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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 and the quality of the data produced. The European Union (EU) Good Clinical Practice (GCP) Directive (2005/28/EC) outlines the implementation of GCP in relation to archiving in clinical trials. The Medicines for Human Use (Clinical Trials) Amendment Regulations (SI2006/1928) describe the additional safeguards which UK-based Sponsors of Clinical Trials of Investigational Medicinal Products (CTIMPs) must have in place in order to assure the security and integrity of clinical trial data.

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).

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. 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.

The SOP also details the archiving arrangements for non-CTIMPs where the UHB is the study Sponsor or where the UHB is a host organisation under the UK policy framework for health and social care research 2017.

Objectives

To clarify the responsibilities of the Chief or Principal Investigator of a research study in relation to the archiving of clinical trial data and other trial-related material at the appropriate time. To ensure confidential information is:

- *Stored correctly*
- *Not passed on without appropriate consent*
- *Accessed in line with the UHB policies and procedures*
- *Only used for the defined purpose*

And also to ensure

- *Patient safety in using and recording information*
- *Up to date information is stored*
- *Protection of sensitive data*
- *Staff awareness of responsibilities and accountability*
- *Information is accessible when required*

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Scope

This procedure applies to all individuals undertaking or involved in UHB Sponsored or Hosted research studies 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 trial Unit (CTU) should comply with this SOP in the case of C&V UHB sponsored studies.

Equality Health Impact Assessment	An Equality Impact Assessment has been completed on the Research Governance policy 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) Files and Filing SOP (UHB126) Data Management Guidelines (UHB139) Record Management Policy (UHB142)
Approved by	Research Governance Group

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

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](#).

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Summary of reviews/amendments			
Version Number	Date of Review Approved	Date Published	Summary of Amendments
2	20/01/2015	23/03/15	<p>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:</p> <p>Objectives now include bullet points Section 2.0 wording changed to “<i>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).</i>”</p> <p>Section 2.6 second last paragraph the word <i>spreadsheet</i> replaces <i>database</i></p> <p>Section 2.8 End of 1st paragraph the wording “<i>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.</i>”</p> <p>Section 3.0 see 2nd paragraph wording altered “<i>as detailed in section 2.1 above, the CI/PI should contact the R&D office to request the appropriate archiving paperwork.</i>”</p> <p>Section 3.0 see 3rd paragraph wording altered “<i>the CI/PI must prepare the essential documentation for archiving.</i>”</p> <p>Section 3.1 see 1st paragraph wording altered “<i>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.</i>”</p>

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3	06/02/18	01/05/18	<p>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.</p> <p>The EU Clinical Trial Regulation will come into application during 2019 instead of October 2018, as previously scheduled.</p> <p>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</p>
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1.0 BACKGROUND

During the set up and active phases of a clinical trial, the Chief or Principal Investigator (CI/PI) has a responsibility to ensure the safekeeping of all clinical trial related data and documentation and must guard against their premature destruction. After a clinical trial has closed, any data queries resolved, the data are analysed and the final report produced, the trial Sponsor is responsible for advising the CI/PI of the arrangements for archiving the clinical trial data.

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.1 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).

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.

Investigators and/or Sponsor institutions are required to maintain essential documents (as specified in ICH-GCP Section 8)4 and to "*take measures to prevent accidental or premature destruction of these documents.*" (ICH-GCP Section 4.9.4).

2.0 PROCEDURE FOR ARCHIVING

The archiving of research project and clinical trial data rests with the Sponsor, 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).

Essential documents must be retained (archived) for sufficient periods to allow for audit and inspection by Regulatory Authorities and should be readily available upon request. Whenever possible prior to the archiving stage, trial

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documentation should be stored in secure, fireproof cupboards or filing cabinets and access restricted, to maintain trial subject confidentiality and to assure trial data integrity. Refer to Table 1 (page 17) for a summary of archiving responsibilities for different study types.

2.1 WHEN TO ARCHIVE

Records should be archived:

- After the final trial visit has been completed by the last trial subject
- When all trial data have been verified as accurate and complete by the CI/PI
- When all data queries have been resolved and the data analysed
- After the final report has been produced.

The trial documents should be collated prior to archiving taking place.

