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ARCHIVING OF CLINICAL TRIAL AND RESEARCH STUDY DATA: STANDARD OPERATING PROCEDURE

Introduction and Aim

Archiving is the long term storage of all essential documents which individually and collectively permit the evaluation of the conduct of a clinical trial or research study and the quality of the data produced.

This Standard Operating Procedure (SOP) aims to regulate the way in which essential documentation from research studies and trials that are sponsored by or hosted by Cardiff and Vale University Health Board (the UHB) are managed and archived under the UK policy framework for health and social care research 2017, ICH-GCP and European Union (EU) GCP directive (2005/28/EC) and the Medicines for Human Use (Clinical Trials) Amendment Regulations SI2006/1928. It will ensure the Research Governance Policy (UHB 099) is being implemented and that the Health Board delivers its objectives in relation to the safe handling and long term storage of data generated during research activity.

Objectives

To clarify the responsibilities of the Chief or Principal Investigator (CI/PI) for archiving study data and other study related material of UHB sponsored or hosted CTIMPs (including devices) as required under the Medicines for Human Use (Clinical Trials) Regulations (and any amendments) and to describe the procedure for archiving UHB sponsored or hosted non-CTIMP study documentation.

Scope

This procedure applies to all individuals undertaking or involved in UHB Sponsored or Hosted research studies (where provision for third party archiving is not made by the sponsor) within the UHB where the individual has any responsibility for record keeping and archiving. This includes those individuals:

- holding substantive or honorary contracts/titles with the UHB;
- holding ‘letters of access’ to UHB;
- undertaking clinical research involving UHB patients or staff undertaking clinical research on UHB premises

Any procedure developed by a Clinical Trials Unit (CTU) should comply with this SOP in the case of C&V UHB sponsored studies, unless otherwise specified within the contract.

Equality Health Impact Assessment	An Equality Impact Assessment has been completed on the Research Governance policy (UHB099) under which this SOP sits. The Equality Impact Assessment completed for the policy found there to be a no impact.

Documents to read alongside this Procedure	Research Governance Policy (UHB099) Data Management For Clinical Trials SOP (UHB449) Record Management Policy (UHB142)
Approved by	Research Governance Group

Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Research Governance

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
2	20/01/2015	23/03/2015	This is a revised document the content was previously included within the Archiving of Clinical Trial Research Study Data (SOP) UHB121 now written in the new format in compliance with the Policies, Procedures and Other Written Control Documents Management Policy. The following sections have been updated: Objectives now include bullet points Section 2.0 wording changed to "*but may be delegated to the Chief Investigator (CI), Principal Investigator (PI), member of the research team and/or R&D office staff including Designated Archivists (R&D Officers).*" Section 2.6 second last paragraph the word *spreadsheet* replaces *database*

			Section 2.8 End of 1st paragraph the wording "*For Hosted CTIMPs this SOP should be referred to at study start up and again as soon as practicable, within 12 months of the end of the research study. The PI should contact the R&D office to request the appropriate archiving paperwork*." Section 3.0 see 2nd paragraph wording altered "*as detailed in section 2.1 above, the CI/PI should contact the R&D office to request the appropriate archiving paperwork."* Section 3.0 see 3rd paragraph wording altered "*the CI/PI must prepare the essential documentation for archiving*." Section 3.1 see 1st paragraph wording altered "*at study start and again as soon as practicable, within 12 months of the end of the research project. The PI should contact the R&D office to request the appropriate archiving paperwork."*
3	06/02/2018	01/05/2018	Minor changes throughout document removing reference to Cardiff University until the Clinical Trial Regulation (EU) No536/2014 as Article 58 comes into force. Please note that this SOP **will** require further updating when the new Clinical Trial Regulation comes into force. Regulation (EU) No536/2014 as Article 58 within the revised regulation states that the sponsor and the investigator shall archive the content of the clinical Trial Master File for at least 25 years after the end of the clinical trial. However the medical files of subjects shall be archived in accordance with national law. The **EU Clinical Trial Regulation** will come into application during 2019 instead of October 2018, as previously scheduled. Therefore this SOP has received minor updates to ensure fit for purpose until the new EU Clinical Trial Regulation come

			into force and general update as an interim measure
4	14/07/2021	25/01/2022	The new EU Clinical Trial Regulation has not come into application so has not been updated in this iteration. The structure of this SOP has been changed significantly to simplify the archiving process for researchers involved in all types of clinical research carried out in the UHB. Accompanying forms have been changed and standardised across all types of clinical research and should be used by all research teams in the UHB for each study that is archived, where provision for third party archiving is not made by the sponsor. This change allows the R&D office to have increased oversight of the archiving processes undertaken within the UHB and our external storage provider.

