Quality Control Document:

Archiving Plan

# Purpose

This document contains a template that can be used to document the archiving plan for a clinical research project. For CTIMPs, although completion of an archiving plan and the steps detailed below are mandatory the use of this template is optional. Completion of an archiving plan is advised for all other research projects.

# Instructions

1. Remove this first instruction page.
2. Update the header to include the study/trial ID.
3. Update the footer; retaining the reference information to this quality control document (QCD).
4. Remove the red instructional text.
5. Complete the archiving plan (this should be done at the time of setting up the project).
6. File the archive plan in the study/trial master file (S/TMF).
7. Upon project closure, update the fields ‘Date archived’ and ‘Destruction date’ and file the updated version in the S/TMF.

* For CTIMPs, send the updated archive plan to the [Research, Ethics and Governance Team](mailto:researchgovernance@contact.bham.ac.uk) (REGI).

# Related documents

* UoB-ARC-QCD-002 Archive Label
* UoB-ARC-QCD-003 Guide to Retention Times
* UoB-ARC-SOP-001 Archiving

Access to the full UoB QMS for clinical research is available via the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx).

# Archiving plan

|  |  |
| --- | --- |
| Project title: |  |
| Sponsor: |  |
| Sponsor ID: |  |
| Chief investigator (CI): |  |
| Principal investigator (PI): |  |
| Person responsible for archiving: | <Insert name and job title of person delegated the responsibility of archivist> |
| Date archived: | <Insert ‘to be confirmed upon project closure’ in the first instance and then update this field at the end of the project and save as a new version> |
| Destruction date: | <Insert ‘to be confirmed upon project closure’ in the first instance and then update this field at the end of the research project and save as a new version> |

|  |
| --- |
| Material covered within this plan |
| This section should list the documents that are to be archived, e.g. contents of the study/trial master file, case report forms and other essential documents such as regulatory reports etc.  This section should also list any digital data that are to be archived, e.g. study/trial systems, databases, other digital files such as audio files.  Where applicable include justification. |
| Archive set-up and retention timelines |
| Insert a flow chart or a description of the timelines in accordance with applicable regulations or UoB policy. |
| Preparation of material for archive |
| This section should cover the points listed below.   * Preparation of material (paper and electronic documents & data) for archiving. * Ordering of archive supplies e.g. boxes, box labels, paper sleeves or files to re-file paper documents. |
| Location of archive |
| Include the off-site archive company’s name, address and point of contact, if using. This can be obtained from the archivist. Include details of the on-site archive’s location, if used. For an electronic archive, include the server location where electronic material is being stored. |
| Quality checking of archived materials |
| This section should include details of the quality checks that will be performed on archived material, including the frequency at which quality checking will be performed (this should be determined using a risk- based approach considering the type of project, type of material and duration of archiving material).  If it is decided, based on the risk profile of the research and archived material, that quality checking is not required this should also be detailed along with the justification for this decision. |
| Archive end date |
| This should cover the planned end date for the destruction of the archive. For example, 10 years after the end of the project, the material will be reviewed for destruction. If no longer required, the material will be destroyed in accordance with the off-site company’s procedures or if situated on-site in line with the sponsor’s procedures. |