Quality Control Document:

Processing of Damaged, Unexpected or Mislabelled Samples

# Purpose

When the laboratory receives samples which are damaged, unexpected or mislabelled, they must be handled in accordance with trial/study specific procedures. These procedures must be defined and documented before the laboratory begins to receive samples.

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 procedure for processing damaged, unexpected, or mislabelled samples, 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. Define the trial/study specific procedures to be followed in each relevant section (‘Damaged Samples’, ‘Unexpected Samples’ and ‘Mislabelled Samples’).
5. File a blank version of this form in the ‘Damaged, Unexpected or Mislabelled Samples’ section of the Laboratory Master File (LMF). See quality control document (QCD) Setting Up a Laboratory Master File (UoB-CRL-QCD-001).
6. Complete the Incident Report whenever there is an instance of damaged, unexpected or mislabelled samples being received by the laboratory.
7. File completed versions of this form in the ‘Damaged, Unexpected or Mislabelled Samples 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).

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# 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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| Procedure to be followed in the event of the receipt of: | | | |
| Damaged samples | | | |
|  | | | |
| Unexpected samples | | | |
|  | | | |
| Mislabelled samples | | | |
|  | | | |
| Incident Report: | | | |
| Name of laboratory team member dealing with incident: | |  | |
| Date of incident (dd-mmm-yyyy): | |  | |
| Type of incident (tick all that apply): | | | |
| * Damaged samples | * Unexpected samples | | * Mislabelled Samples |
| Description of incident: | | | |
| Corrective and Preventative Action taken (as per relevant procedure): | | | |
| Description of Incident Resolution: | | | |
| Incident Closure: | | | |
| Name: |  | | |
| Date (dd-mmm-yyyy): |  | | |
| Signature: |  | | |