Archiving

Division: Trust-Wide

Specific staff groups to whom this policy directly applies	Likely frequency of use	Other staff who may need to be familiar with policy
Staff employed by North Bristol Trust who directly or indirectly work on Clinical Research within the Trust	Role Dependant	Staff not employed by North Bristol NHS Trust who are working on Research studies sponsored or hosted by NBT

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Consultation:	R&D Sponsorship Team
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KEYWORDS:	Archiving, Retention period, Destruction of records, Study close out, Trial close out
Summary of changes since the previous version	Changed format to align with NBT SOP template Changed R&I to R&D Update on retention period of archived records in line with the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025/538). Clarification on Electronic archiving Clarification on Funding requirements for archiving Added information in relation to responsibilities when working with Clinical Trials Units.

	Change the naming convention of R&D SOP's Regulatory and ICH references updated to align with the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025/538) and latest ICH GCP E6 (R3)

1. Purpose	This SOP describes the requirements and procedures for the archiving and retention of study records for Clinical Trials of Investigational Medicinal Products (CTIMPs) sponsored by North Bristol NHS Trust (NBT), in accordance with the Medicines for Human Use (Clinical Trials) Regulations, as amended in 2025, and ICH Guideline for Good Clinical Practice E6(R3). While this SOP is primarily focused on CTIMPs, the principles and standards described may also be applied to the archiving of records for all other research studies sponsored or hosted by NBT, where appropriate.
2. Key Messages	Archiving of research records is a legal and regulatory requirement for CTIMPs and a critical element of sponsor oversight and Good Clinical Practice (GCP). For CTIMPs sponsored by North Bristol NHS Trust (NBT), essential study records must be archived for a minimum of 25 years, in accordance with the Medicines for Human Use (Clinical Trials) Regulations (2004), as amended in 2025, and ICH GCP E6(R3). Although there is no explicit legal requirement to archive essential records for non-CTIMP studies, NBT requires proportionate archiving of all sponsored research as a matter of good governance, data integrity, and inspection readiness. The Sponsor retains overall responsibility for archiving, even where archiving activities are delegated to Chief Investigators, Clinical Trials Units, or third-party providers. Archiving arrangements, including retention periods, storage location, and funding, must be clearly defined, documented, and recorded (including within EDGE, where applicable).

	Archived records must remain secure, retrievable, complete, legible, and accessible for audit, inspection, and regulatory purposes throughout the retention period. Destruction of archived records must not occur without sponsor confirmation and must be fully documented and undertaken in accordance with confidentiality and data protection requirements. Terminology note: For the purposes of this SOP, the term "participating site" is used throughout and should be read interchangeably with "trial location" where applicable for clinical trials of investigational medicinal products, in line with the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. **Abbreviations** **CI** Chief Investigator **CIMD** Clinical Investigation of a Medical Device **CTIMP** Clinical Trial of an Investigational Medicinal Product **CTU** Clinical Trials Unit **HRA** Health Research Authority **ICH GCP** International Conference on Harmonisation Guidelines for Good Clinical Practice **ISF** Investigator Site File **NBT** North Bristol NHS Trust **R&D** Research and Development **REC** Research Ethics Committee **MHRA** Medicine Healthcare Regulatory Agency **SOP** Standard Operating Procedure **TMF** Trial Master File
3. Relevant Policies & Guidance	**Policies and Guidance:** Health Research Authority (HRA) UK Policy Framework for Health and Social Care Research www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research

	ICH Secretariat *Guidelines for Good Clinical Practice (GCP) (E6 R3 Step 4, 2025)* https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (SI 2025/538). • The following NBT documents are available on the R&D website: www.nbt.nhs.uk/research **Associated SOP's and Templates:** RD QMS SOP 011 Closing suspending and terminating research RD QMS SOP 007b Terms and conditions of Sponsorship RD QMS SOP 007c Delegation of Responsibilities
4. Operational Areas Included	This SOP is applicable to: • CTIMPs sponsored by NBT • Non-CTIMPs sponsored by NBT • CTIMPs hosted by NBT and where provision for third party archiving is not made by the sponsor. • Non-CTIMPs hosted by NBT and where provision for third party archiving is not made by the sponsor.
5. Operational Areas Excluded	All other externally sponsored research and non-research related records.
6. Who should read this	This SOP should be used by Investigators and other members of the research team involved in research studies sponsored by NBT. It can also be used for research team members involved in externally sponsored studies.

