeling was appropriate, any participant identifiable information present is removed and the error is reported to the shipping site
- The transit condition and the condition of the samples received is in accordance with the written instructions and/or the Laboratory Manual
- All movements have been signed and dated to maintain a complete clear documented audit trail for all samples,
- Confirmation of receipt has been sent to the shipping site

7.7. Sample disposal or long term storage

- Once a trial has closed any remaining samples classed as relevant material must be disposed of or transferred to long term storage depending on the conditions set out in the IRAS form and participant's consent status, this should be detailed in the Laboratory Manual
- If consent has been given for further unrelated research the samples must be transferred to a licenced tissue bank in accordance with the Human Tissue Act and Local policy
- It is unlawful to hold tissues on premises without a storage licence from the Human Tissue Authority or without a valid favorable ethical opinion
- Any tissue samples that are not for long term storage must be disposed of through the tissue bank and confirmation of disposal filed in the TMF

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness

As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators

This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

9. References

The Institute of Clinical Research, Abbreviations used in Clinical Trials.

MHRA, Good Clinical Practice "Grey Guide"

Trust Access to The human tissue samples policy found on connect

10. Associated Documents

NA

11. Equality and Diversity Statement

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer

It is the user's responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

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