Quality Control Document:

Version Control Log

# Purpose

This document contains a template that can be used to create a version control log. This log can be used to keep track of the essential documents used for the research project, and their latest approved versions.

# Instructions

1. Remove this first instruction page.
2. Update the identifier in the header e.g. study/trial identifier or researcher group.
3. Update the footer; keeping reference information to this quality control document (QCD).
4. Insert the document title/ID at the top of each column in the version control log.
5. For each document listed, enter: version number and date; date of regulatory approval including REC, MHRA etc. (list either all dates, last approval date or ‘N/A’ if not required); date of NHS approval (either list the date, ask the site to list it, or enter ‘N/A’ if not required).
6. Each version of every document must be recorded on the version control log. If additional rows are needed to record more versions, insert additional ‘amendment’ rows to the table as required.
7. Where fields are not relevant, mark as such rather than leaving blank.
8. Update the version control log following subsequent amendments to the project document(s).
9. File completed versions of this record and all related documents in the relevant study/trial files.

# Related documents

* UoB-CLN-PRO-QCD-002 Protocol Template for CTIMPs
* UoB-ESD-QCD-003 Protocol Development Tool for non-CTIMPs and Studies
* UoB-ESD-QCD-004 Protocol Template for non-CTIMPs and Studies
* UoB-ESD-QCD-005 Essential Documents Checklist
* UoB-ESD-SOP-001 Essential Documents Development and Maintenance

Note the 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)).

|  |  | Document Title/ID (e.g. protocol) | Document Title/ID (e.g. consent form) | Document Title/ID (e.g. participant information sheet) | Document Title/ID (e.g. participant information sheet) | Document Title/ID (e.g. CRF) | Document Title/ID (e.g. GP letter) |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Initial Document  Version  (first used by Site) | Version Number and Date |  |  |  |  |  |  |
| Date of Regulatory Approval\* |  |  |  |  |  |  |
| Date of NHS Approval\*\* |  |  |  |  |  |  |
| Amendment  Ref (1): | Version Number and Date |  |  |  |  |  |  |
| Date of Regulatory Approval\* |  |  |  |  |  |  |
| Date of NHS Approval\*\* |  |  |  |  |  |  |
| Amendment  Ref (2): | Version Number and Date |  |  |  |  |  |  |
| Date of Regulatory Approval\* |  |  |  |  |  |  |
| Date of NHS Approval\*\* |  |  |  |  |  |  |
| Amendment  Ref (3): | Version Number and Date |  |  |  |  |  |  |
| Date of Regulatory Approval\* |  |  |  |  |  |  |
| Date of NHS Approval\*\* |  |  |  |  |  |  |
| Amendment  Ref (4): | Version Number and Date |  |  |  |  |  |  |
| Date of Regulatory Approval\* |  |  |  |  |  |  |
| Date of NHS Approval\*\* |  |  |  |  |  |  |

\* Including REC, MHRA etc.: either list last approval date or ‘N/A’ if not required

\*\* Either list the date, have the site list the date or enter ‘Not required’