UNIVERSITY OF LEICESTER, LOUGHBOROUGH UNIVERSITY
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

UHL Research Support Office
SOP S-1029 UHL v7 November 2019

Standard Operating Procedure for Archiving Paper and Hybrid Format Trial Master Files and Essential Documents for Research Studies sponsored by University Hospitals of Leicester NHS Trust (UHL)

PGC Reference No: C37/2014

OFFICE BASE

Research & Innovation
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW
1. Introduction

This Standard Operating Procedure (SOP) describes the requirements for archiving of all research sponsored by the University Hospitals of Leicester NHS Trust (UHL). Its purpose is to ensure that Trial Master Files (TMFs) for studies are readily available at all reasonable times for inspection by Regulatory Authorities or any person appointed by the Sponsor to audit the study.

Retention of the TMF (including the Investigator Site Files) for Clinical Trials of Investigational Medicinal Products (CTIMPs) and the medical records of subjects involved is a legal requirement. The Sponsor and Chief/Principal Investigator (CI/PI) must ensure that the documents contained, or that have been contained in the TMF, as well as the medical files of trial subjects are retained for at least 5 years after the conclusion of a study and that they are complete and legible. Studies where the data are used to support a marketing application have further requirements as per Directive 2003/63/EC or the prevailing relevant legislation at the time. Subjects' medical records must be retained for at least 5 years in their original format and in accordance with the maximum period of time permitted by the institution to whom they belong.

Arrangements for retention of documents for non-CTIMP studies must be appropriate to the requirements for each individual study.

2. Scope

This SOP applies to all research studies that are sponsored by the UHL. At the time of writing (September 2018) there are no studies sponsored by UHL which use 100% electronic TMF so this SOP refers only to paper and hybrid filing systems. NB Hybrid format refers to where both paper documents, copies of documents scanned or held electronically and electronic platforms e.g. e-CRF are used.

Electronic format refers to a dedicated 100% electronic system e.g. a proprietal system being used to record and store all clinical trial information.

3. Definition

Clinical trial information must be stored in such a way that it can be accurately reported, interpreted and verified. The TMF is a collection of the documentation that allows the conduct of a clinical trial, the integrity of the trial data and the compliance of the trial with GCP and applicable regulatory requirements to be evaluated. SOP S-1015 UHL, Essential Documents and Trial Filing for Research Sponsored by the University Hospitals of Leicester NHS Trust, provides more information on the requirements for the TMF.

4. Individual Responsible for Archiving

At UHL Head of Research Operations is the named person responsible for archiving of CTIMP documentation and for ensuring that access is restricted to themselves, their delegate, auditors and inspectors. The CI is responsible for the completeness and the quality of the documentation that makes up the TMF.

5. Archiving Arrangements

For all studies the Sponsor will inform the investigator(s)/institution(s) in writing of the need for record retention. The Sponsor delegates responsibility for notifying the Head of Research Operations, the investigator(s)/institution(s) in writing to the Chief Investigator (CI) when the trial related records are no longer needed and can therefore be archived.
The provisional arrangements and costings (if applicable) for archiving the TMF will be agreed between the CI and the Sponsor during the initial Sponsor review process. Costs for archiving are the responsibility of the CI and where possible must be included in an application for funding.

The TMF may be filed locally if suitable facilities are available or alternatively off-site through a Sponsor-approved external archiving facility.

The length of time required for archiving depends on the type of research activity. Appendix 5 provides an Archiving Guideline of required length of time.

For multicentre studies, each participating site will be responsible for archiving their Investigator Site File (ISF). The Sponsor (UHL) is not responsible for archiving participating sites’ essential documents.

The Archiving Workflow in EDGE must be completed to detail the archiving arrangements. The Workflow will include: the data format (electronic and/or paper), date of archiving, the exact location of archived study data (including any relevant references e.g. Stor-a-File barcode, box numbers etc), the expected date of destruction and the required method of destruction.

5.1 On Site Archiving

For all research including CTIMPs archived on site the proposed archiving area will be assessed by the Sponsor to ensure it is suitable unless the facilities and storage conditions are already known and approved by the Sponsor. This assessment must be documented using the UHL Archiving Assessment Checklist (Appendix 1). It is possible that at the start of a study facilities may not be 100% ready to be used for Archiving, but there must be a plan of action to ensure that by the time the study is ready for Archiving the facilities are fit for purpose. Each iteration of the Archiving Assessment Checklist must be saved to show progress and will form part of the TMF and audit trail.