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1.0 BACKGROUND

During the set up and active phases of a research study, the CI/PI has a responsibility to ensure the safekeeping of all study related data and documentation and must guard against their premature destruction. After a research study has closed, any data queries resolved, the data is analysed and the final report produced. The study Sponsor is responsible for advising the CI/PI of the arrangements for archiving the study data. Archived material comprises of project documentation for closed studies (i.e. studies where all patient activity and data analysis are completed) and which are no longer in the custody of the CI/PI.

Archiving of clinical trial data must be carried out in compliance with the EU Clinical Trials Directive (2001/20/EC), Volume 10 of Eudralex - The Rules Governing Medicinal Products in the European Union, International Conference for Harmonisation - Good Clinical Practice (ICH-GCP) Guidelines (CPMP/ICH/135/95) and GCP Directive. Whilst the ICH-GCP Guidelines do not explicitly define 'archive' in the Glossary (Section 1), they state that, *"all clinical trial information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification."* (Section 2.10) and, "*The confidentiality of records that could identify subjects should be protected…"* (Section 2.11). Investigators and/or Sponsor institutions are required to maintain essential documents (as specified in ICH-GCP Section 8) and to "*take measures to prevent accidental or premature destruction of these documents.*" (ICH-GCP Section 4.9.4).

It is a legal requirement of the Medicines for Human Use (Clinical Trials) Regulations (2004) [SI1031] that essential documents and the medical records of trial participants are retained following the end of a Clinical Trial of an Investigational Medicinal Product (CTIMP) in order to allow reconstruction of a trial, potential further analysis of project data and to enable MHRA or any other inspection and monitoring in accordance with SI 2004/1031 and GCP.

Archived data must conform to the "Data Protection Legislation" which means all (i) applicable laws governing the processing of personal data, including the UK GDPR (as defined in section 3(10) of the Data Protection Act 2018), the Data Protection Act 2018, and the Privacy and Electronic Communications (EC Directive) Regulations 2003, as may be amended, re-enacted or replaced from time to time; and (ii) all guidance and codes of practice issued by the Information Commissioner's Office or other regulatory body which are relevant to the processing of personal data in relation to the activities associated with this SOP.

In addition, for trials involving a medicine for which a Marketing Authorisation application dossier will be required, Annex 1 of Directive 2003/63/EC (*Analytical, Pharmacotoxicological and Clinical Standards and Protocols in respect of the testing of Medicinal Products, Module 5: Clinical Study Reports*) must be complied with. This will usually only apply to commercially sponsored CTIMPs being run at the UHB.

2.0 RESPONSIBILITIES

The archiving of research study and clinical trial data rests with the Sponsor, but may be delegated to the CI, PI, member of the research team and/or Cardiff Joint Research Office (JRO) staff including the Designated Archivist. Refer to Table 1 for a summary of archiving responsibilities for different study types.

2.1 SPONSOR

- The sponsor has overall responsibility for ensuring that the Trial Master File (TMF) (comprising of the sponsor TMF and the Investigator Site File [ISF]) are archived appropriately.
- The task of ensuring that the ISF documents at each host site are prepared for archiving and placed into a storage facility (as applicable) is delegated to the host site, and should set out in the Site Agreement/Organisation Information Document (OID)/Protocol.
- The Sponsor, or the CI/CTU or CRO if delegated by the Sponsor, is responsible for notifying sites when archived material may be destroyed. Until such notice is received, measures should be taken by the CI/PI to prevent accidental loss or destruction of the ISF. Dates for destruction of the TMF for all UHB sponsored studies should be documented in ReDA by the JRO.

