STANDARD OPERATING PROCEDURE FOR ARCHIVING CLINICAL RESEARCH DATA FOR HOSTED STUDIES

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1. PURPOSE

This document describes the procedure used in NHS Fife for archiving clinical research data from studies hosted by NHS Fife.

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via StaffLink, the R&D section of the NHS Fife website (www.nhsfife.org/research) and EDGE (https://www.edge.nhs.uk). For guidance, contact the R&D Department via fife.randd@nhs.scot

2. APPLICABILITY

This SOP applies to research studies hosted by NHS Fife.

The document applies to Principal Investigators, individuals delegated the task of preparing study data for archiving and RIK staff responsible for the management of archived data within NHS Fife.

This document also covers the procedure for archiving R&D Office study files. Although there is not the same legal requirement to retain this information, it must be kept for the same period of time as the study data, to allow reconstruction of the governance and financial arrangements of the study, if necessary.

3. POLICY

3.1 Archiving is the long-term storage of essential study documentation, held in the Investigator Site File (ISF), which individually and collectively permits the evaluation of the conduct of the study and the quality of the data. All study data must be accessible after the study has finished for further analysis if required, for example, if an unexpected side effect occurs after a trial drug has been approved. Essential documents must be retained (archived) in such a way that ensures they are complete and legible for sufficient periods to allow for audit and inspection by regulatory authorities and should be readily available upon request.

3.2 The requirements for the retention of essential documents, data and tissue at the end of a study vary according to the type of research activity.

The Sponsor is responsible for determining the archiving period. For studies where the Sponsor does not specify a retention period then guidance in Appendix 1 must be followed.

3.3 The Principal Investigator (PI) is responsible for archiving, however they may choose to delegate the duty of archiving to another member of the Research Team. Such delegation of duty should be agreed at study set-up and should be clearly documented in the study Delegation of Duties Log.

3.4 Support Departments (e.g. Pathology and Pharmacy) must retain central records that may be relevant for studies e.g. calibration logs/training logs for a period of 25 years.

3.5 Archiving of Hard Copy Data

3.5.1 Facilities for the archiving of hardcopy research documentation and electronic data stored on removable media have been established within the RIK Department at Queen Margaret Hospital, Dunfermline. The rooms are kept locked and the R&D Support Officer holds the key.

3.5.2 Boxes stored in the Archive Rooms are shelved in order of their box number.

3.5.3 All documentation from Clinical Trials of an Investigational medicinal product (CTIMP), Clinical investigation or other study of a medical device (CMD) or Combined trial of an investigational medicinal product and an investigational medicinal device archived locally must be stored within the RIK department.

3.6 Electronic data must be archived on a secure server using a validated system, with access restricted to those authorised only. Electronic data sent to the R&D Support Officer for archiving will be archived in a secure folder in T:\Research Project Archive, with access restricted to the R&D Support Officer and the Assistant Director RIK.

3.7 Details of the material archived for each study is maintained by the NHS Fife R&D Support Officer using the ‘Archiving Process’ form in EDGE.

3.8 The medical records (hard copy and electronic) of study participants must be marked for retention for the same period of time as the rest of the study data.

3.9 Final reports as required by Medicines & Healthcare products Regulatory Agency and Research Ethics Committees are not required prior to archiving as they are often not available for some time after a study closes. Therefore the report can be added to the archive box at a later date or held electronically in the e-archive as long as it is easily retrievable if requested. Details of the archive location must be recorded on the ‘Archiving Process’ form in EDGE by the R&D Support Officer.

4. PROCEDURE

4.1 ARCHIVE PLANNING

The archiving arrangements, including location, costs and any special storage requirements for source data such as electronic records, x-rays, or video clips, must be agreed with the Sponsor or Sponsor's representative at study set-up. For studies supported by the R&D Research Nurse Team, details of the archiving arrangements must be documented in the 'Research Team – Study set-up Checklist' Workflow in EDGE. For studies which are not supported by the R&D Research Nurse Team, the archiving arrangements must be established by the R&D Approvals Team as part of the R&D Approvals Process.