Before the TMF is archived, it is recommended that it is checked to ensure that it is complete and that all necessary documentation has been filed. This check should be comprehensive as described in SOP S-1024 UHL.

A Checklist to aid the archiving process can be found at Appendix 2. This final check will usually be undertaken by the trial manager but may also be undertaken by other appropriate personnel. Preparation for archive is expected to be completed by the study personnel.

Before archiving, the contents of the TMF should also be assessed for any records that could be disposed of (for example, duplicates) and those that may be subject to rapid deterioration and will therefore require transferring to a more robust media prior to archiving.

Patient medical records will be subject to arrangements within the NHS Organisation that owns them, but clear identification that the patient has been involved in a Clinical Trial must be evident, e.g. a sticker on the front of the records. In addition, it must be clear if the record must be retained and not destroyed before a specified date.
It is important that where centralised records have been held — for example — staff training records or CVs, that these are considered in the arrangements for archiving and retention as they may be required to be produced in addition to the TMF to demonstrate compliance.

Documentation and records from supporting services i.e. laboratories are required to be archived alongside the TMF, where appropriate.

In addition, pharmacy records and records of vendors or other agents of the Sponsor also form part of the TMF and appropriate arrangements must be made to ensure this documentation is stored appropriately for the required length of time and is retrievable if required.

The ultimate responsibility for the documents to be retained by the investigator or institution resides with the investigator or institution. If the investigator becomes unable to be responsible for their essential documents (for example due to retirement) the Sponsor should be notified in writing and informed to whom the responsibility has been transferred.

Where electronic systems for activities such as data management (e-CRFs), statistical analysis and storing scanned copies of documents are being utilised, the electronic data /documentation needs to be retained. The data may be on a server or transportable media. It is recommended that more than one copy of the data is retained (e.g. a back-up server or back up media stored in a separate location) Consideration should be given to storing the data in differing formats on different types of media or even on the same media from different manufacturers.

Access to archived data must be suitably restricted, either by user access levels to the archive area of a server or by controls to access the storage area where the media are retained. Additionally the electronic documents or data that have been archived must be protected from unauthorised changes to maintain authenticity.

It is important to consider the most appropriate media for archiving electronic documentation. The selected medium should be unlikely to become obsolete during the archiving period. Archived data should be transferred to a newer or more appropriate media if necessary. Consideration must also be given to the software/hardware requirements in order to maintain readability of the data for the archive period.

Where electronic data is produced by a Clinical Trials Unit (CTU), the responsibility for archiving this data is delegated to the CTU.

5.2 Off Site Archiving

For all research including CTIMPs archived off site and not using the Sponsor approved facility (Stor-a-File), the proposed archiving area will be assessed by the Sponsor to ensure it is suitable unless the facilities and storage conditions are already known and approved by the Sponsor.

This assessment must be documented using the UHL Archiving Assessment Checklist (Appendix 1). It is possible that at the start of a study facilities may not be 100% ready to be used for Archiving, but there must be a plan of action to ensure that by the time the study is ready for Archiving the facilities are fit for purpose. Each iteration of the Archiving Assessment Checklist must be saved to show progress and will form part of the TMF and audit trail.
Before the TMF is archived, it is recommended that it is checked to ensure that it is complete and that all necessary documentation has been filed. This check should be comprehensive as described in SOP S-1024 UHL.

A flow chart detailing the process is available at Appendix 3.

5.3 Preparation for archiving

A Checklist to aid the archiving process can be found at Appendix 2. This final check will usually be undertaken by the trial manager but may also be undertaken by other appropriate personnel. Preparation for archive is expected to be completed by the study personnel.

Before archiving, the contents of the TMF should also be assessed for any records that could be disposed of (for example, duplicates) and those that may be subject to rapid deterioration and will therefore require transferring to a more robust media prior to archiving.

Patient medical records will be subject to arrangements within the NHS Organisation that owns them, but clear identification that the patient has been involved in a Clinical Trial must be evident, e.g. a sticker on the front of the records. In addition, it must be clear if the record must be retained and not destroyed before a specified date.

It is important that where centralised records have been held – for example – staff training records or CVs, that these are considered in the arrangements for archiving and retention as they may be required to be produced in addition to the TMF to demonstrate compliance.