2.2 DESIGNATED ARCHIVIST

- The Sponsor of a CTIMP must have in place a Designated Archivist, defined as the person/s who has oversight for the archiving of sponsored CTIMP documentation.
- At the UHB, the role of Designated Archivist is undertaken by R&D Managers. An R&D manager in the Research Governance Team will oversee CVUHB sponsored study archiving. An R&D manager in the Registration and Permissions team will oversee hosted non-commercial CTIMP study archiving. An R&D manager in the Commercial team will oversee hosted commercial study archiving. These Designated Archivists will delegate tasks set out in section 2.4 to other members of the R&D Office.
- The archivist is not responsible for the content of the archived material. Further details are show in 2.4 of their responsibilities.

2.3 CI/PI

- The CI/PI is responsible for archiving the data generated by the UHB in accordance with this SOP and applicable legislation.
- If the CI/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 appropriate member of the research team and informing the R&D office of the handover arrangements.
- For multi-centre trials sponsored by the UHB, the site agreement/OID/protocol should delegate responsibility to the participating sites for archiving and for ensuring that data and documentation are available for the purposes of monitoring and inspection.

2.4 JOINT RESEARCH OFFICE

- The JRO maintains a record in its research management system of all its archived studies for UHB sponsored studies, commercially sponsored studies and UHB non-commercial hosted CTIMPs, which includes an Archiving Record,

List of Archived Documents and Archiving Label, the location of the ISF and Sponsor TMF (for UHB sponsored studies) and the due date of destruction.

- The JRO is responsible for recouping archiving costs and raising invoices for commercial studies requiring local archiving.
- The day-to-day responsibilities of the Designated Archivists are delegated to a named person in the R&D Department. These responsibilities include:
    - Ensuring there is a completed Archiving Record, List of Archived Documents and Archiving Label provided to the R&D Department for all closed UHB sponsored studies, commercially sponsored studies and UHB non-commercial hosted CTIMP studies in the e-study folder and that the information is entered on ReDA.
    - Maintaining a record of the transfer of the ISF and Sponsor TMF into external storage where applicable for UHB sponsored studies. (The external storage facility used by the UHB is OASIS, details in section 3.4)
    - Maintaining a record of due destruction dates for studies put into internal or external storage for UHB sponsored studies, commercially sponsored studies and UHB non-commercial hosted CTIMP studies.
    - Oversight of arrangements for destruction of the ISF and sponsor TMF of UHB sponsored studies at the UHB and other participating sites.
    - Ensuring Sponsor confirmation of destruction of UHB non-commercial hosted CTIMP studies and commercially sponsored studies at the UHB in a timely manner before destruction is implemented. Further details of this are documented in section 7.

2.4 CLINICAL BOARD/DIRECTORATE

- The Clinical Board/Directorate are responsible for maintaining an archiving log (TPL-003-11) (summarised in section 4.5) for their clinical area.
- Finding/providing space for the storage of archiving materials for CIs/PIs if archiving onsite.
- Funding archiving offsite if no funding is available.

2.5 RESEARCH DELIVERY TEAM

- If the research delivery team are involved in supporting a study, they can be delegated the task of archiving by the CI/PI.
- A member of the research delivery team must be suitably trained and delegated the task on the delegation log in order to proceed with archiving.
- This must be agreed as part of discussions surrounding research delivery support at the start of the study.
- The CI/PI still holds overall responsibility for the archived material.

3. STANDARDS FOR ARCHIVING

3.1 PREPARATION OF SPONSOR TMF AND ISF- OVERVIEW

- Section 8 of ICH-GCP4 defines the minimum set of documents to be archived. A ‘List of Archived Documents form’ (FRM-003-05) for researchers outlining the types of document which should be archived must be completed and returned to the R&D office before archiving is complete.
- Essential documents should be complete, legible, accurate, unambiguous, authentic and, as appropriate, certified after verification. Sections 5.1.1 and 5.1.3

of ICH-GCP state the responsibilities of the Sponsor for implementing quality assurance and quality control to assure the quality of essential documents. It is the PI's responsibility to ensure that the archived material complies with the standards set out in this SOP. For UHB sponsored studies, the CI must retain oversight and ensure that PIs at external sites are aware of their responsibilities to archive appropriately.

