Quality Control Document:

Sample Receipt, Labelling, Tracking and Storage

# Purpose

To allow complete and robust traceability of all human biomaterial samples (and aliquots thereof), receipt into the laboratory, labelling, tracking and storage must be considered and recorded.

This document is designed to be used for clinical trials and for clinical studies using human tissue. It is possible to create a project specific sample management plan, in which case it should contain the specifications outlined in the *Sample Management SOP (UoB-CRL-SOP-003)*.

# Instructions

1. Remove this first instruction page.

## Sample Management Plan

1. Update the header to include the trial/study ID.
2. Update the footer; include a version date and retain the document reference information relating to this quality control document (QCD).
3. Detail how samples and their aliquots should be labelled in the ‘Sample and aliquot labelling’ section.

* Ensure all samples have a unique identifier.
* Ensure the labelling method enables the linking of all aliquots (and their derivatives) back to the original sample.

1. Document the sample pathway through the laboratory.

* This could be illustrated through a written description or with the aid of a flow chart.
* Consider sample receipt, processing, storage, usage and disposal stages.

1. Record the sample storage locations to be used.

* For example, “Urine aliquots will be stored in -80 Freezer Number 3 (-80) in Laboratory 4”.

1. Detail the system (either electronic or paper based) that will be used to track samples through the laboratory

* For example, “Pro-Curo will be used for sample tracking and can be accessed via (K:)/Laboratory/Trial/Sample Tracking”

1. Provide instructions for tracking system users. Consider:

* User access levels
* Back-up requirements (if electronic)
* What information should be entered in each field
* When to update the tracking system
* How quality checks will be performed

1. File a copy of this form in the ‘Sample Tracking’ section of the Laboratory Master File (LMF). See quality control document (QCD) Setting Up a Laboratory Master File (UoB-CRL-QCD-001). *A*rchive with the other trial/study records upon closure; see the Archiving SOP (UoB-ARC-SOP-001).

## Sample Receipt Form

1. Update the header to include the trial/study ID.
2. Update the footer; include a version date and retain the document reference information relating to this QCD.
3. Add any trial-specific quality checks as appropriate.
4. File a blank copy of this form in the ‘Sample Tracking’ section of the LMF. See QCD Setting Up a Laboratory Master File (UoB-CRL-QCD-001). Use the form whenever samples are received into the laboratory.
5. Send a copy of the completed form to the sender.
6. File completed versions of this form in the ‘Sample Tracking’ section of the LMF; see QCD Setting Up a Laboratory Master File (UoB-CRL-QCD-001). Archive with the other trial records upon closure; see Archiving SOP (UoB-ARC-SOP-001).

# Related documents

* UoB-ARC-SOP-001 Archiving
* UoB-CRL-QCD-001 Setting Up a Laboratory Master File
* UoB-CRL-QCD-005 Key Contacts
* UoB-CRL-SOP-001 Laboratory Set-up and Management
* UoB-CRL-SOP-002 Laboratory Facilities
* UoB-CRL-SOP-003 Sample Management
* UoB-CRL-SOP-004 Laboratory Analysis
* UoB-CRL-SOP-005 Reportable Issues

UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (<mailto:crct@contacts.bham.ac.uk>) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

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| --- |
| Sample and aliquot labelling |
|  |
| Sample pathway through the laboratory |
|  |
| Sample storage location(s) |
|  |
| Sample tracking system and user instructions |
|  |

|  |  |
| --- | --- |
| Sample Details | |
| Name of person receiving samples into the laboratory |  |
| Date (dd-mmm-yyyy) |  |
| Originating Site |  |
| Sample Type |  |
| Sample IDs |  |

|  |  |
| --- | --- |
| Sample Quality Checks | **Yes / No** |
| Was the physical integrity of samples maintained during transport? |  |
| Are all samples accounted for? |  |
| Are samples free from patient identifiers?  (unless specific consent obtained for identifiers to remain) |  |
| Where samples require temperature control during transport, was this maintained? |  |
| Are samples to be accepted and processed by the laboratory?  (in the case of damaged, unexpected or mislabelled samples follow the study specific processes) |  |
| If ‘No’, detail course of action to be taken | |