Quality Control Document:

Computerised Systems and User Access Levels

# Purpose

All computerised systems used for the collection, processing and storage of data generated in clinical must be maintained in ways that ensure the validity, integrity and security of the data. Access to computerised systems should therefore be appropriately controlled.

This document provides a User Access Level Record to document user access rights and instructions on how to complete this record. It is appreciated that some systems have the capacity to record user access levels within the system. In this case, the User Access Record could be used alongside print outs of the system records to document the review of user access, for example.

This document is designed to be used for Clinical Trials of Investigational Medicinal Products (CTIMPs) but could also be used for non-CTIMPs and studies to support best practices. It is possible to create a project specific User Access Level Record, which 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. Set up a separate User Access Level Record for each computerised system.
5. Record the name of the computerised system.
6. Record the location of the computerised system, e.g. lab number or office number
7. Record the name of the system administrator, as defined in the Laboratory Facilities SOP (UoB-CRL-SOP-002).
8. User access levels must be subject to periodic review to ensure they remain appropriate. Record the frequency at which the user access levels need to be reviewed.
9. Document the definition of each access level, e.g. ‘general user’, ’data acquisition only’.
10. Record in the form the user access level for each individual who requires access to the computerised system.
11. Ensure a review of the user access levels performed at the required frequency. Document in the Review Log each time a review is performed.
12. Store the User Access Level Record safely and securely in the Laboratory Master File throughout the trial and archived with the other trial documents when the trial closes. Refer to the Archiving SOP (UoB-CLN-ARC-SOP-001).

# Related documents

* UoB-ARC-SOP-001 Archiving
* 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).

# Name of Computerised System:

# Location:

# System Administrator:

# Review Frequency:

# Definition of Access Levels:

|  |  |
| --- | --- |
| **Access Level** | **Definition**  |
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**Record the access level of each user in the table below**

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| **Name**  | **Role**  | **Access Level** | **Date** |
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# Review Log:

**Record in the table below each time a review is performed**

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| --- | --- | --- | --- |
| **Name**  | **Signature** | **Role** | **Date of Review** |
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