1. PURPOSE

This document describes the procedure used in NHS Fife for archiving clinical research data.

It is the responsibility of all researchers using this SOP to ensure they are using the latest version of it. The latest version is available via the Research & Development (R&D) pages on the NHS Fife Intranet (www.nhsfife.org/research) or for guidance, contact the R&D Department (fife-uhb.randd@nhs.net).
2. APPLICABILITY

Unless otherwise specified in a site agreement, this SOP applies to research studies both sponsored and hosted by NHS Fife.

The document applies to all individuals involved in research studies taking place within NHS Fife and all individuals involved in research studies taking place at another site, where NHS Fife is the Sponsor.

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 should be kept for an appropriate period of time 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 Study Master File (SMF) and/or 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 There are different regulatory requirements for the retention of tissue, data and essential documents at the end of a study. The Sponsor will determine the archiving period for hosted studies. For studies sponsored by NHS Fife, data must be retained as follows:
   - Study records for all CTIMPs, Interventional and Observational studies for at least 15 years after receipt of notice to archive.
   - Study records for Advanced Therapy studies for at least 30 years after receipt of notice to archive.

3.3 The Chief Investigator (CI) is responsible for archiving, however for multi-site studies and external sites, a CI may choose to delegate the duty of archiving to a local Principal Investigator (PI), or to other individual(s) as appropriate. Such delegation of duty should be agreed at trial set-up and should be clearly documented in a clinical trial site agreement and 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 15 years.

3.5 Sponsor confirmation of agreement to destroy archives must be sought prior to destruction taking place for all studies. Where no response is received from the Sponsor after two attempts at contact this will be referred to the Assistant R&D Director to decide how to proceed.
3.6 All sites used to archive study materials should provide a secure and safe archiving facility. As a minimum the following archive facility conditions are required:
- controlled access to archive facility
- up to date inventory of archive contents maintained

Secure Archiving Rooms (2.PG.22 and 2.HL.12) for hardcopy research documentation and electronic data stored on removable media has been established within the R&D Department at Queen Margaret Hospital, Dunfermline. The rooms are kept locked and the R&D Support Officer holds the key. The R&D Department has responsibility for the physical maintenance of the rooms which are checked on a monthly basis. Boxes stored in the Archive Rooms are shelved in order of their box number.

3.7 Archived electronic data should be:
- secured by physical or electronic means against wilful or accidental damage and unauthorised changes
- stored in more than one place (multiple copies)
- stored under conditions that minimise or prevent degradation
- stored in such a manner that it can be readily accessed by those with permission

It is advisable to archive software needed to reconstruct the database along with the data, but it is preferable to store data in a format likely to be easily read in the future e.g. comma separated values, XML. The data should be saved in more than one file format and should be backed up on a server.

It may be necessary to retrieve it from archive and transfer it into a more modern format to ensure continuing accessibility. Any such transfer should be validated to ensure that there has been no loss, change or corruption of the data and the process should be documented.

For NHS Fife sponsored studies, where records are held centrally such as electronic CRF databases, this should be referred to the Assistant R&D Director for risk assessment and confirmation of what action to take, if any.

3.8 Archiving on a server

The server should be subject to back-up, and the back-up media stored in a separate location. Access to the data on this server must be restricted by user access controls. If data are on an NHS Fife drive then user access levels and daily back-up are dealt with by the eHealth Department as a matter of routine. At the end of the archiving period, assuming that there is no reason to extend it, the data should be removed from the server by the data custodian or delegate.

A secure folder, with restricted access, for archiving of electronic research data has been set-up at T:\Research Project Archive.

3.9 A register of archived materials is maintained by the NHS Fife R&D Support Officer and stored in S:\Research\PROJECTS\PROJECT DOCUMENTATION\ARCHIVING\ARCHIVE REGISTER.
3.10 The medical records (hard copy and electronic) of study participants must be retained for the same period of time as the rest of the study data.

3.11 Final reports as required by MHRA/REC 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 Archive Register.

3.12 Study archives will be stored and monitored according to WI04 (Fife) - Archiving Research Documentation.

4. PROCEDURE

4.1 ARCHIVE PLANNING

4.1.1 The archiving arrangements, including location, costs and any special storage requirements for source data such as electronic records, x-rays, or video clips, should be agreed with the Sponsor at study set-up. For external Sponsors these arrangements should be reviewed as part of the Local Management Approval process.