- The CI/PI, by signing off the Archiving Record, is providing confirmation that they are satisfied that these standards have been met.
- The sponsor TMF may comprise documentation held by the main study team, the JRO, support departments and external suppliers. When the study is ready to be archived, the TMF should ideally be brought together as a single file. If it is not possible to physically store all the documentation 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 may be archived separately from the main TMF for UHB sponsored studies. It is anticipated that the database would usually be held by the CTU or study team on their university or NHS server.
- Trial prescriptions for Investigational Medicinal Products (IMP), IMP accountability records and documentation of IMP destruction included in the pharmacy site file need to be archived together with other trial-related documentation in the TMF/ISF. The clinical trials pharmacist will not archive the pharmacy documents separately.
- The transfer of study documentation between parties (i.e. the CI/PI and the external storage facility) should be properly documented. This is also known as 'the chain of custody'.
- 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
    - 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, which should be detailed in the site agreement/OID/protocol.
    - Any alteration to records should be traceable. Particular attention needs to be taken when records are stored on electronic, magnetic, optical or other non-indelible media, in which case suitable controls should be implemented to ensure that these records cannot be altered without appropriate authorisation and the creation of an audit trail.
    - When original records are copied or transferred to other media for archiving, the system of copying or transfer should be validated to ensure that information will not be lost or altered. Such copies or transfers should be certified for accuracy and completeness by someone with appropriate authority (e.g. Trial Manager/medical records staff), as part of the quality control / quality assurance procedures.
    - For media that require processing in order to render records into a readable format, the availability of appropriate equipment should be ensured so that this processing can be done.

3.2 PREPARATION OF DOCUMENTS

- Documents should be removed from ring binders or lever arch files, if possible, to keep storage space to a minimum.
- Documents may be held together by plastic archiving clips, but plastic wallets and all paper clips, staples or metallic means of combining sheets should be removed to prevent rusting or other chemical deterioration. It may not always be practical to remove metallic staples therefore (and in accordance with sponsor requirements) they may not be removed unless it is considered that there is a reasonable risk of damaging the records.
- Duplicate copies of documents should be destroyed.
- Post-it notes may be mis-placed and should therefore be removed and typed up as file notes as appropriate.
- Documents vulnerable to deterioration should be identified and appropriate arrangements put in place. For example, thermochromic paper should not be put into storage as this will deteriorate; instead certified copies should be made or alternative arrangements made for long term storage.
- Consideration should be given to potential risk of obsolescence of data held in non-paper format e.g. film or magnetic tape and whether this can, or should, be transferred to a different media format before putting into archiving.
- Specialised archiving boxes should be used for the long term storage of all essential clinical trial documentation (excluding information contained within the Health Record). Each box should have an archiving label attached in a visible location and the box should be sealed around the lid with packing tape. The person with responsibility (or delegated responsibility) for archiving should sign across the packing tape to ensure that the contents cannot be disturbed without it being obvious. The signature must be dated.

3.3 STORAGE FACILITES

- Storage facilities should ensure that essential records are maintained in a legible condition and can be retrieved promptly. Any change in the location and ownership of the documentation should be documented in order to allow tracking of the stored records.
- Personal data must be stored in compliance with the requirements of the Data Protection Legislation.
- Adequate and suitable space should be provided for the secure storage of all essential records from completed studies. The facilities should be secure, with appropriate environmental controls and adequate protection from fire, flood and unauthorised access. A reputable external storage facility provider should be able to satisfy these criteria.
- The storage of the Sponsor's documentation may be transferred to a sub-contractor (e.g. a commercial archive) but the ultimate responsibility for the quality, integrity, confidentiality and retrievability of the documents resides with the Sponsor (ICH-GCP 5.2.1).
- For those studies which are not being put into external storage, access to the research data should be restricted to authorised personnel with controlled access, for example in a locked cabinet within an area with swipe card access.
- The UHB holds a contract with OASIS, an external storage facility, for storing research documentation. The head office details for OASIS are: Quadrant 1

Homefield Road, Haverhill, Suffolk, England, CB9 8QP, UK. The storage facility details are: Glanusk Park, Crickhowell, Powys NP81LP, UK.

