Quality Control Document:

Sample Transport

# Purpose

Human tissue samples for clinical trials and clinical studies should be transported in a way which maintains their integrity and viability.

This document contains a form which can be used to develop a Sample Transport Procedure to follow when samples require transportation and instructions on how to complete this form.

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 transport procedure, 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.
2. Update the header to include the trial/study ID.
3. Update the footer; include a version date and retain the document reference information relating to this quality control document (QCD).
4. Record the type of samples that are to be transported. For example, blood, tumour biopsy, urine.
5. Record the location that the samples will be transported from.
6. Record the location that the samples will be transported to.
7. Record the type of transport that will be used to transport the samples. For example, via a courier or on foot by a member of the research team.
8. Document how long the samples are expected to be in transit for. Consider the implications if this time is exceeded and consider whether this would be a reportable issue. See quality control document (QCD) Reportable Issues (UoB-CRL-QCD-024).
9. Document the sample temperature requirements. For example, samples must be transported at -20°C, at 4°C, samples have no temperature requirements. Where temperature requirements are applicable consider the acceptable temperature range.
10. Define how the temperature of samples will be monitored while in transit. For example, the courier provides a temperature monitoring service for the shipment or a max/min thermometer be included in the package along with the samples. If thermometers are used they must be calibrated. See QCD UoB-CRL-QCD-012 (Calibration of Thermometers).
11. Document the sample packaging requirements. For example, consider whether dry ice, any specific boxes or labelling is required.
12. Record whether a Material Transfer Agreement (MTA) is required. See QCD *Laboratory Contracts and Agreements Checklist (UoB-CRL-QCD-004)*. MTAs must be in place whenever human tissue samples are transferred between institutions.
13. Record whether an MTA is in place, if required.
14. Store the Sample Transport Procedure safely and securely in the Laboratory Master File throughout the trial and 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-004 Laboratory Contracts and Agreements Checklist
* UoB-CRL-QCD-012 Calibration of Thermometers
* UoB-CRL-QCD-024 Reportable Issues
* 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)).

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of sample:** |  | | |
| **Expected total number of samples:** |  | | |
| **Samples transported from:** |  | | |
| **Samples transported to:** |  | | |
| **Transport type:** |  | | |
| **Expected time the samples will be in transit:** |  | | |
| **Temperature requirements:** |  | | |
| **Temperature monitoring requirements in transit:** |  | | |
| **Sample packaging requirements:** |  | | |
| **Is a Material Transfer Agreement required?**  **(yes/no)** |  | **If yes, is a Material Transfer Agreement in place?**  **(yes/no)** |  |