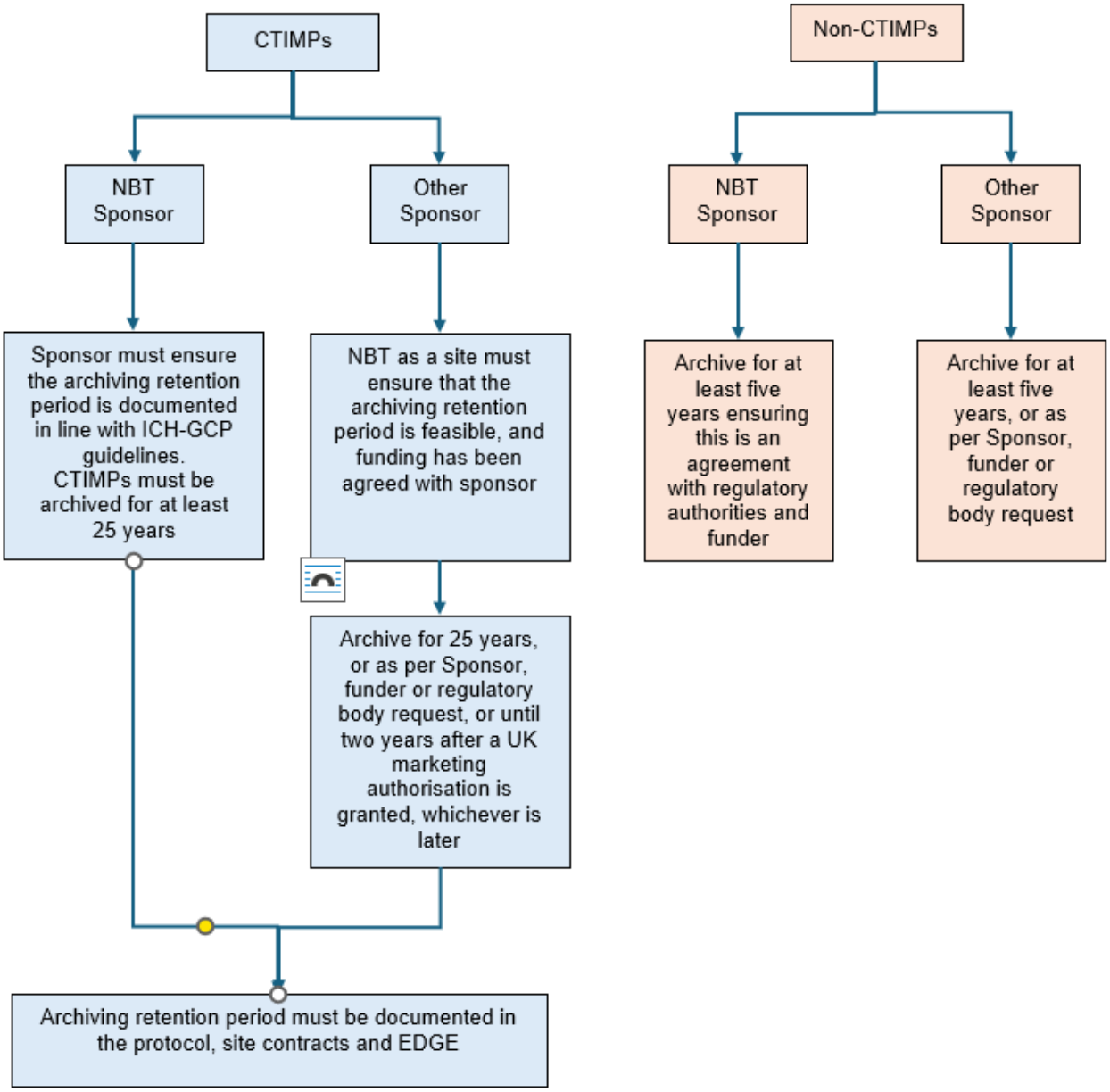
	When collaborating with external stakeholders, such as Clinical Trials Units, on NBT- sponsored projects, it may be appropriate to utilise external SOPs to ensure proper project governance and the fulfillment of delegated roles and responsibilities. In such instances, both the external stakeholder and the NBT sponsorship team must ensure that the external SOP aligns with the procedures outlined in this SOP. If there is a conflict between the external SOP and NBT's procedures, the NBT SOP will take precedence, except in exceptional cases where approval is obtained from the Research Operations Manager or the Deputy Director of Research
7. Roles responsible for carrying out this procedure	**Sponsor (North Bristol NHS Trust – NBT)** Retains overall responsibility and accountability for the archiving, retention, retrieval, and destruction of essential study records for studies sponsored by NBT. Ensures that archiving arrangements comply with: • The Medicines for Human Use (Clinical Trials) Regulations (2004), as amended in 2025 • ICH GCP E6(R3) • Applicable data protection and confidentiality requirements. Approves any delegation of archiving activities to Chief Investigators (CIs), Clinical Trials Units (CTUs), or third-party providers. Retains the right of access to all archived study records for audit, inspection, and regulatory purposes. Ensures that archiving arrangements are adequately funded as part of study planning. **Research & Development Department** Acts on behalf of the Sponsor to oversee and coordinate archiving arrangements for studies. Is responsible for ensuring archiving costs are met, assessed during study set up and recouping these costs Provides guidance to study teams on: • Preparation of records for archiving • Approved archiving providers and processes • Retention periods and destruction requirements