4.2 END OF STUDY PROCEDURES

4.2.1 Once a study has completed the R&D Quality & Performance Team will add the 'Research Team - Closed/Completed Studies' or 'QA – Annual Progress Monitoring Check – Abbreviated / Timelines' workflow as appropriate and the 'Archiving Process' form to the project record in EDGE, and contact the PI/delegate to establish the archiving arrangements.

4.2.2 Where the study is supported by the R&D Nursing team, they must prepare the study documentation for archiving, liaise with the R&D Support Officer to arrange the storage of the archived data and keep a record of their progress in EDGE using the 'Research Team - Closed/Completed Studies' Workflow.

4.2.3 Where the R&D Nursing Team are not supporting the study, the Quality & Performance Team must contact the PI to establish the archiving arrangements and record the details and track the progress of the archiving process using a 'QA – Annual Progress Monitoring – Abbreviated / Timelines' Workflow.

- Where documentation is being stored locally in NHS Fife the Quality & Performance Team must notify the R&D Support Officer in order that they can liaise with the PI to supply the appropriate archiving forms and, where necessary, arrange for any hard copy documentation to be transferred to the RIK Department in QMH.

- Where documentation is being stored locally, outside of the RIK Department, the R&D Support Officer must request that the PI completes and returns the appropriate archiving forms and the provided information must be used by the R&D Support Officer to update the Archiving entities in EDGE.

- Where hardcopy data is being stored outside of the RIK Department, a copy of the Hardcopy Archiving form must be attached to the outside of the box or folder containing the documentation

4.2.4 Where necessary, the PI/delegate must contact the Sponsor or Sponsor's representative to obtain approval to proceed with the archiving of study documents.

4.2.5 If the Sponsor or Sponsor's representative wishes to delay archiving, the PI/delegate must inform the R&D Quality & Performance Team.

4.3 PREPARING DATA FOR ARCHIVING – HARDCOPY DOCUMENTS

4.3.1 All study data, excluding patient medical records, should be archived together. This includes the ISF, Case Record Forms (CRFs) and data from Support Departments if applicable, e.g. Pharmacy Site File (PSF).

4.3.2 Paper study files must be prepared for archiving as follows:

- Folders should not be overfilled or damaged.
- All folders should be clearly identified.
- Paper-clips and rubber bands should be removed (staples can be left if they are not too close to the wording so that any rust that may develop would not obscure the data).
- All plastic wallets should be removed as they may remove ink from documents.
- Faxes or emails on thermal paper should be photocopied onto standard paper as they will deteriorate over time and may become unreadable.
- Electrocardiogram (ECG) reports on thermal paper should be copied onto standard paper.
- Where required, calibration and training logs must be included in the ISF.
- A Hardcopy Data Archiving Record Form (Doc Ref 35-02) should be completed detailing the documents held in each box. No abbreviations should be used in the description of the data being archived e.g. ISF should be written as Investigator Site File.
- If CRFs are being archived, the Hardcopy Data Archiving Record Form must list the individual patient numbers to enable identification of which CRFs are held in the box. Ranges can be used if numbers are consecutive e.g. 001-085.

4.3.3 The Hardcopy Data Archiving Record Form must be signed or approved via email by the PI. In the absence of the PI, the Assistant Director RIK must sign this form.

4.3.4 Once the box(es) are ready for archiving, the PI or delegate must contact the R&D Support Officer to arrange for the prepared archiving box(es) to be brought to the R&D Office for the final stages of the archiving process to be undertaken.

4.3.5 The R&D Support Officer must check that the contents of the Archiving Box(s) match the Hardcopy Archiving Record Form and:

- Complete and attach an Archiving Label (Doc Ref 35-03) to the handle end of the box.
- Countersign the Hardcopy Archiving Record Form.
- Email a scanned copy of the Hardcopy Archiving Record Form to the PI or delegate for them to retain.
- Upload a scanned copy of the Hardcopy Archiving Record Form to the Project File in EDGE.
- Place the original Hard Copy Archiving Form in the box, before sealing the box.