- The UHB expects OASIS, as a data processor, to maintain the necessary standards for storing records. The UHB conducts monitoring visits at OASIS routinely. The UHB may undertake checks which cover, but are not limited to: suitability of the physical environment, security of documents during transportation and storage, authorised movement of documents, timely destruction of archived material and General Data Protection Regulation (GDPR) compliance.
- External sponsors may choose to make their own arrangements for the storage of ISFs.
- It is preferable that arrangements for archiving are identified and addressed at study set up by the study team, in consultation with the sponsor. For UHB sponsored CTIMPs, this should be documented in the roles and responsibilities section of the contract.
- For Hosted CTIMPs the PI should contact the JRO to request the appropriate archiving paperwork.
- For UHB Sponsored CTIMPs the functions of storage and archiving should be specified and the role assigned to an identified archivist(s). Access to archives should be restricted to authorised personnel, which will be recorded on ReDA. At the UHB these roles are undertaken by Designated Archivists.

3.4 DURATION OF RETENTION OF ESSENTIAL STUDY DOCUMENTS

- Documents must be retained for the minimum length of time stipulated in Table 1 whilst at the same time taking full account of the principles enshrined in data protection legislation that personal data should be held for no longer than is absolutely necessary.
- In accordance with the Medicines for Human Use (Clinical Trials) Amendment Regulations (SI2006/1928), the UHB recommends that essential documentation should be retained for at least 15 years for C&V UHB sponsored CTIMPs.
- There is no legal requirement to archive documentation for non-CTIMPs, but for UHB Sponsored non-CTIMPs, archiving is advised and the retention period of 5 years is acceptable.
- For C&VUHB hosted studies, Table 1 stipulates that the retention time should be in accordance with the Sponsor's requirements. This will not necessarily be in line with the time scales indicated for C&VUHB sponsored studies.
- 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/OID between the Sponsor and UHB.
- For trials that include regulatory submission, they will be archived in accordance with the Sponsor's regulatory submissions and approvals in compliance with the legislation at the time.

3.4.1 DURATION OF RETENTION OF PATIENT MEDICAL RECORDS

- For CTIMPs, the Clinical Trials Regulations stipulate that the medical records of clinical trial subjects must be retained for at least 5 years after the official end of the trial (longer for paediatric studies).

- Medical notes should be marked with a label stating that the documents should not be destroyed until 5 years after the close of the study for CTIMPs. The date until which the notes are to be maintained must be clearly specified on the label, which should be placed where it can be readily seen (usually inside the front cover). In addition, the existence of this internal label must be flagged by the CI/PI placing an orange sticker stating 'do not destroy' on the outside front cover of the medical notes. A Label for Patient Medical Notes (FRM-003-06) is available from the R&D Office, but researchers must provide their own orange stickers.
- In general, patient healthcare records should be kept for 8 years from the conclusion of treatment or last patient contact, as a minimum requirement.
- Patient medical notes are no longer digitised at the UHB; instead, the medical records are archived 18 months after the last patient contact (retained at an external archiving facility) until the retention period has expired. For the majority of patients in its care, the UHB has a duty to maintain medical notes for 8 years after the last contact; Mental Health, Child Health and Maternity records are kept for longer (between 20-25 years) depending on the patient group
- Special archiving arrangements apply to data concerning children, maternity and mental health patients (Welsh Health Circular (2000)71, *For the Record*). In the case of data from children, records should be retained at least until the patient's 25th birthday or their 26th birthday if they were aged 17 years at the conclusion of treatment, or 8 years after the patient's death if death occurred before their 18th birthday. Maternity records (including obstetric and midwifery records) should be retained for 25 years from the patient's last contact. Medical records of mental health patients should be retained for 20 years after no further treatment was considered necessary, or 8 years after the patient's death if the patient died whilst still receiving treatment.
- In all cases of retaining patient medical notes, the principles of the Data Protection Legislation will apply.
- It is recognised that CVUHB are in a period of change concerning Health Records, but where electronic health records are used as source data, they should be at least as good and secure as paper. This included audit trail of data entries, corrections and the CI/PI should be able to 'sign' to indicate s/he has seen the data to demonstrate oversight. Electronic health records should be kept on up to date, viewable media for the specified archiving period.

4.0 PROCEDURES FOR ARCHIVING SITE DOCUMENTATION

- For UHB sponsored studies, the CI or CTU has delegated responsibility for initiating archiving procedures of the ISF at all participating sites.
- The CI/PI is responsible for undertaking the following procedures or delegating them to appropriately qualified staff in their team if appropriate.

