Quality Control Document:

Refrigerator or Freezer Failure Management

# Purpose

To ensure integrity of human tissue for clinical studies, human biomaterials, analytical reagents, and clinical sample kit components which contribute to the (primary, secondary and/or exploratory) endpoints of clinical trials, and therefore the reliability of data, the temperature of refrigerators and freezers used to store human tissue samples for clinical studies or trials must be monitored to confirm it remains within acceptable limits.

This document provides a template which can be used to create a Refrigerator or Freezer Failure Record to capture the procedure followed in the case of refrigerator or freezer failure and to evidence that this procedure was followed, as well as instructions on how to complete this document.

This document is designed to be used for clinical trials and for clinical studies using human tissue. It is possible to set up a project specific Refrigerator or Freezer Failure Record, in which case it should contain the specifications outlined in the Laboratory Facilities SOP (UoB-CRL-SOP-002).

# Instructions

1. Remove this first instruction page.
2. Update the trial/study ID in the header.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. Document the procedure to be followed in the event of refrigerator or freezer failure.

* Consider prioritisation for salvage
* Include the documentation that must be completed i.e. Refrigerator/Freezer Failure Record, **Incident Documentation Record. See** the Reportable Issues SOP (UoB-CRL-SOP-005) and the quality control document (QCD) Reportable Issues (UoB-CRL-QCD-024). Ensure that these contact details are subject to regular review so that the information remains up to date.

1. Record the ID number and lab number of the back-up refrigerator/freezer.
2. Record the name and phone number of the person(s) responsible for impact assessment as outlined in the document Reportable Issues (UoB-CRL-QCD-024). Ensure that these contact details are subject to regular review so that the information remains up to date.
3. Complete a Refrigerator/Freezer Failure Record each time a refrigerator or freezer failure occurs.
4. Record the ID and lab number of the refrigerator/freezer that has failed.
5. Record the date and time that the refrigerator/freezer failure was identified.
6. Record the date/time refrigerator/freezer was last observed to be working correctly.
7. Ensure samples are transferred to the backup refrigerator/freezer and document on the record to confirm.
8. Record the date and time that the samples were moved to the backup refrigerator/freezer.
9. Ensure the person(s) responsible for impact assessment and escalation as outlined in the Refrigerator/Freezer failure procedure is contacted and document on the record to confirm.
10. Ensure the impact of the failure has been assessed and confirm on the Refrigerator/Freezer Failure Record. For Clinical Trials of Investigational Medicinal Products, the impact assessment of the refrigerator/freezer failure will be captured on the **Incident Documentation Record as per QCD** Reportable Issues (UoB-CRL-QCD-02).
11. Record the IDs of the samples that have been moved to the back-up refrigerator/freezer.
12. Document any additional information regarding the refrigerator/freezer failure in the comments section. Consider including information that may aid impact assessment, such as the temperature the failed refrigerator/freezer reached prior to samples being moved, the cause of the refrigerator/freezer (if known) etc.
13. Record the name and signature of the person who is completing the Refrigerator/Freezer Failure Record.
14. Record the date on which the Refrigerator/Freezer Failure Record was completed.
15. Store the Refrigerator or Freezer Failure Record in the Laboratory Master File throughout the trial/study and archive with the other trial/study records upon closure. Refer to the Archiving SOP (UoB-ARC-SOP-001).

# Related documents

* UoB-ARC-SOP-001 Archiving
* UoB-CRL-QCD-007 Temperature Monitoring
* 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 ([crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

# **Refrigerator/Freezer Failure Procedure**

**In the event of a refrigerator/freezer failure follow the procedure below.**

|  |  |  |
| --- | --- | --- |
| **Procedure:** |  | |
| **Back up Refrigerator/Freezer details:** | ID: | Lab Number: |
| **Contact details of person(s) responsible for impact assessment:** | Name(s) | Phone number(s): |

# **Refrigerator/Freezer Failure Record**

**To be completed following refrigerator/freezer failure.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Details of Failure** | | | |
| Failed Refrigerator/Freezer ID: | Failed Refrigerator/ Freezer Lab number: | Date/time failure was identified: | Date/time Refrigerator/ freezer was last observed working: |
| **Were samples moved to backup Refrigerator/ Freezer? (yes/no)** | Date/Time that samples were moved: | Person responsible for impact assessment and escalation contacted? **(yes/no)** | **Has the impact of the failure been assessed (for trials – has an Incident Documentation Record been completed?) (yes/no)** |
| **ID of samples moved:** |  | | |
| **Comments:** |  | | |
| **Name of person completing form:** |  | | |
| **Signature of person completing form:** |  | | |
| **Date form completed: (dd-mmm-yyyy)** |  | | |