4.1.2 For NHS Fife sponsored studies, details of the study archiving plan should be documented in the study protocol and/or SMF and ISF.

4.2 END OF STUDY PROCEDURES

4.2.1 If the CI/PI has not already contacted NHS Fife R&D Department, the R&D Support Officer will send an Archiving Notification Form (Doc Ref 35-01) to the CI/PI 30 days after the study end date to establish the archiving requirements.

4.2.2 The CI/PI/delegate must contact the Sponsor to obtain approval to proceed with the archiving of study documents.

4.2.3 If the Sponsor wishes to delay archiving or make changes to the documented archiving plan, the R&D Support Officer must advise the R&D Research Coordinator of the changes.

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 SMF/ISF, Case Record Forms (CRFs) and data from Support Departments if applicable, e.g. Pharmacy Site File (PSF).

4.3.2 When the CI/PI/delegate is ready to archive the study material, they should contact the NHS Fife R&D Department (fife-uhb.randd@nhs.net) to discuss archiving requirements. The R&D Support Officer will provide the appropriate archiving forms and, if necessary, arrange for the provision of archiving boxes.
4.3.3 Study files should 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.
- Emails which record decisions made regarding study participants should be printed and archived as these are source documents.
- Where required, calibration and training logs must included in the ISF.
- It is advisable that only one study is included per box.
- 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 e.g. ISF should be Investigator Site File.
- If CRFs are included in a box, the Hardcopy Data Archiving Record Form should list the 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

4.3.4 The Hardcopy Data Archiving Record Form must be signed by the CI/PI.

4.3.5 An Archiving Label (Doc Ref 35-03) should be completed and attached to the handle end of the box.

4.3.6 Once the box(es) are ready for archiving, the CI/PI or delegate should contact the R&D Support Officer to arrange an appointment for the prepared archiving box(es) to be brought over to the R&D Office for the final stages of the archiving process to be undertaken.

4.3.7 The R&D Support Officer Office should, in the designated appointment time slot:
- Check the contents of the box matches that listed on the Hardcopy Data Archiving Record Form and countersign the form as confirmation.
- Allocate the box a number, record this on the top of the Hardcopy Data Archiving Record Form.
- Take a scanned copy of the Hardcopy Data Archiving Record Form and save this in a study specific folder in T:\Research Project Archive.
- Give the CI/PI or delegate a copy of the countersigned Hardcopy Archiving Record Form which should be retained by the CI/PI. The original copy must be placed in the archive box.
- Add the box number to the box label
- Seal the box by taping securely around the edges and twice across the top with brown tape and then sign and date across the tape.
- Transfer the box to the Archiving Room.
- Add the details to the Archiving Register and SReDA.
4.4 ARCHIVING ELECTRONIC DATA

4.4.1 All electronic study data, excluding patient medical records, should be archived together. This includes the files relating to the SMF/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 CI/PI/delegate is ready to archive the study material, they should contact the NHS Fife R&D Department (fife-uhb.randd@nhs.net) 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 035-04) 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 electronic data files to be archived match those listed on the Electronic Data Archiving Record Form and countersign as confirmation before taking a scanned copy of the form and saving this in a study specific folder in T:\Research Project Archive.
   - The CI/PI should retain the original countersigned Electronic Data Archiving Record Form
   - Transfer the electronic data files to the study specific folder in T:\Research Project Archive.
   - Add the details to the Archiving Register and SReDA.

4.4.5 Data on removable media e.g. CDs, and DVDs, must be archived alongside any Hardcopy study data (see section 4.3) and labelled with the following information:
   - The Study Title
   - Study Reference Numbers e.g. NHS Fife R&D Reference number, REC Reference Number
   - CI/PI name

4.4.6 Instructions must also be included as to how to reconstruct the data and testing carried out to ensure the process works correctly. Preferably this testing should be carried out by someone different to the person who has written the instructions to ensure that they are clear.

4.5 PROCEDURE FOR ARCHIVE AT SPONSOR ARRANGED ARCHIVE FACILITY (HOSTED STUDIES ONLY)

4.5.1 This must be agreed in writing or in the Contract/Clinical Study Agreement

4.5.2 The Research Team should follow the Sponsor process for preparation to archive and archiving.

4.5.3 No original documents should be taken by the Sponsor; however, photocopies can be given. NHS Fife should always retain control of the original documentation held in the ISF to ensure the Sponsor does not have uncontrolled access to the source data (the ISF should never be sent directly to the Sponsor for archiving except where the Sponsor and CI/PI are the same).
4.5.4 Once the study team has prepared the material for archiving and boxed it up according to the Sponsor’s instructions, the R&D Support Officer must:

- Double check the contents of the box matches that listed on the Sponsor supplied paperwork and sign as confirmation.
- Take a scanned copy of the Sponsor paperwork and save this in a study specific folder in T:\Research Project Archive.
- A copy of the countersigned Sponsor paperwork should be retained by the CI/PI.
- Add the details of the archive box(es) to the Archiving Register and SReDA
- Log if any study information has been saved in the e-archive on the e-archive tab in the Archiving Register
- Arrange for the transfer of the box(es) to the Archive Facility requested by the Sponsor.
- Ensure the representative of the Archive Facility provides confirmation that the responsibility of the box has been transferred to the Archive Facility e.g. signature on pick-up request form.
- Record on the Archive Register the date the box was sent to the Archive Facility and state the address of the facility

4.6 PROCEDURE FOR ARCHIVE WHERE NHS FIFE IS THE SPONSOR FOR EXTERNAL SITES

4.6.1 In most cases NHS Fife will delegate responsibility for archiving to the host site in the Clinical Trial Agreement or in writing.

4.6.2 The R&D Office will have oversight of the archiving procedures and ensure the name and location of essential study documentation storage is logged on the Archiving Register.

4.6.3 External sites that require NHS Fife to archive on their behalf will be provided with guidance on the archiving process to follow including instructions to be followed to ensure the files will remain only accessible by the site themselves.

4.7 RECALL AND RETRIEVAL FROM THE ARCHIVE – HARDCOPY DATA

4.7.1 The person requesting access to the archived material must contact the Sponsor to obtain authorisation to do so before completing Part 1 of a Hardcopy Data Archive Access Request Form (Doc Ref 035-05) and forwarding to the R&D Support Officer.

4.7.2 For studies Sponsored by NHS Fife the requester must provide a reason why they need access to the archived material. These may include:

- Addition of documents
- Review of information
- Access for data audits or inspections

The R&D Office will assess the request and either approve or reject it based on the above criteria and record the decision on the Archiving Register. Advice will be sought from the Assistant R&D Director if there is uncertainty as to whether a request should be approved or rejected.
4.7.3 Upon confirmation by the appropriate person/organisation, the requester should arrange with the R&D Support Officer a suitable date and time to meet and access the archive.

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

No documents can be removed but copies can be provided/taken. No alterations to study data can be made.

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

4.7.6 The R&D Support Officer must take a scanned copy of the completed Archive Access Form and save this in the study specific folder in T:\Research Project Archive. The original copy must be placed inside the archiving box.

4.7.7 The R&D Support Officer must then seal the box by taping securely around the edges and twice across the top with brown tape and sign and date across the tape before transferring the box to the Archiving Room.

4.7.8 The R&D Support Officer must update the Archive Register to record the retrieval reason, who has accessed the records, what, if anything, was copied and date it was returned to the archive.

4.8 RECALL AND RETRIEVAL FROM THE ARCHIVE – ELECTRONIC DATA

4.8.1 The person requesting access to the archived material must contact the Sponsor to obtain authorisation to do so before completing Part 1 of an Electronic Data Archive Access Request Form (Doc Ref 035-06) 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.

4.8.2 For studies Sponsored by NHS Fife the requester must provide a reason why they need access to the archived material. These may include:
- Addition of documents
- Review of information
- Access for data audits or inspections

The R&D Office will assess the request and either approve or reject it based on the above criteria and record the decision on the Archiving Register. Advice will be sought from the Assistant R&D Director if there is uncertainty as to whether a request should be approved or rejected.

4.8.3 Upon confirmation by the appropriate person/organisation, 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.

No files can be deleted or altered but copies can be taken or printed.
4.8.4 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.

4.8.5 The R&D Support Officer must take a scanned copy of the completed Archive Access Form and save this in the study specific folder in T:\Research Project Archive.

4.8.6 The Archive Register will be updated to record who has accessed the records and what has been copied/printed.

4.9 **DESTRUCTION OF ARCHIVE MATERIAL – HOSTED STUDIES**

4.9.1 When the archiving period for a study has been completed the R&D Support Officer will contact the Sponsor to ask for permission to destroy boxes.

4.9.2 The R&D Support Officer will also notify the PI, where possible, of the intent to destroy study boxes.

4.9.3 Once agreement from the Sponsor has been received, sign off by the Assistant R&D Director will be sought.

4.9.4 Destruction will then be completed in accordance with NHS Fife General Procedure GP/R4-1 - Disposal of Confidential Waste Procedure - Paper Records

4.9.5 A record of the destruction of study material (Doc Ref 35-06) should be retained for **5 years**.

4.10 **DESTRUCTION OF ARCHIVE MATERIAL – SPONSORED STUDIES**

4.10.1 When the archiving period for a study has been completed the R&D Support Officer will contact the CI and PI to ask for permission to destroy boxes.

4.10.2 Once agreement has been received, sign off by the Assistant R&D Director will be sought.

4.10.3 Destruction will then be completed in accordance with NHS Fife General Procedure GP/R4-1 - Disposal of Confidential Waste Procedure - Paper Records

4.10.4 A record of the destruction of study material (Doc Ref 35-07) should be retained for **5 years**.

4.11 **ARCHIVING MEDICAL RECORDS**

It is essential that arrangements are made to ensure that participant medical records containing source data are retained throughout the archiving period, in secure conditions, on media that preserve the integrity and readability of the materials for the required duration. Scanning of participants’ medical records is acceptable provided the process has been formally validated, in order to demonstrate that it is an authentic copy of the original and is stored in a format that allows for retrieval of the data throughout
the required archiving period. The notes of participants involved in research studies must be clearly identified as such in order to prevent premature destruction.

4.12 ARCHIVING R&D STUDY FILES

4.12.1 Once a study has ended, all study procedures and all R&D governance processes are completed the R&D study record should be archived. The R&D Support Officer will confirm where the study file is located and whether archiving is appropriate.

4.12.2 The file should be organised as per the index and any duplicate hard copy items disposed of in confidential waste. The documents can then be scanned in to the R&D category of the Board’s “Therefore” electronic Archiving system.

4.13 STORAGE OF BOXES AWAITING ARCHIVING

4.13.1 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 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. Stored box(es) can be recalled by the local study team for close-out/addition of documents as required.

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

4.13.3 The R&D Office will log the retrieval on the Archiving Register.

4.13.4 The Research Team is 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. They research Team must ensure that the data is stored in a secure location.

4.13.5 The R&D Support Office will update the Archive Register with the storage location of the box(es).

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

4.13.7 Once the box is returned, the R&D Support Officer will re-sign the Hardcopy Data Archiving Record Form to confirm the contents of the box before returning it to the Archiving Room.

4.13.8 The R&D Support Officer will record the date the box was returned to the Archiving Room on the Archiving Register.

5. ASSOCIATED DOCUMENTS

Doc Ref 035-01 - Archiving Notification Form
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
6. ABBREVIATIONS

CI  Chief Investigator
CTIMP  Clinical Trial of an Investigational Medicinal Product.
ISF  Investigator Site File
MA  Marketing Authorisation
MHRA  Medicines & Healthcare products Regulatory Agency
PI  Principal Investigator
PSF  Pharmacy Site File
REC  Research Ethics Committee
R&D  Research & Development
SMF  Study Master File
SOP  Standard Operating Procedure
TASC  Tayside Medical Science Centre
WI  Working Instruction

7. REFERENCES

World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects.  
(https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)

Medicines for Human Use (Clinical Trials) Regulations 2004.  
It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.

UK Policy Framework for Health and Social Care Research  

The Data Protection Act 1998  

Records Management: NHS Code of Practice (Scotland)  
(http://www.gov.scot/Publications/2012/01/10143104/0)