brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

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Archiving Paper Trial Documents – (For BSUH as a Research Site)

SOP Reference:	**SOP/RD/004**
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Version	Date	Reason for Change	Author
2.0	13th Aug 2009	Change in review and implementation policy	Gemma Earl
3.0	13th January 2014	SOP required review and update. Addition of BSUH sponsored, multi-centred archiving arrangements	Gemma Earl
4.0	17th February 2014	Alert sticker process to flag research participants to Health Records has changed	Gemma Earl
1.0	5th February 2016	Alteration to preparation of documents for archiving – no longer need to remove paper clips, plastic wallets, rubber bands Separation of sponsor and site archiving into 2 SOPs	Hannah Butler
2.0	08th Nov 2016	Updated with record retention requirements	Gemma Earl

1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for archiving site study documents in a research study being conducted at Brighton and Sussex University Hospital (BSUH).

2.0 Introduction

Essential documents must be kept so that trial data remains accessible after the study has been completed. The documentation may be needed for a number of reasons including:

- Future studies suggesting a further period of follow-up
- Allegations of fraud
- Patients needing to be contacted due to concerns over side-effects
- Compliance with audit or inspection requirements

Off-site archiving facilities are provided under contract number ELN03 by Iron Mountain. The R&D department should be contacted for any archiving queries or requests. Essential documents should be archived once the site has been closed and the end of study declaration has been received from the sponsor, giving permission for the site to archive.

3.0 Responsibilities

Named Archivist

The named archivist for the Research & Development department (R & D) is responsible for the coordination and compliance of all archiving performed. This includes the following functions:

- Sending documents for archiving
- Retrieving documents from archiving
- Authorising destruction of archived documents

Principal Investigator (PI)

It is the responsibility of the PI to ensure that approval to archive has been received from the sponsor, and that all the essential documents are correct and complete before sending them to the archivist for transfer off-site. This responsibility may be delegated to another member of the research team but must be recorded on the delegation log.

4.0 Procedure

Essential documents for the research site include but are not limited to the following:

- the Investigator Site File (ISF)
- Completed Case Report Forms (CRFs)
- Pharmacy files
- Laboratory records
- Source data

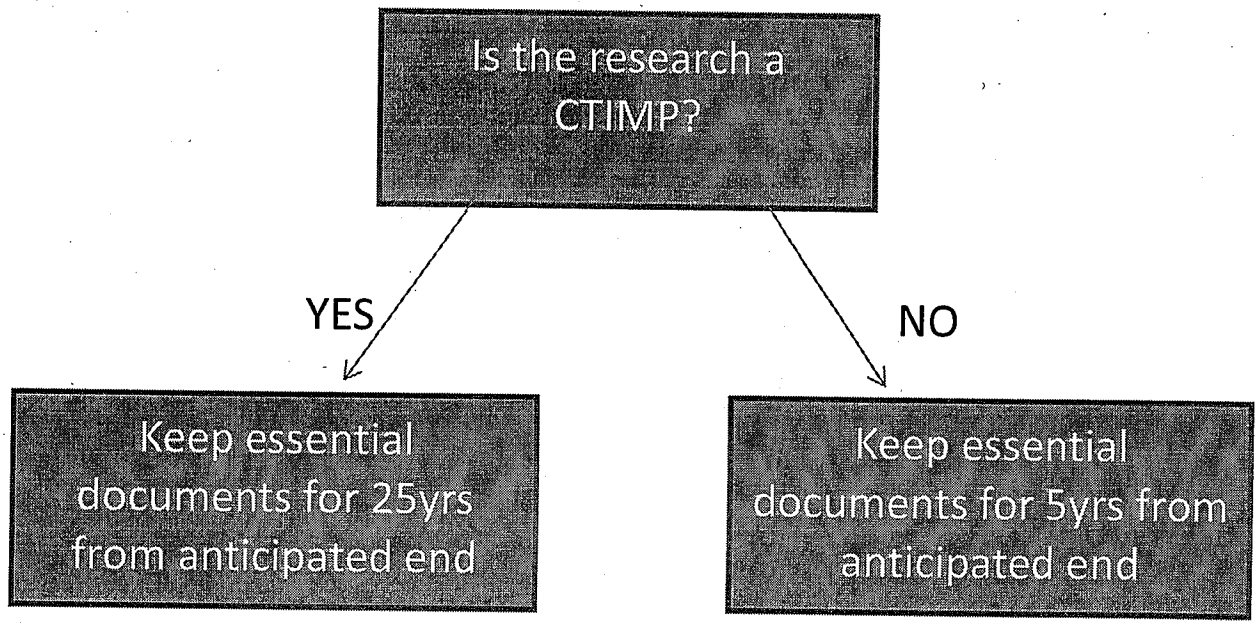
If source data is in the participant's health records then archiving of these should be carried out in accordance with the BSUH Health Records policy and **section 4.1** of this SOP 'Labelling Participant Health Records'.

