Quality Control Document:

Reportable Issues

# Purpose

Where incidents arise during the analysis of clinical trial samples which may affect patient safety or future patient care, robust and documented processes must be in place to enable the impact of the incident to be assessed by the correct person(s) and the appropriate actions, for example, the expediting of anomalous results to be completed promptly. Documentation of these instances and their resolutions must be maintained and archived to allow the re-construction of the trial.

This document is designed to be used for clinical trials of investigational medicinal products (CTIMPs) but could also be used for non-CTIMP trials and studies to support best practice. It is possible to create project specific sample kit management documents, which should contain the specifications outlined in the Reportable Issues SOP (UoB-CRL-SOP-005).

# Instructions

1. Remove this first instruction page.
2. Update 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).

## Define reportable issues

1. Document each potential reportable issue in the ‘Pre-defined reportable issues’ table, for example, consider:
* Anomalous or out of range results that that are of clinical significance to the patient or indicate incorrect dosing
* Deviations from analytical plan, clinical trial protocol and/or contract/agreement which could impact on the integrity of trial samples or data
* Equipment failure, to include refrigerators or freezers where samples are stored and equipment used in the analysis of samples which could impact on the integrity of trial samples or data.
1. Record whether the defined reportable issues would constitute a serious breach; see the Deviations and Serious Breach Reporting SOP (UoB-DBS-SOP-001). Where this is a Serious Breach the procedures outlined in the Deviations and Serious Breach Reporting SOP must be followed.
2. Select an appropriate staff member to assess the impact of any incidents to determine whether they would be considered reportable issues.
* Consider instances where non-laboratory members must make the assessment, for example anomalous or out of range results may need to be assessed by a clinician.
1. Record to whom the issue should be reported. Consider whether this should be;
* The sponsor (or their representative)
* The investigator or
* The co-ordinating centre.
1. File a blank version of this form in the ‘Reportable Issues’ section of the Laboratory Master File (LMF). See the quality control document (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).

## Documenting an incident

1. The person who discovered the incident will complete Section 1 of the ‘Incident Documentation Record’ with a detailed description of the incident, their name and the date on which the event occurred.
2. The person responsible for performing an impact assessment will detail their conclusions in Section 2 of the ‘Incident Documentation Record’. Note whether the incident has the potential to impact on the integrity or reliability of the trial data, participant confidentiality, consent or safety and if so should be considered to be a reportable issue. For example, in the instance of the failure of a sample storage freezer, the impact assessment would record whether or not the integrity of the samples has been compromised. If it is possible that integrity has been compromised the incident would become a reportable issue. If samples were quickly moved to a back-up freezer, the assessor may conclude that sample integrity was not compromised and the incident is not a reportable issue.
3. The person performing the impact assessment will then record what action must be taken in Section 3 of the ‘Incident Documentation Record’.
* This will include following the reporting process defined in the ‘Pre-defined reportable issues’ table, where applicable.
* Where the instance constitutes a serious breach the procedures UoB Deviations and Serious Breach Reporting SOP (DBS-SOP-001) must be followed.
* Consider corrective and preventative actions (CAPA) to limit the impact of the incident and prevent it recurring.
1. When all action points have been resolved, close the incident by completing Section 4 of the ‘Incident Documentation Record’.
2. File completed versions of this form and all related correspondence in the ‘Reportable Issues’ section of the Laboratory Master File (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-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-DBS-SOP-001 Deviations and Serious Breach Reporting

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).

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| Pre-defined Reportable Issues  |
| Description of Issue | Would this constitute a Serious Breach? (Y/N) | Staff member(s) to assess impact | To be reported to |
|  |  |  |  |

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| --- |
| Incident Documentation Record |
| 1. Description of incident |
| Incident documented by |  | Date of incident (dd-mmm-yyyy) |  |
| 2. Impact Assessment (including whether the incident constitutes a reportable issue) |
| 3. Action required (including reporting as per pre-defined reportable issues above, where required) |
| Impact assessment performed by |  | Date of impact assessment (dd-mmm-yyyy) |  |
| **4. Incident Closure** |
| Incident closed by |  | Date of closure (dd-mmm-yyyy) |  |