Documentation and records from supporting services i.e. laboratories are required to be archived alongside the TMF, where appropriate.

In addition, pharmacy records and records of vendors or other agents of the Sponsor also form part of the TMF, and appropriate arrangements must be made to ensure this documentation is stored appropriately for the required length of time and is retrievable if required.

The ultimate responsibility for the documents to be retained by the investigator or institution resides with the investigator or institution. If the investigator becomes unable to be responsible for their essential documents (for example due to retirement) the Sponsor should be notified in writing and informed to whom the responsibility has been transferred.

5.4 Arranging for archiving

Storage is available at Stor-a-File, Wenlock Way, Leicester, LE4 9HU (part of Leicester Micro Bureau Limited (LMB)) who have NHS relationships throughout England and Wales. They offer a fully comprehensive security system together with every possible retrieval and storage requirement, both now and in the future. Bar coding at the point of
collection, together with full tracking facilities exist to ensure knowledge of wherever a particular set of data is at a particular time.

In order to request boxes for storage at the facility please complete FORM A.

All related costs in relation to the archiving process are at the Chief Investigator’s expense e.g.:

- Boxes – minimum of 10
- Archiving to Stor-a-File
- Storage
- Retrieval

Relevant invoices will be sent to the billing address given on the attached form(s) and must be paid promptly.

5.5 Sending files to storage

A designated individual within the research team must take responsibility for the process for a specific trial. The Research & Innovation (R&I) Office must be contacted at the outset for details of current costings. Boxes and Barcodes may then be ordered on the attached ‘Form A-Request for Boxes & LMB ‘Barcodes for Archiving’

The R&I Office will contact Stor-a-file to place the order and arrange delivery of printed Barcodes and boxes to a specified location. A minimum of 10 boxes and Bar Codes will be provided at each request.

Following receipt of the boxes and LMB barcodes and archive completion, the boxes must be filled in accordance with Appendix 2. Once the boxes have been checked by the Research Manager, a FORM B must be completed and forwarded to the R&I office.

A copy of all 3 sections of the form - numbered FORM B (1), (2) & (3) should be retained for your records and a copy of the sheet noting the LMB barcodes and contents of the boxes should be placed with the boxes to be archived.

The R&I Office will then contact Stor-a-file who in turn will arrange the date and time of collection with the contact person named on the form.

5.6 Change of ownership/responsibility

There may be occasions where change of ownership may be required e.g. Investigators may retire, CTU/external vendors may close or be acquired by other organisations such that the responsibility for the TMF is transferred. The Sponsor must be informed of any transfer of ownership. This is to ensure that the TMF remains available for inspection for the required retention time.

5.7 Retrieval of Archived documents

The R&I Office will facilitate all requests for retrieval of Archived documentation. Only authorised personnel from the R&I Office are permitted to request retrieval. A test of the system is made annually.
In order to request retrieval of archived documents, FORM C must be completed and sent to the R&I Office using RIAdmin@uhl-tr.nhs.uk. On receipt the request will be sent to Stor-a-File with details of delivery point and responsible person.

Once a request has been made, Stor-a-File will scan the stated LMB Barcode permitting 'exit from store'. The box can be tracked en route to stated location and on reaching its destination the same mechanism is used to identify that the box is now at that location. This ensures that the LMB database identifies retrieval from store and the date and time the box arrived at the requested location.

On arrival of the box, the receiver must notify the R&I Office of arrival. The R&I Office will then return Form C to the requestor. The box(s) can be logged out for a period of one month only for Investigator File/Case Notes and therefore must be returned within a maximum of one month unless express arrangements have been made with the Head of Research Operations, in advance for the documentation to be retained out of storage for longer periods.

For return, Part 2 of the original FORM C must be completed and forwarded to the R&I office who in turn contact Stor-a-file regarding collection. It is essential that the documents retrieved are returned in full and R&I are informed of completed collection.

A flow map detailing the process is available at Appendix 4.

5.8 Destruction

It is the responsibility of the Sponsor to alert investigators when the archiving period has expired for their study. (Appendix 6).

It is the responsibility of the investigator/research team to complete the destruction of study data, as per UHL Waste Management Policy and Guidance. Where the investigator/research team is no longer employed by the trust, the relevant CMG or research group will be contacted to complete the destruction process.

For multicentre studies, it is the responsibility of the CI/PI/Delegated individual to ensure that all sites receive and complete Form D Part 2 and Part 3 (where applicable). Each site should retain a copy of the form and file in the Investigator Site File with a copy being provided for the Trial Master File.

Upon expiry of the archiving period, the Sponsor will email the investigator with a copy of Form D and instructions on the destruction process. The Sponsor will require confirmation of receipt of the email within 10 working days.

Where electronic documents have been used, the Investigator will ensure that all copies of archived study data held in any format i.e. individual devices, hard drives, CD, USB sticks and computer servers are permanently deleted as soon as the study has been reported and the participants notified of the results.

If study data has been archived with Stor-a-File, Form D Part 1 will outline the details of the team completing destruction, and to whom the archived data will be sent. This needs to be returned to the R&I Admin team, who will contact Stor-a-File to retrieve the data. If study data was not archived with Stor-a-File (e.g. if onsite local research
storage is available) then this must be communicated to the Sponsor via email, and Form D Part 1 does not need to be completed.

Completion of Form D Part 2 is mandatory for all UHL sponsored studies, and is not dependent on the location of archiving. Form D Part 2 and Part 3 (where applicable) confirms destruction of the study data; this must be sent back to the Sponsor once the destruction has been completed. The Sponsor will only consider the Archiving-Destruction process complete upon receipt of Form D Part 2/3.

### 6. Responsibilities

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 UHL Head of Research Operations &amp; CI</td>
<td>UHL Head of Research Operations &amp; CI</td>
<td>Agree the provisional arrangements for archiving and the costings (if any) during the Sponsor review process.</td>
</tr>
<tr>
<td>2 UHL Head of Research Operations</td>
<td>UHL Head of Research Operations or delegate</td>
<td>Perform and document an assessment of proposed on-site archiving area if it is not already known to be suitable.</td>
</tr>
<tr>
<td>3 UHL Head of Research Operations</td>
<td>UHL Head of Research Operations or delegate</td>
<td>Responsible for Archiving TMFs.</td>
</tr>
<tr>
<td>4 CI</td>
<td>CI</td>
<td>Responsible for costs of archiving using an external archive facility where required</td>
</tr>
<tr>
<td>5 CI</td>
<td>CI or delegate</td>
<td>Responsible for the contents of the TMF.</td>
</tr>
<tr>
<td>6 CI</td>
<td>CI</td>
<td>Appoint another person responsible for the TMF and inform the Sponsor if they are no longer able to be responsible.</td>
</tr>
<tr>
<td>7 CI</td>
<td>Monitor or other appropriate individual</td>
<td>Perform a TMF Archiving Readiness check prior to archiving.</td>
</tr>
<tr>
<td>8 UHL Research &amp; Innovation</td>
<td>UHL Research &amp; Innovation Admin</td>
<td>Inform investigator of expiration of archiving period, advise that destruction needs to be completed.</td>
</tr>
<tr>
<td>9 CI</td>
<td>CI or delegate</td>
<td>Complete destruction per SOP S-1029 &amp; Form D</td>
</tr>
</tbody>
</table>
This table is used to track the development and approval of the document and any changes made on revised / reviewed versions:

**DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT**

<table>
<thead>
<tr>
<th>Author / Lead Officer:</th>
<th>Job Title: Medical Writer, Clear Clinical Research Ltd &amp; Head of Research Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carolyn Maloney</td>
<td></td>
</tr>
<tr>
<td>Reviewed by:</td>
<td>UHL R&amp;I Management Meeting</td>
</tr>
<tr>
<td>Approved by:</td>
<td>Professor Nigel Brunskill</td>
</tr>
<tr>
<td>Date Approved:</td>
<td>9/12/2019</td>
</tr>
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**REVIEW RECORD**

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<th>Date</th>
<th>Issue No.</th>
<th>Reviewed By</th>
<th>Description Of Changes (If Any)</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2015</td>
<td>2</td>
<td>Carolyn Maloney</td>
<td>Change of Logo and corporate identity</td>
</tr>
<tr>
<td>December 2016</td>
<td>3</td>
<td>Carolyn Maloney</td>
<td>Addition of Appendices to manage archive storage and retrieval. Management of archive and responsible individuals. Consistency check</td>
</tr>
<tr>
<td>March 2017</td>
<td>5</td>
<td>Carolyn Maloney</td>
<td>Update to logo.</td>
</tr>
<tr>
<td>September 2018</td>
<td>6</td>
<td>CCL, JJ, LW</td>
<td>Update to R&amp;I logo. Clarification of ISF archiving responsibilities §5 - Addition of EDGE workflow Addition of §5.7 Destruction Updated responsibilities</td>
</tr>
<tr>
<td>November 2019</td>
<td>7</td>
<td>AM, CM</td>
<td>Strengthen inclusion of support services documents. Inclusion of ‘hybrid’ TMF / ISF</td>
</tr>
</tbody>
</table>