For all Clinical Trials of Investigational Medicinal Products (CTIMPs), essential documents must be kept for **25 years** after the completion or discontinuation of the trial. **Please note, this does not include trial participant's health records** (see section 4.1 for more information). For all other research studies (all non-CTIMPs), essential documents must be retained for at least **5 years** after the end of the trial.

If you are unsure or working on a trial involving paediatrics or any other patient population where documentation needs to be kept for a longer period of time, please

consult with the sponsor of the study to determine document retention times frames. If the sponsor is unable to advise, please consult with R&D.

The below flow chart shows general record retention guidelines for essential documents. This flow chart does not apply to health records containing source data (see below paragraph).



For participant's health records that include source data, health records must be retained for at least 5 years from the end of the trial in their original format and in accordance with the maximum period of time permitted by the hospital. **This applies to both CTIMPs and all other research.**

4.1 Labelling Trial Participant Health Records

Health records for all research participants should have a pink sticker placed on the front of the outside cover. The sticker should be placed on the participant's notes as soon as they have consented to participate in the research. This alerts the Health Records team to look inside the front cover of the health record for that patient.

The R&D Health Records sticker should be placed on the inside cover of the participant's health record and the date of destruction entered. The date of destruction must be entered as 5 years from the anticipated end of the trial. If the trial is extended or discontinued early then the date of destruction of health records for existing participants should be reviewed to ensure the health records are not destroyed prematurely or kept on unnecessarily.

4.2 Preparing the documents for archiving

The sponsor should determine the time point at which to archive essential documents for a trial and will notify the site when this is permitted. If the sponsor has not provided information on when archiving will be permitted, after requests by the site have been made, a pragmatic approach will be used.

The PI or delegated individual must ensure that all relevant trial documents are present and ready for archiving prior to contacting the Named Archivist.
For CTIMPs, a close out visit will typically be performed by the sponsor Clinical Trial Monitor. Once all findings have been resolved from this visit and the PI has confirmed all study documentation is present then the sponsor should provide confirmation that archiving can proceed. The R&D department should then be contacted to arrange archiving.

Before sending the documents to the Named Archivist, the PI or delegate must ensure that any documentation on thermal paper prone to fading (e.g. ECG printouts, faxes) is photocopied onto standard paper before archiving. All documents must be placed in standard envelopes available from the Named Archivist on request (do not overfill envelopes).
Once all documentation is complete, the envelopes must be placed within a standard Iron Mountain archiving box (available from the Named Archivist). The box must also contain two copies of a full inventory list detailing the contents of the box. (Appendix 1).

Once the above has been completed the boxes should be sent to the Named Archivist.

4.3 Sending boxes to archiving

Upon receipt of a completed box the Named Archivist will complete an Iron Mountain transmittal sheet taking care to affix a barcode label to the box and transmittal sheet.

The transmittal sheet must contain the following information:

- Customer ID – This will always be ELN03
- Date Sent
- Telephone Number
- Customer Name – This will always be Brighton & Sussex University Hospitals NHS Trust
- Department ID – This will be R & D
- Major Description – this should indicate the type of trial e.g. Oncology Clinical Trial
- Minor Description – this should indicate the Disease area e.g. Breast

The date ranges and destruction date do not have to be completed; in the case of the destruction date this can be added at a later date if required.

Up to 5 Archiving boxes can be included on each transmittal sheet.