	Maintains a central log of archived studies, including archive provider, locations, retention periods, and destruction dates. Coordinates the retrieval of archived records, subject to appropriate approval. Liaises with third-party archiving providers to: • Arrange storage • Authorise destruction following confirmation from the Sponsor • Obtain and retain evidence of secure destruction. Ensures that EDGE (or equivalent sponsor systems) is updated with: • Retention periods • Planned destruction dates, where required. **Chief Investigator (CI)** (for studies sponsored by NBT) Holds **delegated responsibility** for ensuring that study records are complete, accurate, and prepared for archiving at study and/or trial close-out. Ensures that: • All essential records are finalised, indexed, and organised prior to archiving. • Retention periods are correctly defined and communicated to R&D • Archiving costs are included in the study budget. Notifies R&D when essential records are ready for archiving and provides required archiving records and indices. Informs the Sponsor where extended retention beyond minimum requirements is necessary (e.g. for regulatory submissions). If the CI leaves their employing organisation during the designated archiving period s/he is responsible for ensuring that there is a documented handover of responsibility to another clinician or other suitably qualified person (e.g. lead research nurse) and informing the R&D Department of the handover arrangements. For situations where this has not been implemented or the designated member of staff cannot be identified, the R&D team should identify a suitable senior member of staff to fulfil this role within the team, e.g. Lead Research Nurse, Clinical Trial Manager, etc.

	For multi-centre trials sponsored by NBT, the site agreement delegates responsibility to the participating sites for archiving and for ensuring that data and records are available for the purposes of monitoring and inspection. **Principal Investigator (PI)** Is responsible for archiving site-specific essential records following sponsor approval. Ensure that: • Site files are complete and reconciled with sponsor requirements. • Archived records remain retrievable and accessible when required. Cooperates with R&D and the CI to support sponsor inspections, audits, and retrieval requests. If the PI leaves their employing organisation during the designated archiving period s/he is responsible for ensuring that there is a documented handover of responsibility to another clinician or other suitably qualified person (e.g. lead research nurse) and informing the R&D Department of the handover arrangements. For situations where this has not been implemented or the designated member of staff cannot be identified, the R&D team should identify a suitable senior member of staff to fulfil this role within the team, e.g. Lead Research Nurse, Clinical Trial Manager, etc. **Clinical Trials Units (CTUs)** May be delegated responsibility for archiving on behalf of the Sponsor, subject to formal agreement. Must conduct archiving in accordance with: • Agreed SOP • The approved protocol • ICH GCP E6(R3) • Sponsor requirements

8. Procedure:

SOP Flowchart – Archiving sponsored research



8.1 Purpose and Scope

The purpose of this SOP is to describe the procedures for the archiving and retention of essential study records for Clinical Trials of Investigational Medicinal Products (CTIMPs) sponsored and hosted by North Bristol NHS Trust (NBT). While the primary focus of this SOP is CTIMPs, the principles and standards described may also be applied, where appropriate, to other research studies sponsored by NBT.