2.2 DOCUMENTS TO BE ARCHIVED

Section 8 of ICH-GCP4 defines the minimum set of documents to be archived. A 'List of Archived Documents form' for researchers outlining the types of document which should be archived is available from the UHB R&D Office. This can be used as a checklist to record where and when each type of document has been archived, and the individual or Sponsor representative with designated responsibility for it.

Trial prescriptions for Investigational Medicinal Products (IMP), IMP accountability records and documentation of IMP destruction may either be archived by the relevant Pharmacy or requested from the relevant Clinical Trials Pharmacist (by the CI/PI) and archived with other trial-related documentation.

2.3 PATIENT MEDICAL NOTES

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). Further details are given in Section 4 below.

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 (see Section 4.0 below).

For patients involved in CTIMPs, the UHB retains the medical notes for 15 years after the conclusion of treatment, as stipulated in the European

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Economic Community (EEC) Note for Guidance: Good Clinical Practice for Trials on Medicinal Products in the European Community (EC), section 3.17 (see Pharmacy and Toxicology 1990, 67, 361-372).6

In all cases of retaining patient medical notes, the principles of the Data Protection Act (1998) will apply.

2.4 QUALITY OF ESSENTIAL DOCUMENTS

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.

2.5 MEDIA TO BE USED

The media used to store essential documents should ensure that these documents will be promptly available, complete and legible throughout the required period of retention.

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.

2.6 STORAGE CONDITIONS

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.

Adequate and suitable space should be provided for the secure storage of all essential records from completed studies. The facilities should be secure, with

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appropriate environmental controls and adequate protection from fire, flood and unauthorised access.

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 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. At the UHB these roles are undertaken by two Designated Archivists (R&D Officers).

The Designated Archivists maintain an archive index recording all essential documents that have been entered into the archive, and track and retrieve documents on loan from the archive. This is managed by the R&D Office via an in-house Archiving spreadsheet.

Personal data must be stored in compliance with the requirements of the Data Protection Act (1998); specifically Principles 5 and 7. Compliance with this Archiving Procedure will satisfy the requirements of these Principles.

2.7 HOW TO ARCHIVE

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 be sealed around the lid with packing tape and should be signed over by the person with responsibility (or delegated responsibility) for archiving to ensure that the contents cannot be disturbed without it being obvious. The signature must be dated.

2.8 WHERE TO ARCHIVE

All clinical trial documentation for UHB-Sponsored CTIMPs should be archived externally. The precise location of archived material for Hosted CTIMPs is at the discretion of the Sponsor, but as a minimum the material should be stored in a secure, fireproof cupboard or filing cabinet and access restricted to maintain trial subject confidentiality and to assure that trial data integrity is maintained. Where storage space is at a premium, Investigators may make arrangements to have research study related documentation archived 'off-site'. 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.

2.9 FUNDING FOR ARCHIVING

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There is no central R&D funding available to meet the costs of archiving clinical trial documentation off site. If this is likely to be required the cost should be built into any grant funding applications or contract for commercially sponsored trials at the outset. In the case of unfunded clinical trials, the cost of archiving must be met from within the appropriate Clinical Board / Directorate R&D budget.

2.10 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) should be recorded using the R&D/Commercial Trials (as appropriate) Archiving Log available from the R&D Office upon request.

3.0 ARCHIVING ARRANGEMENTS FOR UHB-SPONSORED CTIMPS

For UHB-Sponsored CTIMPs, arrangements must be made with the Designated Archivist for CTIMPs (R&D Officer) in the UHB R&D Office for archiving clinical trial documentation on completion of the trial. In order to demonstrate compliance with GCP in this respect, the UHB must retain responsibility for archiving trial material for its Sponsored CTIMPs.

At the appropriate time as detailed in section 2.1 above, the CI/PI should contact the R&D office to request the appropriate archiving paperwork. 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 Log and the List of Archived Documents and copies sent to the UHB R&D Office.

For UHB-Sponsored CTIMPs, the CI/PI must prepare the essential documentation for archiving and contact the UHB Designated Archivist for CTIMPs (R&D Officer) to make arrangements for archiving off site.

For UHB-Sponsored CTIMPs only, the UHB R&D Office 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 Log as being eligible to do so.

For UHB-Sponsored CTIMPs, the archiving boxes must be sealed and signed over by the Designated Archivist (R&D Officer). Once sealed, these boxes and their contents will become the responsibility of the UHB R&D Office.