4.3.6 The R&D Support Officer must:

- Use the information on the Hardcopy Archiving Record Form to update the 'Archiving Process' form in EDGE.
- Update the Project Site status to 'Archived' in EDGE and delete all staff at the Project Site level and Project Level in EDGE.

4.4 ARCHIVING ELECTRONIC DATA

4.4.1 All electronic study data, excluding patient medical records, must be archived together. This includes the files relating to the ISF, CRFs, and PSF. Where special software is required to read source data, a copy of this software should also be archived, where it is practical to do so.

4.4.2 When the PI/delegate is ready to archive the study material, they must contact the NHS Fife R&D Department (fife.randd@nhs.scot) to discuss archiving requirements. The R&D Support Officer will provide the appropriate archiving forms and instructions on how to transfer the study files to the R&D Office.

4.4.3 An Electronic Data Archiving Record Form (Doc Ref 35-04) detailing the electronic data to be archived must be completed and forwarded to the R&D Support Officer along with the electronic data files.

4.4.4 The R&D Support Officer must then check the data supplied, countersign the Electronic Data Archiving Record Form and:

- Email a scanned copy to the PI or delegate.
- Upload a scanned copy of the Electronic Data Archiving Record Form to the Project File in EDGE.

4.4.5 For studies where the eISF is held in a study specific folder on T:\, the R&D Support Officer must copy the folder to T:\Research Project Archive and check that everything has copied over correctly, before deleting the original folder.

4.4.6 The R&D Support Officer must:

- Use the information on the Electronic Data Archiving Record Form to update the 'Archiving Process' form in EDGE
- Update the Project Site status to 'Archived' in EDGE.
- Delete all staff at the Project Site level and Project Level in EDGE.

4.5 PROCEDURE FOR ARCHIVE AT SPONSOR ARRANGED ARCHIVE FACILITY

4.5.1 This must be agreed in writing between the Sponsor and NHS Fife or in the Contract/Clinical Study Agreement.

4.5.2 The Research Team must follow the process for preparation for archiving specified by the Sponsor or third parties acting on behalf of the Sponsor.

4.5.3 For CTIMPs, NHS Fife must retain control of the original study source data, to ensure the Sponsor or third party acting on behalf of the Sponsor does not have uncontrolled access to the source data. If requested, verified photocopies can be provided to the Sponsor or third parties acting on behalf of the Sponsor. The ISF must never be sent directly to the Sponsor or third parties acting on behalf of the Sponsor for archiving.

4.5.4 For Non-CTIMPs, where possible NHS Fife must retain control of the original documentation unless otherwise requested by the Sponsor or third parties acting on behalf of the Sponsor. Where original documentation is requested by the Sponsor or third parties acting on behalf of the Sponsor, NHS Fife must retain a verified copy of all documentation provided to the Sponsor or third parties acting on behalf of the Sponsor.

4.5.5 Once the study team has prepared the material for archiving and boxed it up, the boxes must be delivered to the R&D Support Officer for onward transport to the archive facility.

4.5.6 A copy of the signed study contract, countersigned archiving paperwork and instructions for retrieval of archived data must be retained by the PI and archived in the Project Files in EDGE.

4.5.7 The R&D Support Officer must update the 'Archiving Process' form in EDGE to record the archiving location and retrieval information.

4.5.8 The R&D Support Office must update the Project Site status to 'Archived' in EDGE and delete all staff at the Project Site level and Project Level in EDGE.

4.6 RECALL AND RETRIEVAL FROM THE ARCHIVE – HARDCOPY DATA

4.6.1 The person requesting access to the archived material must contact the Sponsor or Sponsor's representative to obtain authorisation to do so before completing Part 1 of a Hardcopy Data Archive Access Request Form (Doc Ref 35-05) and forwarding to the R&D Support Officer.

4.6.2 Upon confirmation by Sponsor or Sponsor's representative, the requester should arrange with the R&D Support Officer a suitable date and time to meet and access the archive.

4.6.3 The archived material must remain within the R&D Office after retrieval to ensure access is supervised as the R&D Support Officer retains responsibility for it. It cannot be taken back to the requestor's department.

Note: no documents can be removed but copies can be provided/taken and no alterations to study data can be made.

4.6.4 Having accessed the archived documentation, the requester must complete Part 2 of the Hardcopy Date Archive Access Request Form and this should then be countersigned by the R&D Support Officer.

4.7 RECALL AND RETRIEVAL FROM THE ARCHIVE – ELECTRONIC DATA

4.7.1 The person requesting access to the archived material must contact the Sponsor or Sponsor's representative to obtain authorisation to do so before completing Part 1 of an Electronic Data Archive Access Request Form (Doc Ref 35-06) and forwarding to the R&D Support Officer. If the applicant wishes to copy or print all or part of the study folder, the authorisation must explicitly confirm this.

4.7.2 Upon confirmation by the Sponsor or Sponsor's representative, the R&D Support Officer will arrange a suitable date and time to meet with the applicant and access the archive. The R&D Support Officer will remain with the applicant while they use the folder, assisting them to copy or print as appropriate.

Note: No files can be deleted or altered but copies can be taken or printed.

4.7.3 Having accessed the archived data, the applicant must complete Part 2 of the Electronic Data Archive Access Request Form and this should then be countersigned by the R&D Support Officer.

4.8 ARCHIVING MEDICAL RECORDS

4.8.1 Where appropriate, the Research Team must ensure that copies of Patient Information Sheets and Consent forms have been uploaded to each patient's medical records via SCi-Store and that a 'Medical Records Retention Date' alert has been added to the patient's TrakCare record in order to prevent premature destruction (See R&D WI09 and WI22).

4.8.2 At the end of a study, the Investigator or delegate must review the 'Medical Records Retention Date' alert on all research participants to check that the earliest destruction date is accurate, particularly where there have been extensions to the expected study end date.

4.8.3 For older studies which pre-date the process of adding a 'Medical Records Retention Date' alert, if the paper and/or medical records cannot be located at the end of the study then the Sponsor must be notified.

4.9 STORAGE OF BOXES AWAITING ARCHIVING

4.9.1 If a study has completed but is not yet ready to be archived e.g. End of Study Declaration not yet received, acknowledgement of the End of Study Declaration from REC not received and/or Sponsor or Sponsor's representative has not yet confirmed that the study can be archived or wishes archiving to be delayed, then the study documentation can prepared for archiving as in 4.3 and the boxes stored in the Archiving Room, labelled 'Awaiting Archiving'. Stored box(es) awaiting archiving can be recalled by the local study team for close-out/addition of documents as required.

4.9.2 For retrieval of a box which has been stored, the requester must contact the R&D Support Officer to request access.

4.9.3 The Research Team will be allowed to take the box back to their department if required but must advise the R&D Support Officer where it is to be held and when they expect to return it. The Research Team must ensure that the data is stored in a secure location until its return to the Archiving Room.

4.9.4 The Research Team must inform the R&D Office if the box is moved from the location at any point to ensure it is traceable.

4.10 DESTRUCTION OF ARCHIVED DATA

4.10.1 The R&D Support Officer or delegate must run a report each month from EDGE to identify studies that have reached their earliest destruction date for archived data.

4.10.2 The R&D Support Officer or delegate must contact the CI and/or Sponsor representative to request written confirmation from them that destruction of the archived data held in NHS Fife may proceed or a revised earliest destruction date.

4.10.3 A minimum of 2 attempts must be made to contact the CI and/or Sponsor Representative to obtain authorisation.

4.10.4 The R&D Support Officer must record key information about the process in the 'Archiving Process' form. The 'Archiving Comments' field of the form must be used to record the steps taken to obtain written permission for document disposal to proceed.

4.10.5 If after 2 attempts there has been no response received then the Assistant Director RIK will be asked to authorise the destruction. Destruction must not proceed until this has been authorised by an appropriate representative of the Sponsor. The CI or the Assistant Director RIK.

4.10.6 The R&D Support Officer or delegate must upload a pdf copy of the authorisation from the CI and/or Sponsor's representative or Assistant Director RIK to the Project File in EDGE.