The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025, place a legal requirement on Sponsors to

retain essential records for CTIMPs. The processing and storage of personal data within research records is also subject to the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

The ICH Guideline for Good Clinical Practice (E6(R3)) defines and describes the records that are essential for the conduct, oversight, and evaluation of a clinical trial.

Essential records refer to the documents, data, and associated metadata, in any format, which individually and collectively permit evaluation of the conduct of a study and the quality and integrity of the data produced.

There is no explicit legal requirement to retain essential records for non-CTIMP studies under the Clinical Trials Regulations. In addition, the Medical Devices Regulations 2002 do not place a specific statutory obligation to archive records generated from clinical investigations of medical devices. However, the principles set out in ICH GCP may be applied to other clinical investigations that may have an impact on the safety and well-being of human participants.

The ICH GCP Guidelines state that the Sponsor or owner of the data should retain all sponsor-specific essential records pertaining to a trial. In light of this, and the potential for inspection by regulatory authorities, it is considered good practice for essential research records to be retained for non-CTIMP studies sponsored by NBT. Accordingly, this SOP also applies to NBT-sponsored non-CTIMP research, unless alternative archiving arrangements are formally agreed and documented.

8.2 Procedure for archiving site records

For NBT sponsored studies, the CI or trials unit has delegated responsibility for initiating archiving

procedures of the ISF at all participating sites.

For NBT sponsored studies and non-NBT sponsored studies, the PI is responsible for preparing study records for archiving or delegating them to appropriately qualified staff in their team:

The PI or delegating team member must liaise with the sponsor to initiate archiving procedures and obtain approval to archive the study records.

8.3 Preparing Records for Archiving

At the end of a clinical trial and follow sponsor request to proceed with archiving all essential records should be checked to ensure the following:

(a) All records should be complete and legible

(b) The study file is complete, tidy and records are stored in a logical order.

(c) All Case Report Forms (CRFs) and other patient-related medical documentation are collated and ensure all data queries are resolved.

(d) Records held in lever-arch files are removed in preparation for archiving to reduce the space required for archiving.

(e) Records may be held together by plastic archiving clips but all paper clips, elastic bands, staples or metallic means of combining sheets should be removed to prevent rusting or other chemical deterioration.

(f) Records are indexed in a manner that allows all records to be traceable at all times and readily accessible to the authorities upon request.

(g) An NBT Archiving Record Form should be completed, filling out the list of records to be archived (or attaching a separate list).

(h) The TMF and ISF of NBT sponsored studies should be archived separately, except where it has been previously agreed with the R&D Department that they may be archived together

8.4 Arranging for Records to be Archived- Paper Records

Research data must be stored in a physical location that is weatherproof, pest-proof, secure at all times and environmentally controlled/protected. A reputable external storage facility provider should be able to satisfy these criteria. The trust holds a contract with Iron Mountain, an external storage facility, for storing research records and medical records.

To arrange storage, follow the below steps:

(a) Once records are prepared and ready for archiving, please contact R&D for the archiving boxes.

(b) Complete a 'Completing the transmittal/using the barcode label' document, if appropriate.

(c) Contact R&D to arrange for collection of the archive boxes to be transferred to the off-site storage facility.

(d) A copy of the archiving indices, file location identification (third party barcode/ unique identifier) and archive provider must be provided to R&D when the essential records are archived.