Once all transmittal sheets are completed they should be stapled together and placed in an "Incoming Records Jacket", The Customer Information details should be completed on the front with details of the number of new boxes.

Once all boxes and transmittal sheets are completed, the Named Archivist will telephone Iron Mountain customer services on 0844 5607080 to request collection of the boxes from 16 Bloomsbury Street, Brighton, BN2 1HQ. This will either be the next day or on a specified date. Iron Mountain will allocate an order number which must be recorded on the archiving excel spreadsheet held on the network shared drive T:\Research&Development\Archiving.

The following information must also be recorded on the spreadsheet:

- R & D Trial Ref/IRAS Number
- Name of PI
- Trial Name
- Sponsor
- Destruction Date (if known)
- Barcode number
- Date Sent
- Order Number

The Named Archivist will keep a copy of the transmittal sheet and separate inventory for each box as a hard copy in the storage room located on level 10 of CIRU and also as a scanned copy uploaded to the network drive archiving folder.

Iron Mountain will provide a packing slip quoting the order number when collecting the boxes for archiving; these will be kept with the transmittal sheets and inventories.

4.4 Retrieving Documents from Archiving

The standard retrieval time of documents from archiving is next day delivery. Documents must be requested by 3.00 pm for delivery by 5.30pm the next day.

As soon as you are aware that you need documents to be retrieved from archiving – e.g. as a result of a MHRA inspection - contact the R&D department by email/telephone with details of the box that needs to be retrieved and when it is needed by.

The Named Archivist will phone Iron Mountain customer services giving details of the customer ID and barcode number of the box required. The Named Archivist will note the details on the archiving spreadsheet including the order number allocated by Iron Mountain for this transaction.

When the boxes are delivered, the date delivered will be entered on the archiving spread sheet by the Named Archivist.

4.5 Returning previously retrieved documents to archiving

Please arrange with the Named Archivist to return previously retrieved documents as soon as they are no longer required for inspection purposes etc.

The Named Archivist will telephone Iron Mountain customer services to request return of documents and will record date sent and allocated order number on the archiving spreadsheet.

A Returned Records Listing (triplicate NCR) must be completed for all returned boxes/documents; Iron Mountain will allocate an order number when the telephone request is made. This must be recorded on the returned records listing together with the barcode number of the returned boxes. The top white copy is given to the Iron Mountain driver on collection, the pink copy is placed with the boxes and the yellow copy is retained by the Named Archivist.

4.6 Destroying Archived Documents

Iron Mountain will not destroy any documents until they have received email confirmation from the Named Archivist that the documents/boxes can be destroyed. It is the responsibility of the sponsor to inform the PI when the essential documents can be destroyed.

If the boxes have been originally archived with a destruction date, Iron Mountain will automatically contact the Named Archivist to confirm that destruction can take place on this date. The Named Archivist will contact the PI or authorised member of the research team and ask for email confirmation that records can be destroyed; once this has been received the Named Archivist will authorise destruction with Iron Mountain and record this on the archiving spreadsheet.

Iron Mountain will issue a certificate of destruction and this must be kept with the transmittal sheets, inventories etc.

If a box was archived without a destruction date this can be requested by the Named Archivist by contacting Iron Mountain customer services.

5.0 Training

This is a 'read and understand' SOP. To evidence that you have read and understood this SOP, please complete your SOP Training Matrix.

Please note that the R&D department discourages the retention of hard copies of SOPs and can only guarantee that the most up-to-date version is on the Trust website.

6.0 Cross Referenced SOPs

n/a

7.0 References

ICH GCP (1996) Section 5.5

Statutory Instrument 1928 (2006), 31A: Trial Master File & Archiving

EU Regulation #536/2014 on Clinical Trial on Medicinal Products for Human Use, 2014

Appendix 1

Archiving Inventory

Date sent to R & D Archivist	Trial Name/Protocol Number	Full Trial Title	Brief description of contents e.g. Trial Master File documents/correspondence	PI	Sponsor	Date to be destroyed (if known)

Appendix 2

R&D Department
This patient is involved in research
DO NOT DESTROY UNTIL
Year of Destruction: ....

R&D Department
This patient is involved research
DO NOT DESTROY UNTIL
Year of Destruction: ....

R&D Department
This patient is involved research
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