4.10.7 Once destruction has been approved, the R&D Support Officer will arrange for document disposal in accordance with *NHS Fife General Procedure GP/R4-1 - Disposal of Confidential Waste Procedure - Paper Records.*

4.10.8 Details of the destruction must be recorded in the 'Archiving Process' form in EDGE and the project site status updated to 'Destroyed'.

5. ASSOCIATED DOCUMENTS

Doc Ref 035-02 - Hardcopy Data Archive Record Form
Doc Ref 035-03 - Box Label
Doc Ref 035-04 - Electronic Data Archive Record Form
Doc Ref 035-05 - Hardcopy Data Archive Access Request Form
Doc Ref 035-06 - Electronic Data Archive Access Request Form

R&D WI22 - Documenting Informed Consent Process, Confirmation of Eligibility & Study Participation

NHS Fife General Procedure GP/R4-1 - Disposal of Confidential Waste Procedure - Paper Records

6. ABBREVIATIONS

CTIMP	Clinical Trial of an Investigational Medicinal Product.
ISF	Investigator Site File
PI	Principal Investigator
PSF	Pharmacy Site File
R&D	Research & Development
SOP	Standard Operating Procedure

7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	David Chinn	02 Feb 2015	New - adapted from TASC SOP 13, version 4.1.
2	Julie Aitken R&D Trials Facilitator	13 Dec 2017	Revised to reflect current practice.
3	Julie Aitken R&D Trials Facilitator	13 Jan 2020	• Format updated in line with revised SOP template. • Updated to clarify that for CTIMPs, original documentation should not be provided directly to the Sponsor or Sponsor's representative. • The archive location for scanned copies of R&D Study Files has been updated.
4	Julie Aitken R&D Quality & Performance Lead	10 Nov 2023	• Applicability changed and this SOP now applies only to studies hosted by NHS Fife. • Clarified that R&D Approvals files must be archived for the same duration as the Investigator Site File. • References to the Archive Register have been replaced with the Archiving Form in EDGE. • Appendix 1 added to give guidance on retention periods where this is not specified by the study Sponsor. • Reference to WI04 have been removed as these are no longer applicable. • Details of Research Team and Quality & Performance Team workflows in EDGE used for tracking archiving arrangements have been added. • Process for data stored by research team outside of RIK Department added. • Details of the process for destruction of archived data has been added. • Doc Ref 35-01 withdrawn – archiving arrangements will be checked by the R&D Quality & Performance Team as part of the Annual Governance Monitoring process (see R&D WI28). • Doc Ref 35-07 withdrawn as details will now be recorded in EDGE.

8. APPROVAL

APPROVED BY	Date
Professor Frances Quirk, Assistant Director RIK, NHS Fife Signature: 	10 Nov 2023

APPENDIX 1

The table below is designed to provide guidance on the minimum requirements for archiving of study data for studies hosted by NHS Fife, where the Study Sponsor has not specified a retention period.

There is no legal requirement to archive documentation for non-CTIMPs, including investigations of Medical Devices, however the ICH GCP Guidelines state that the same principles for CTIMPs "may also be applied to other clinical investigations that may have an impact on the safety well-being of human subjects."

The Guidelines state that "the Sponsor or owners of the data should retain all of the Sponsor-specific essential documents pertaining to the trial."

Joint guidance issued by the Department of Health and the MRC (Medical Research Council) recommends 5 years.

Type of study	Retention Time Period
Clinical Trial of an Investigational medicinal product. Clinical investigation or other study of a medical device. Combined trial of an investigational medicinal product and an investigational medicinal device.	Twenty five years after completion or discontinuation of the trial.
Clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice	Five years
Basic science study involving procedures with human subjects. Study administering questionnaires/interviews for quantitative analysis or using mixed quantitative/qualitative methodology	Two years
Studies involving qualitative methods only, Studies limited to working with Human tissue samples (or other human biological samples). Studies working with data (specific project only). Research Tissue Banks Research Databases	One year