(e) R&D will maintain a log of archived projects including their box numbers and locations for retrieval

(f) If it is not possible to physically store all the records in one place (for example, research data held on electronic databases), then the location of these records should be clearly flagged in the TMF, and arrangements should be made so that they can be readily accessed for the purpose of monitoring and inspection. Databases and associated documents (e.g. metadata) may be archived separately from the main TMF. It is anticipated that the database would usually be held by the trials unit or study team on their university or NHS server, although for some studies it may be more appropriate to be held on the R&D Department's server. This will be reviewed on a case-by-case basis and, for sponsored CTIMPs or other complex trials, will be captured in the Data Management Plan (DMP) or the sponsor's study closure checklist.

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8.5 Arranging for Records to be Archived- Electronic

The Trust does not currently operate an electronic archiving system. Where an external Sponsor requires study records to be archived electronically, this arrangement must be reviewed and approved by the R&D Senior Team prior to implementation ensuring the below:

The MHRA requires that sponsors need to make reasonable effort to ensure readability of data during and for the life of the study archive retention period.

The following issues need to be considered when archiving electronic filing (e-filing'):

- Access to software which allows the data to be read for the duration of the period of retention.
- Ensuring that data is not locked in proprietary or end-of-life systems. Essential data should be accessible and portable.
- Controlled access to data.
- Disaster Recovery Plan in the event of loss of data
- Sponsor permission for use of e-filing or conversion of paper filing into e-files.

Electronic filing forming part of the Investigator Site File (ISF) must be held on an approved NBT system.

Records forming part of the ISF must not be stored on the Sponsor's server or on the server of a Sponsor appointed agent.

The study team must specify the exact location of all electronic ISF records within the Project Archiving Record Form.

The nominated archivist for the project must ensure that access to electronic ISF records is restricted to the team and their line manager, in line with access control and information governance requirements.

8.6 Archiving Period

For all clinical trials, records must be retained for at least 25 years after the conclusion of a trial and during that period must be:

- Readily available to the licensing authority on request (for CTIMPs).
- Complete and legible.

Shorter retention periods (for example, 5 years) may apply only to non-CTIMP studies or to legacy trials not intended to support regulatory submissions, subject to sponsor determination. Where applicable, longer retention periods must be applied where required by the Sponsor, funder, regulatory authorities, or other applicable legislation.

(a) Where NBT is the Sponsor of **non-CTIMPs**, essential records must be retained for a period of at least **5 years**.

(b) Where NBT is the Sponsor of **CTIMPs**, essential records must be retained for a period of at least **25 years.** If trials are to be included in regulatory submissions, then study-specific records should be retained until at least 2 years after the last approval of a marketing application to the MHRA or EMA (where appropriate). The Chief Investigator must inform the Sponsor via R&D, where longer retention is required.

Some studies are abandoned before they start or before a patient is consented into the study. In such cases, the PI should seek guidance from the sponsor about archiving requirements and/or follow any advice as set out in the protocol and/or the site agreement between the sponsor and NBT.

8.7 Retrieval of archived Records

R&D will coordinate the retrieval of archived records.

Retrievals from archive are restricted to a limited number of circumstances and should be kept to an absolute minimum. Retrieval may be permitted where audit of the results is required to comply with a Department of Health, regulatory authority, NBT Trust Board or other quality assurance request.

The retrieval of any records held under an account with NBT will require the approval of the Deputy Director of Research. Sponsors of externally sponsored studies will be expected to meet the costs of retrieval.

8.8 Destruction of Archived Records

After the retention period has passed, R&D will inform the third-party provider as to whether the records can be destroyed after this period or arrange for the records to be stored for longer. The Sponsor (if not NBT) will need to be contacted and asked if the records is to be archived for a longer period of time, or if it can be destroyed.

All essential records must be destroyed in accordance with confidentiality guidelines.
Where third party organisations destroy the essential records on behalf of NBT, evidence of this must be provided to R&D.

R&D will record the destruction documentation in the corresponding R&D study folder.

9. Dissemination and Training

SOPS will be distributed in accordance with the SOP on Preparation of R&D Research SOPs (RD/QMS/SOP/001). This SOP and any associated templates and forms will be uploaded to the NBT website (www.nbt.nhs.uk/research) shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP.