Quality Control Document:

Temperature Monitoring

# Purpose

Areas and equipment within a laboratory must be monitored for temperature if they are used to store: human tissue for clinical studies; human biomaterials; analytical reagents; and clinical-sample-kit components that contribute to the (primary, secondary and/or exploratory) endpoints of clinical trials. Temperature must be monitored to assess whether or not it remains within prescribed, acceptable limits. These limits ensure the integrity of human biomaterials and/or analytical reagents, and in turn, this helps to ensure the reliability of data.

The purpose of this document is to provide a Temperature Monitoring Record template that can be used to document temperature monitoring where a physical, manual check has been made. This document also includes instructions on how to complete these records. The Temperature Monitoring Record template is optional however it, or something similar, must be used for trials and studies where temperature is being monitored manually.

# Instructions

1. Remove this first instruction page.
2. Update the header to include the trial ID.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. Enter the laboratory location and the name of the area/equipment that is being monitored.
5. Determine the acceptable temperature limits for this area/equipment and document them on the form.
6. Determine how frequently the temperature of this area/equipment is to be monitored and document it on the form.
7. Document the temperature on the form each time a manual check is made, along with all other required details.
* For clinical trials of investigational medicinal products (CTIMPs), ensure that the minimum, maximum and current temperatures are recorded for areas and equipment used to store samples, reagents and clinical kits.
* For non-CTIMP trials and clinical studies, ensure that as a minimum, the current temperature is recorded for areas/equipment storing samples (amend the form as necessary).
1. If monitoring is missed for any reason, do not leave the record blank. Instead, state this on the form using a phrase such as ‘not taken’ or ‘not carried out’.
2. If the temperature is outside of the acceptable range, record this information on the form and investigate whether the storage unit has failed or is failing. If it is, follow the procedures for the failure of a refrigerator or freezer detailed in the quality control document (QCD) Refrigerator or Freezer Failure Management (UoB-CRL-QCD-008). For CTIMPs, determine whether or not a reportable issue has occurred; see *QCD* Reportable Issues (UoB-CRL-QCD-024).
3. Store all temperature-monitoring records in the laboratory master file (LMF). Temperature monitoring records must be maintained on an ongoing basis throughout the trial/study and be archived with the other documents when the trial/study closes. See the Archiving SOP (UoB-ARC-SOP-001).
4. Calibrate the equipment used to monitor temperature, and document evidence of this, See QCD Calibration of Thermometers (UoB-CRL-QCD-012).

# Related documents

* UoB-ARC-SOP-001 Archiving
* UoB-CRL-QCD-008 Refrigerator or Freezer Failure Management
* 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 (crct@contacts.bham.ac.uk) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

# Area/Equipment being monitored:

# Laboratory location:

# Acceptable temperature limits:

# Frequency of temperature monitoring:

### Complete contemporaneously at the time of temperature monitoring

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Date(dd-mmm-yyyy) | Temp(°C) | Max Temp(°C) | Min Temp(°C) | Temps within range(y/n) | Initials | Comments |
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