Each archiving box must have a fully completed label on the outside which contains the following information (as outlined in the Label for Archiving Box):

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- R&D Project ID Number
- REC Number
- IRAS Number
- European Union Drug Regulating Authorities Clinical Trials (EudraCT) Number
- Project Title (Full and Short title)
- Name and contact details of the CI and/or PI
- List of the contents of the archiving box, prepared by the CI, including the study subject ID Numbers of any CRFs to facilitate resolution of any post-archiving data queries
- Date of Archiving and length of time the documentation should be kept for
- Date of destruction and individual who may authorise this
- Total number of boxes for the study (e.g. Box 1 of 6)
- Responsible person(s) to whom the archiving box may be released (for the UHB-Sponsored CTIMPs this will always be the UHB's Designated Archivist).

4.0 ARCHIVING ARRANGEMENTS FOR EXTERNALLY-SPONSORED CTIMPS

For other externally-Sponsored CTIMPs carried out at the UHB (Hosted CTIMPs), responsibility for archiving rests with the Sponsor. This is often delegated to the host organisation through the site agreement. The PI is responsible for making appropriate arrangements with the Sponsor for archiving local trial materials e.g. ISF. The PI should notify the UHB R&D Office of these arrangements 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.

In the case of Commercially-Sponsored clinical trials, archiving of the Trial Master File and information/activities external to the UHB and not part of the Investigator/Trial Site File should be organised by the Sponsoring Company or agent (e.g. Contract Research Organization managing the trial) at an external facility.

The UHB will retain and archive the local ISF and patient identifiable documentation unless a specific arrangement for external archiving for the former only have been agreed and documented in the site agreement with the Sponsor. A fully itemised Archiving Log outlining the contents of each archiving box for a given trial must be completed and submitted to the Commercial Trials Office at the UHB to enable the Commercial Sponsor to be invoiced for meeting the costs of archiving. The predicted cost of archiving Commercially Sponsored CTIMP data must be accounted for in the trial set up process and the Commercial Sponsor invoiced accordingly either at initiation of the trial and reconciled at the time of archiving, or more commonly at the end of the trial, as agreed in the site agreement.

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The Commercial Trials Office can provide a box label template that contains the recommended minimum information to be displayed on the exterior of each box to be archived. Due to the usual large number of boxes associated with each commercial trial to be archived, boxes should be collected from the research team directly and not sent to the Commercial Trials Office. Should archived boxes need to be released from the archiving facility for a regulatory inspection or other legitimate reason a request for retrieval must be made to the Commercial Trials Office who will arrange the retrieval and ensure that the costs are reimbursed by the Commercial Company.

5.0 ARCHIVING ARRANGEMENTS FOR NON CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (NON-CTIMPS)

The conduct of non-CTIMPs must comply with the UK policy framework for health and social care research 2017. The archiving arrangements for non-CTIMPs must be agreed with the Sponsor.

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

In view of the above, it is therefore good practice to archive research documentation for all non-CTIMP studies.

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.

UHB Sponsored non-CTIMP documentation should be retained for a period of 5 years following completion of the study, unless otherwise stated in essential trial documents. Archiving arrangements for study data will usually be delegated to the CI/PI. 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.

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6.0 DURATION OF RETENTION OF ESSENTIAL DOCUMENTS

In accordance with the Medicines for Human Use (Clinical Trials) Amendment Regulations (SI2006/1928), the UHB recommends that documentation should be retained for at least 5 years.

Where the study involves an investigational medicinal product, ICH-GCP requires retention, *“until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region OR at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product.”*

In general, patient healthcare records should be kept for 8 years from the conclusion of treatment or last patient contact, as a minimum requirement.

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.

6.1 TRIALS TO BE INCLUDED IN REGULATORY SUBMISSIONS

6.1.1 SPONSOR RESPONSIBILITIES

- The Sponsor should retain all Sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of the country(ies) where the product is approved, and/or where the Sponsor intends to apply for approval(s).
- If the Sponsor discontinues the clinical development of an investigational medicinal product, (i.e. for any or all indications, routes of administration, or dosage forms), the Sponsor should maintain all Sponsor-specific essential documents for at least 2 years after formal discontinuation or in conformance with the applicable regulatory requirement(s).
- The Sponsor-specific essential documents should be retained until at least 2 years after the last approval of a marketing application in the EU and until there are no pending or contemplated marketing applications in the EU/EEA or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational

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product. These documents should be retained for a longer period if required by the applicable regulatory requirement(s) or if needed by the Sponsor.