**DISTRIBUTION RECORD:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Name</th>
<th>Dept</th>
<th>Received</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Archiving of Essential Documents for Research Studies Sponsored by the University Hospitals of Leicester NHS Trust with SOP S-1029 UHL

This document must be completed during the Sponsor application process where a request has been submitted for University Hospitals of Leicester (UHL) to act as the sponsor for a research study. This form only needs to be completed if the intention is to archive Trial Master Files (TMFs) in alternative storage facilities than Stor-a-file. Once completed the document must be sent to the Head of Research Operations and a copy stored in the Trial Master Files (TMFs).

The purpose is to ensure that the TMF for research studies are readily available at all reasonable times for inspection by the MHRA or any person appointed by the UHL to audit the study.

Please complete the form clearly and if not using typescript, please PRINT the words to enable legibility.

<table>
<thead>
<tr>
<th>Full Study Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Reference Number</td>
</tr>
<tr>
<td>Chief Investigator</td>
</tr>
<tr>
<td>Point of Contact (contact details)</td>
</tr>
</tbody>
</table>

| Is the storage facility on or off site? (If offsite is the facility sponsor approved?) |
| Where is the storage facility located? |
| How long is this study documentation to be stored for? |
| Which individual is responsible for the day to day management of the facility? Include contact details |
| Who has access to the storage facility? (please list the names & contact details) |
| Are the rooms/ cabinets lockable? |

Confirm the facilities are secure, with appropriate environmental controls and adequate protection from fire, flood, rodent, pest and unauthorized access.

**NB:** If the investigator becomes unable to store their essential documents, the sponsor should be notified in writing so that alternative storage arrangements can be agreed. If the investigator is no longer able to maintain custody of the essential documents, the sponsor should be notified in writing to arrange an appropriate alternative.

Chief Investigator: .......................................................... Date: ..........................................................
Sponsor: .......................................................... Date: ..........................................................

Appendix 1 – UHL Archiving assessment checklist
SOP S-1029 UHL

Version 7 November 2019
Pre-archiving check list

The purpose of this document is to ensure that all archiving is completed to an approved standard. That all archived materials are stored appropriately and for the correct period of time.

Please note that archived documents must NEVER be sent to the Sponsor and must be facilitated by an intermediary e.g. Sponsor Monitors.

Please complete the form clearly and if not using typescript, please PRINT the words to enable legibility.

<table>
<thead>
<tr>
<th>Has the sponsor confirmed close out</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have copies of the close out documentation to evidence sponsor close out?</td>
</tr>
<tr>
<td>Have all patient complete all treatments &amp; visits?</td>
</tr>
<tr>
<td>Has all data been collected?</td>
</tr>
<tr>
<td>Where appropriate, has all drug accountability been performed?</td>
</tr>
<tr>
<td>Have all outstanding issues been resolved?</td>
</tr>
<tr>
<td>Are all data queries resolved?</td>
</tr>
<tr>
<td>Is the site file complete?</td>
</tr>
<tr>
<td>Has the sponsor stipulated length of archive?</td>
</tr>
<tr>
<td>Have all documents relating to the study been collected from all other departments e.g. Laboratory, Pharmacy etc?</td>
</tr>
<tr>
<td>Where samples are to be retained have the consent forms been saved to evidence consent after the archive has been destroyed?</td>
</tr>
<tr>
<td>Have all records on thermal paper been transferred to normal paper e.g. ECGs, faxes etc?</td>
</tr>
<tr>
<td>Have all plastic / metal clips, rubber bands and plastic wallets been removed?</td>
</tr>
<tr>
<td>Have files been removed from Lever arch files or Manilla wallets?</td>
</tr>
<tr>
<td>Has a cover sheet been created for each section?</td>
</tr>
<tr>
<td>Has an index been created for each box and a complete archive index retained?</td>
</tr>
<tr>
<td>Have dates of destruction been recorded?</td>
</tr>
<tr>
<td>Full Study Title</td>
</tr>
<tr>
<td>----------------------------------</td>
</tr>
<tr>
<td>Study Reference Number</td>
</tr>
<tr>
<td>Chief Investigator</td>
</tr>
<tr>
<td>Point of Contact (contact details)</td>
</tr>
</tbody>
</table>

Chief Investigator: ........................................ Date: ........................................