4.1 UHB SPONSORED CTIMPS

1. Liaise with the JRO Designated Archivists to initiate archiving procedures. In order to demonstrate compliance with GCP in this respect, the UHB must retain responsibility for archiving trial material for its Sponsored CTIMPs.
2. Ensure that the essential documents listed in the TMF/ISF index are present and appropriately filed.

3. The CI/PI is responsible for ensuring that clinical trial data and documentation are placed in archiving boxes with the contents of each box fully documented via both the Archiving Record (FRM/009/03) and the List of Archived Documents (FRM/003/05).
4. Place a copy of the Archiving Record and List of Archived Documents inside the archiving box or attach to the inside lid of the box. A copy of both these logs should also be held in the site research team's office
5. Complete an Archiving Label (FRM-003-04) and attach this to the archiving box
6. Return the completed Archiving Record, List of Archived Documents and Archiving Label to the JRO with the completed archiving boxes.
7. The archiving boxes must be sealed and signed over by the Designated Archivist. Once sealed, these boxes and their contents will become the responsibility of the UHB R&D Office.
8. The JRO is responsible for restricting access to any archived material, and to permitting access, upon receipt of a written request to access specific archived material and only to those individuals who are named on the Archiving Record as being eligible to do so. Responsible person(s) to whom the archiving box may be released for the UHB-Sponsored CTIMPs will always be the UHB's Designated Archivist.
9. All storage boxes going into OASIS should be coordinated with the JRO to ensure appropriate labelling.
10. The JRO will then arrange pick up and storage of the archiving boxes in OASIS.

4.2 UHB SPONSORED NON-CTIMPS

There is no legal requirement to archive documentation for non-CTIMPs. The Medical Devices Regulations 2002 do not include any express legal requirement to archive trial data gathered from clinical investigations of Medical Devices (ciMDs). 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 and 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."* In view of the above, it is therefore good practice to archive research documentation for all non-CTIMP studies. UHB Sponsored non-CTIMP documentation should be archived following the procedure below.

1. Liaise with the UHB R&D office Designated Archivists to initiate archiving procedures.
2. Ensure that the essential documents listed in the ISF/TMF index are present and appropriately filed.
3. The CI/PI is responsible for ensuring that study data and documentation are placed in archiving boxes with the contents of each box fully documented via both the Archiving Record (FRM/009/03) and the List of Archived Documents (FRM/003/05).
4. Place a copy of the Archiving Record and List of Archived Documents inside the archiving box or attach to the inside lid of the box. A copy of both these logs should also be held in the site research team's office
5. Complete an Archiving Label (FRM-003-04) and attach this to the archiving box
6. Return the completed Archiving Record, List of Archived Documents and Archiving Label to the R&D Department.
7. The archiving boxes must be sealed and signed over by the responsible party.

8. The Clinical Board/Directorate is responsible for providing suitable storage areas for archiving purposes. Where no suitable storage areas are available, the CI/PI must contact the UHB R&D Office for advice
9. If the storage boxes are going into OASIS, please seek advice from the R&D office to ensure appropriate labelling and to arrange pickup.

4.3 UHB HOSTED NON COMMERCIAL CTIMPS

For externally-Sponsored CTIMPs carried out at the UHB, responsibility for archiving rests with the Sponsor. This is often delegated to the host organisation through the site agreement/OID/protocol. The archiving arrangements must be agreed with the Sponsor before commencing the study. The PI is responsible for making appropriate arrangements with the Sponsor for archiving local trial materials e.g. ISF. If the sponsor doesn't stipulate archiving requirements for a non-CTIMP, it is still recommended that the below procedure is followed, but this is not a legal requirement. The JRO will not hold a log of these studies, but forms can be provided to allow for archiving under this process.

1. Liaise with the sponsor to confirm initiation of archiving procedures. The JRO will require evidence before providing the archiving documentation.
2. Ensure that the essential documents listed in the ISF index are present and appropriately filed.
3. The PI is responsible for ensuring that study data and documentation are placed in archiving boxes with the contents of each box fully documented via both the Archiving Record (FRM-009-03) and the List of Archived Documents (FRM-003-05).
4. Place a copy of the Archiving Record and List of Archived Documents inside the archiving box or attach to the inside lid of the box. A copy of both these logs should also be held in the site research team's office
5. Complete an Archiving Label (FRM-003-04) and attach this to the archiving box
6. Return the completed Archiving Record, List of Archived Documents and Archiving Label to the JRO
7. The archiving boxes must be sealed and signed over by the responsible party.
8. If the archiving boxes are not going to be archived externally, the Clinical Board/Directorate is responsible for providing suitable storage areas for archiving purposes Where no suitable storage areas are available, the PI must contact the JRO for advice
9. If the storage boxes are going into OASIS, please seek advice from the R&D office to ensure appropriate labelling and to arrange pickup.

