Quality Control Document:

Review and Release of Results

# Purpose

Before data can be reported to the Sponsor (or their representative), appropriate quality checking activity must be performed) and the process documented in some way, for example by the use of the ‘Release of Results’ form on the following page.

This document is designed to be used for clinical trials of investigational medicinal products (CTIMPs), however it could also be used as best practice for non-CTIMPs and studies using human tissue. It is possible to create a trial specific sample transport procedure, in which case it should contain the specifications outlined in the Laboratory Analysis SOP (UoB-CRL-SOP-004).

# 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. File a blank version of this form in the ‘Data Reporting’ section of the Laboratory Master File (LMF). See the quality control document (QCD) Setting Up a Laboratory Master File (UoB-CRL-QCD-001).
5. Complete this form whenever data is quality checked before being reported.
6. File completed versions of this form in the ‘Data Reporting’ section of the LMF; see the 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-002 Laboratory Roles and Duties
* 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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| Batch release of results from the Laboratory | | |
| Results to be released (batch details): | |  |
| Date quality check performed (dd-mmm-yyyy): | |  |
| Description and result of quality check: | | |
| By signing and dating below I confirm that this data can be reported: | | |
| Name: |  | |
| Date (dd-mmm-yyyy): |  | |
| Signature: |  | |