Sponsor: ....................................................... Date: ........................................
Archiving Process

PLEASE NOTE ALL RELATED COSTS IN RELATION TO THE ARCHIVING PROCESS ARE AT THE PRINCIPAL INVESTIGATOR’S EXPENSE

1. Contact R&I for current costings

2. Form A to be completed for boxes and barcodes and forwarded to R&I who will contact Stor-a-File and arrange delivery

3. When documents are ready to archive, complete Form B, parts 1, 2 & 3 and send form to R&I. A copy of all 3 sheets should be retained and another copy of sheet 3 should be placed with the boxes being archived

4. R&I will contact Stor-a-File who will then contact the person named on the form to arrange a date and time for collection

5. Stor-a-File will forward to R&I an electronic spreadsheet of this archived information stored on their database. R&I will forward a copy to the requester who must check this information against their hard copies

Appendix 3 – Archiving process Flowchart Version 7 November 2019
RETRIEVAL PROCESS FLOW CHART

PLEASE NOTE THIS IS A DESIGNATED RESEARCH & INNOVATION PROCEDURE AND IS PASSWORD PROTECTED TO ENSURE THAT ONLY THE R&I OFFICE HAS AUTHORITY TO RETRIEVE REQUESTED INFORMATION

Contact R&I for Form C. Part 1 of this form requests full information of the documents that need to be retrieved

Forward Form C to the R&I office and they will contact Stor-a-File who will then arrange a date and time for delivery with the person named on the form

On arrival of the documents the requester must inform R&I who will return Form C to them. Case Notes may be logged out for a maximum period of one month.

To return the retrieved document, Form C, part 2 must be completed and forwarded to R&I who in turn will contact Stor-a-File regarding collection. All documents retrieved must be returned in full and R&I advised of completed collection.
# Archiving Time Table

The table below is designed to provide guidance on the minimum Sponsor/ regulatory requirements for archiving of study data for studies sponsored by University Hospitals of Leicester NHS Trust. Archiving requirements for individual studies will be reviewed and confirmed at as part of the Sponsor review.

<table>
<thead>
<tr>
<th>Type of study</th>
<th>Retention Time Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial of an Investigational medicinal product</td>
<td>Trials which are not to be used in regulatory submissions</td>
</tr>
<tr>
<td>Clinical investigation or other study of a medical device</td>
<td>At least five years after completion of the trial. These documents should be retained</td>
</tr>
<tr>
<td>Combined trial of an investigational medicinal product and an investigational</td>
<td>for a longer period if required by the applicable regulatory requirement(s), the</td>
</tr>
<tr>
<td>medicinal device.</td>
<td>sponsor or the funder of the trial</td>
</tr>
<tr>
<td>Clinical trial to study a novel intervention or randomised clinical trial to</td>
<td>Trials to be included in regulatory submissions</td>
</tr>
<tr>
<td>compare interventions in clinical practice</td>
<td>The sponsor-specific essential documents should be retained for at least 15 years</td>
</tr>
<tr>
<td>Basic science study involving procedures with human subjects</td>
<td>after completion or discontinuation of the trial or for</td>
</tr>
<tr>
<td>Study administering questionnaires/interviews for quantitative analysis or</td>
<td>at least two years after the last approval of a marketing application in the EU.</td>
</tr>
<tr>
<td>using mixed quantitative/qualitative methodology</td>
<td></td>
</tr>
<tr>
<td>Studies involving qualitative methods only</td>
<td></td>
</tr>
<tr>
<td>Studies limited to working with Human tissue samples (or other human biological samples)</td>
<td></td>
</tr>
<tr>
<td>Studies working with data (specific project only)</td>
<td></td>
</tr>
<tr>
<td>Research Tissue Banks</td>
<td></td>
</tr>
<tr>
<td>Research Databases</td>
<td></td>
</tr>
</tbody>
</table>

Appendix 5: Archiving timetable guidance Version 7 November 2019
(Sponsor Expiry of Archiving Period Notification)

Dear (INSERT NAME)

As sponsor of the above study we are contacting you to advise that the archiving period for the following study has now expired:

EDGE Number/IRAS Number:

Study Title:

Date study archiving period expired:

Please complete and return the attached form to confirm that destruction has occurred.