4.4 UHB HOSTED COMMERCIAL CTIMPS AND NON-CTIMPS

In the case of commercially-sponsored clinical trials, the TMF and information/activities external to the UHB and not part of the local Investigator/Trial Site File will be organized by the Sponsor or agent (e.g. contract Research organization managing the trial) at an external facility and do not form part of local study records.

The UHB will retain and archive the local ISF unless a specific arrangement for external archiving for the local ISF is agreed and documented in the site agreement with the Sponsor. No patient identifiable data or patient medical record will be sent to the Sponsor for archiving.

Local archiving will be at OASIS and the cost will be met by the Sponsor. The fees associated with local archiving will be documented in the site agreement.

1. The study team should liaise with the Sponsor to confirm that archiving procedures can be initiated. The JRO will require evidence before providing the archiving documentation.
2. The study team should ensure that the essential documents listed in the ISF index are present and appropriately ordered..
3. The study team should confirm the number of boxes with the R&D archivist so that an invoice to cover the costs of the entire duration of archiving (usually 15 years) may be raised before financial study close out.
4. The PI or delegated individual within the study team, is responsible for ensuring that entire study documentation are placed in archiving boxes and the contents of each box fully documented via both the Archiving Record (FRM-009-03) and the List of Archived Documents (FRM-003-05).
5. A copy of the Archiving Record and List of Archived Documents should be placed inside the archiving box or attach to the inside lid of the box. A copy of both these logs should also be retained by the research team for future reference.
6. Complete an Archiving Label (FRM-003-04) for each box and attach this to the outside of the archiving box
7. Return the completed Archiving Record, List of Archived Documents and copy of the completed Archiving Label(s) to the R&D Department.
8. The archiving boxes must be sealed and tape signed over by the responsible party.
9. Please seek further advice from the JRO on appropriate labelling and pickup options when using OASIS.

4.5 ARCHIVING LOG

It is the responsibility of each research active Directorate to ensure records of archiving are kept. All archived material arising from CTIMPs carried out at the UHB, whether UHB Sponsored or Hosted (including Commercially-Sponsored CTIMPs) and UHB Sponsored Non-CTIMPs, should be recorded using an Archiving Log (TPL-003-11).

5.0 FUNDING FOR ARCHIVING

There is no central R&D funding available to meet the costs of archiving research study documentation off site. If this is likely to be required the cost should be built into any grant funding applications for UHB sponsor studies or contracts for both non-commercial and commercially sponsored studies at the outset. In the case of unfunded studies, the cost of archiving must be met from within the appropriate Clinical Board / Directorate R&D budget.

6.0 RETRIEVALS

- Any post-archiving access of archived material must be fully documented by the CI/PI, giving reasons for access and describing which documents have been accessed, and the Sponsor notified. When an archiving box is resealed and the tape signed, the date of signature should be included.
- The retrieval of documents from external storage should be kept to an absolute minimum. Retrieval is controlled by the designated archivist (or delegated person) for UHB sponsored studies and non-commercial hosted CTIMPs and

commercially sponsored studies require authorisation from the sponsor before documents can be taken out of storage.

- After authorisation has been obtained, the research team completes *a* Researcher Request to Access Archived Material Form and returns the form to the external storage facility, copied to the JRO
- When the documents are ready to return to storage, the research team need to contact the external storage facility copying in the JRO.
- Access to archived material from UHB-Sponsored CTIMPs will only be permitted via the JRO and such access must be requested by the CI/PI (or their delegate) using the 'Researcher Request to Access Archived Material Form'.
- For UHB sponsored CTIMPs where archiving has been arranged by another party (eg the CTU or CI), any retrievals should only be arranged in consultation with the UHB's designated archivist (or delegated person).
- The movement of documents in and out of storage will be recorded by the JRO for UHB sponsored studies only.
- If the retrieval has been requested by an external Sponsor, the cost of retrieval should be met by the Sponsor. In the case of commercially sponsored trials, this cost is included as part of the archiving fee.

