Standard Operating Procedure CCTU/SOP044

Research Sample Management

(labelling, storage, tracking, shipment and receipt)

1. Scope

For use within designated sample handling areas processing research samples for Cambridge Sponsored CCTU led Clinical Trials.

This SOP does not apply to NHS pathology laboratories.

2. Purpose

To ensure and demonstrate that samples are handled in accordance with GCP and if applicable the sampling area's internal quality standards and/or SOPs.

To document the chain of custody of samples from the time of collection to disposal to provide a complete sample 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 Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) or CPFT jointly with the University of Cambridge
Chain of Custody	A record describing all pertinent information specific to each sample, including signatures of persons handling the sample
Cryo pen	Pen where ink can withstand freezing and thawing when used to label samples
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
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
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
Samples	Any biological sample e.g. Blood, Tissue, Urine, Hair, Skin, collected from participants

3.2. Abbreviations

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

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 system

Storage containers, labels, cryo pen

CCTU/SOP016 Transport of Biological Samples

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

6. Summary of Significant Changes

Addition of Sample Analysis Plan as a valid document where sample analysis and evaluation can be detailed

CCTU accepted labs can also dispose of samples

7. Method

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

7.1. Responsibilities

The Chief Investigator

- Is responsible for oversight of samples collected for a trial, this can be delegated to a member of the trial team on the delegation log
- Should review the integrity of the samples
- Must consider if the samples or results obtained from the samples that do not meet the required standard should be used

7.2. General requirements for research sample management

- Participants must give consent for the use of their samples; this must be managed by the trial team (e.g., email to the laboratory with the list of participants that have given consent)
- 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
- Instructions, processes/analysis and key activities pertinent to the management of samples should be detailed in either
  - The Protocol
  - A Laboratory Manua
  - A sample analysis plan
- 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
- Where samples are managed or analysed within the host organisation it is good practice to have a written understanding of expectation between the trial team and the laboratory for clarity
- Where samples are sent to an external organisation for storage or analyses the R&D Department should be consulted for advice regarding any legal such as a:
  - Material transfer agreement
  - Service level agreement
  - Technical agreement
- Tracking documents for each sample must be kept
- Samples must be stored and transferred in the required condition
- 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
  - Generated from an electronic tracking system
  - Printed and stored in the TMF

7.3. 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 (for frozen samples use a 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 (name code or number)

- 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

7.4. Sample Storage

- All samples must be stored as specified in the protocol/lab manual to protect their integrity
- If back up /duplicate samples have been taken they should be stored in a different location
    - Samples should be kept upright or as specified in the lab manual
    - Containers used must be suitable for the required storage condition
    - Samples may be stored in:
        - Fridges
        - Freezers
        - Liquid nitrogen
        - Ambient temperature
        - Other as specified
- The storage location must be recorded either by using
    - A location map; e.g. location/box/tray/shelf/column/row
    - An electronic tracking system
- A system for recording storage temperature within the location must be in place to ensure storage is within the defined limits documented in the protocol/lab manual either a:
    - Temperature log, recording minimum, maximum and current temperature
    - Continuous automated temperature recording system
- Specific instructions to record any deviation from the defined requirements must be documented

7.5. 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.
- When samples are removed from storage for transfer/shipment, the details must be entered onto the tracking log refer to CCTU/TPL031 Sample Tracking and Processing Template
- The log must be completed in a GCP compliant manner
- Use a new row on the form for each time point for clarity or a new form for each participant as appropriate
- Electronic tracking must record the same level of detail

7.6. Shipping

If back up /duplicate samples have been taken they should be shipped on a different day or using different transport

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 entered 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 TMF (laboratory section)
- If sent by any other method an email should be sent to the receiving site to expect the delivery
- Confirmation of receipt should be requested from the receiving site

7.7. Receipt

Confirmation of receipt should be sent to the shipping site

- The receiving site must check that:
    - The number of samples received should match thenumber of samples expected and be in accordance with the accompanying documents
    - Labeling is appropriate, if any participant identifiable information is present it must be 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 documented audit trail for all samples

7.8. Sample disposal or long-term storage

It is unlawful to hold relevant material without a storage licence from the Human Tissue Authority or without a valid favourable ethical opinion

- Once a trial has closed any remaining samples classed as relevant material must be disposed of or transferred to long term storage according to the:
    - IRAS form
    - Consent given
    - Laboratory Manual
- If consent was given for further unrelated research the samples must be transferred to a licensed tissue bank in accordance with the Human Tissue Act and Local policy
- Any relevant material not for long term storage must be disposed of through a tissue bank or a CCTU accepted laboratory
- Confirmation of storage or disposal must be 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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