

Standard Operating Procedure CCTU/SOP028

Sample Tracking Procedure for Laboratory Samples

1. Scope

This standard operating procedure is used for tracking samples collected and/or stored within research laboratories processing samples for Clinical Trials of Investigational Medicinal Products (CTIMPs), but the SOP can also be followed for samples collected for other clinical research projects. It does not apply to NHS Trust Hospital laboratories processing patient samples.

2. Purpose

To ensure that samples (inclusive of whole blood, serum, plasma or any other) are collected and handled in accordance to GCP for laboratories and protocol standards. Further guidance can be found on <http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPracticeforClinicalLaboratories/index.htm>

To have an audit trail and chain of custody for each sample from the time of collection to appropriate storage at the hospital or at an offsite facility in compliance with the Human Tissue Act

3. Definitions and Abbreviations

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

Common abbreviations and definitions can be found in CCTU/INF001 Common Abbreviations and Definitions.

Term	Definition
Trust-Sponsored	Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH) or sponsored by CUH jointly with The University of Cambridge
Sample	Any biological substance collected for analysis
Chain of Custody	A record describing all pertinent information specific to each sample, including signatures of persons handling the sample

3.1. Abbreviations

Abbreviation	Meaning
ID	Identification
MHRA	Medicinal and Healthcare products Regulatory Agency

4. Undertaken by

All members of research teams and all laboratory staff delegated to process samples and trained to this SOP

5. Items Required

Sample Tracking Log – CCTU/FRM033 or local version

6. Summary of Significant Changes

N/A

7. Method

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

7.1. Logging samples

- Each individual sample is given a unique ID as defined by the protocol or lab manual
- The sample is logged onto the tracking form CCTU/FRM033 or comparable local form
- The unique sample identification is recorded in the sample ID column

7.2. Filing in the Tracking Log

- Each Column should be filled in – leave no blanks
- Do not use dittos or brackets
- Ensure that the processed by column is initialled and dated
- The temperature of storage should be included within the storage location column
- Ensure that times are recorded in 24hr format

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. Documents are reviewed every two years

9. References

The Institute of Clinical Research, 2008, Abbreviations used in Clinical Trials.

10. Associated Documents

N/A

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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