7.0 DESTRUCTION OF ARCHIVED MATERIAL

- The JRO monitors due destruction dates of studies put into archiving. The JRO or the local research team will contact the CI/PI and the Sponsor before the due date for destruction to seek authorisation for destruction. If the Sponsor cannot be contacted or fails to provide a response after several attempts, the JRO may authorise destruction after communicating with the PI/research team.
- If the directorate wishes to extend the duration, this can be discussed and arranged at the directorate's expense.
- The local research team should then arrange destruction of the archived documents and inform the Sponsor and CI/PI (where contactable) that this has been done. The JRO will record the date of destruction in its research management system.
- For UHB sponsored CTIMPs, the JRO (or delegated CI) will authorise destruction of the TMF and is responsible for informing sites about arrangements for destruction.

7.1 RECORD OF DESTRUCTION

- The reasons for destruction of essential documents after the expiry of the time limit should be recorded and signed by a person with appropriate authority. This record must be retained in a secure place for a further 5 years from the date that the essential documents were destroyed. The record of destruction must be copied to the JRO on request.
- Archived documents for UHB-Sponsored CTIMPs will be destroyed at the appropriate time by the JRO Designated Archivists after first checking with the CI/PI that they are happy for this to happen; alternatively the CI/PI may be asked to undertake such destruction on behalf of the UHB, and to subsequently provide written confirmation of destruction. Archived documents for Hosted CTIMPs should be destroyed by the PI only upon receipt of the Sponsor's written authorisation to do so, and such destruction confirmed to the Sponsor in writing.

8.0 RELATED DOCUMENTS

Archiving Record (FRM-009-03)
List of Archived Documents (FRM-003-05)
Researcher Request to Access Archived Material Form (FRM-009-04)
Label for Archiving Box (FRM-003-04)
Label for Patient Medical Notes (FRM-003-06)
Archiving Log (TPL-003-11)

9.0 ABBREVIATIONS AND DEFINITIONS

CI	Chief Investigator
ciMDs	Clinical investigations of Medical Devices (ciMDs
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trial Unit
GCP	Good Clinical Practice
ICH	International Conference for Harmonisation
IMP	Investigational Medicinal Product
JRO	Cardiff Joint Research Office
ISF	Investigator Site File
OID	Organisation Investigation Document
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
R&D	Research and Development Office
REDA	Research Data Application
SOP	Standard Operating Procedure
TMF	Trial Master File
UHB	Cardiff and Vale University Health Board

TABLE 1: RETENTION TIME AND RESPONSIBILITIES FOR DIFFERENT TYPES OF STUDIES

Type of study	Responsible party	Task delegated to	Archive Location	Minimum duration	Authority for Access	Managing Access	Authority for Destruction	Managing Destruction
UHB Sponsored CTIMP	UHB as Sponsor	JRO	Offsite	15 years	JRO	JRO	JRO	JRO/ CI/PI
Externally Sponsored CTIMP	Sponsor	CI/PI in liaison with Directorate/Clinical Board	In accordance with Sponsor's requirements	In accordance with Sponsor's requirements	Sponsor	Sponsor in liaison with CI/PI	Sponsor or JRO depending on contractual arrangements	Sponsor or CI/PI depending on contractual arrangements
UHB Sponsored non-CTIMP	UHB as Sponsor	CI/PI in liaison with Directorate/Clinical Board	Offsite or Onsite	5 years	JRO	CI/PI	JRO	CI/PI
Externally Sponsored non-CTIMP	Sponsor	CI/PI in liaison with Directorate/Clinical Board	In accordance with Sponsor's requirements	In accordance with Sponsor's requirements	Sponsor	Sponsor in liaison with CI/PI	Sponsor or JRO depending on contractual arrangements	Sponsor or CI/PI depending on contractual arrangements

N.B.

- EU Guidance on GCP for Advanced Therapy Medicinal Products 2009 requires that study documentation must be kept for 30 years after the expiry date of the product, or longer if required by the MHRA.
- For some studies, a longer retention period may be required (e.g. clinical genetic studies or some interventional studies involving children). In such circumstances, the appropriate retention period should be determined on a case by case basis.