- Record retention times for Sponsors apply also to the records retained by Contract Research Organisations, Clinical Trial Unit or other agents of the Sponsor, unless arrangements have been made to transfer the documents to the Sponsor. Any transfer of ownership should be documented.

6.1.2 INVESTIGATOR AND INSTITUTION RESPONSIBILITIES

- Essential documents should be retained until at least 2 years after the last approval of a marketing application in the EU and until there are no pending or contemplated marketing applications in the EU or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period however if required by the applicable regulatory requirement(s) or by agreement with the Sponsor. It is the responsibility of the Sponsor to inform the investigator/institution as to when these documents no longer need to be retained.

6.2 TRIALS WHICH ARE NOT TO BE USED IN REGULATORY SUBMISSIONS

It is the responsibility of the Sponsor to consider whether the results of a trial will or may be included in a marketing authorisation application and to take the necessary steps to ensure appropriate retention of the essential documents. Most non-commercial, Investigator-led ('in house') clinical trials are not designed to generate data to support licensing applications for new medicines. It is envisaged that most UHB-Sponsored CTIMPs will fall into this category.

Essential documents of the Sponsor and Investigator from trials which are not to be used in regulatory submissions should be retained for at least 5 years after completion of the trial. These documents should be retained for a longer period if required by the applicable regulatory requirement(s) or by agreement with the Sponsor.

7.0 ACCESSING ARCHIVED MATERIAL

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.

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Access to archived material from UHB-Sponsored CTIMPs will only be permitted via the UHB R&D Office and such access must be requested by the CI/PI (or their delegate) using the 'Researcher Request to Access Archived Material Form' available from the UHB R&D Office. The use of this Form ensures that the integrity of stored clinical trial data is not compromised and enables the UHB to demonstrate control of archiving as required under the Clinical Trials Regulations

8.0 DESTRUCTION OF ESSENTIAL DOCUMENTS

As the permitted destruction date depends upon future events which are unknown at the time of archiving, it is recommended that Investigators should retain essential documents for a minimum of 5 years. The sponsor should notify investigators in writing when their trial records can be destroyed.

All source documentation (e.g. 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. 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 is available from the R&D Office, but researchers must provide their own orange stickers.

8.1 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 UHB R&D Office on request.

Archived documents for UHB-Sponsored CTIMPs will be destroyed at the appropriate time by the UHB R&D Office 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.

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9.0 DOCUMENT FOR USE IN CONJUNCTION WITH THIS SOP

[Archiving Log \(FR-RG-006\).](#)

[List of Archived Documents \(FR-RG-012\).](#)

[Researcher Request to Access Archived Material Form \(FR-RG-007\).](#)

[Label for Archiving Box \(FR-RG-011\).](#)

[Label for Patient Medical Notes \(FR-RG-013\).](#)

10.0 ABBREVIATIONS AND DEFINITIONS

CI	Chief Investigator
ciMDs	Clinical investigations of Medical Devices (ciMDs)
CRF	Case Report Form
CRO	Contract Research Organisation
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTU	Clinical Trial Unit
GCP	Good Clinical Practice
IB	Investigator's Brochure
ICH	International Conference for Harmonisation
ISF	Investigator Site File
MRC	Medical Research Council
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TSF	Trial Site File
UHB	Cardiff and Vale University Health Board
Principal Investigator	The investigator responsible for the research site where the study involves specified procedures requiring site-specific assessment by a REC. For multi site studies, there should be one PI for each research site. In the case of a single site study, the CI and the PI will normally be the same person
Chief Investigator	The investigator with overall responsibility for the research. In a multi site study, the CI has coordinating responsibility for research at all sites.

TABLE 1: ARCHIVING RESPONSIBILITIES FOR DIFFERENT STUDY TYPES.

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	UHB R&D Office	Offsite	5 years	UHB R&D Office	UHB R&D Office	UHB R&D Office	UHB R&D Office/ 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 R&D Office depending on contractual arrangements	Sponsor or R&D Office depending on contractual arrangements
UHB Sponsored non-CTIMP	UHB as Sponsor	CI/PI in liaison with Directorate/Clinical Board	Offsite or Onsite	5 years	CI/PI or delegated individual	CI/PI	CI/PI	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 R&D Office depending on contractual arrangements	Sponsor or R&D Office depending on contractual arrangements