PLEASE BE AWARE THAT WE REQUIRE CONFIRMATION OF RECEIPT OF THIS EMAIL WITHIN 10 WORKING DAYS OF THE DATE OF THIS EMAIL.
Appendix A

Form A-Request for Boxes & LMB Barcodes for Archiving

Please complete this request form & forward it to the Research & Innovation Office
The Manager
Research & Innovation
Research Office
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW
Tel: 0116 258 4109
Email: RIAadmin@uhl-tr.nhs.uk

ALL ARCHIVING MUST BE PROCESSED THROUGH THE RESEARCH OFFICE

<table>
<thead>
<tr>
<th>Research Study Title &amp; UHL Study Number/REC Ref:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Boxes Required:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of A3...............</td>
</tr>
<tr>
<td>Number of A4...............</td>
</tr>
<tr>
<td>Total Number of LMB Barcodes Required.........................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact details at site for delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name..................................Telephone Number.................................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Full address for delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>..................................................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name &amp; Full Billing Address for Invoice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost Code..............................Name of Budget Holder (PRINT)..........................</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature of Budget Holder..................</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Billing Address &amp; Contact Telephone Number</td>
</tr>
<tr>
<td>..................................................</td>
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</tbody>
</table>

Form A: - Request for Boxes & LMB Barcodes for Archiving Version 7 November 2019
Appendix B

Form B - Request for research documentation to be archived by Stor-a-File

Please complete the 3 page request form & forward it to the Research & Innovation Office

The Manager
Research & Innovation
Research Office
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Tel: 0116 258 4109
Email: RIAadmin@uhl-tr.nhs.uk

Form B (1)
ALL ARCHIVING MUST BE PROCESSED THROUGH THE RESEARCH OFFICE

<table>
<thead>
<tr>
<th>Research Study Title &amp; UHL Study Number/REC Ref:</th>
</tr>
</thead>
<tbody>
<tr>
<td>.........................................................................</td>
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<td>.........................................................................</td>
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<td>.........................................................................</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Principal Investigators Name and Contact Details:</th>
</tr>
</thead>
<tbody>
<tr>
<td>.........................................................................</td>
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<td>.........................................................................</td>
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</tbody>
</table>

<table>
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<tr>
<th>Research Nurse/Facilitator and Contact Details:</th>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Date study completed</th>
<th>To be retained for ...... years</th>
</tr>
</thead>
<tbody>
<tr>
<td>----------------------</td>
<td>-------------------------------</td>
</tr>
</tbody>
</table>

The above information must be clearly identified on individual boxes

Name & Full Billing Address for Invoice
Cost Code........................Name of Budget Holder (PRINT)..........................
Signature of Budget Holder................................................
Full Billing Address & Contact Telephone Number
..........................................................................................
..........................................................................................

Study documentation must not be moved or destroyed without permission of both the Sponsor and the Investigator.
Form B (2)

Number of boxes: ............  Size / Dimensions:  ...................... 
FOR FUTURE RETRIEVAL EACH BOX MUST HAVE A LMB BARCODE. The LMB barcode &
contents of each box should be documented and a copy including the completed table retained.

Checked, packed and sealed in secure archive boxes by:  - Name: ......................................................
Job Title: ................................................................
Signature: ........................................  Date: ........................................

Sponsor contact details
Sponsoring Organisation:
...........................................................................................................

Address: ............................................................................................................................
............................................................................................................................
............................................................................................................................

Sponsor notification of archive location
Name of person who agreed to new archived location:
............................................................................................................................

TelephoneNumber: .................................................. (PRINT)
Date person agreed: ........................................

Contact details at site for collection
Name: ............................................................  Tel: ............................................................
Full details of location for collection: ................................................................................
............................................................................................................................

Form Completed by (name) ..........................................................  Signed:  ........................................
Job Title: ............................................................ Signed:  ........................................

PLEASE NOTE:-
FOR PROGRESSION OF THIS FORM THE PI’s SIGNATURES IS REQUIRED AND ALL THE
ABOVE INFORMATION MUST BE COMPLETED BEFORE BEING SENT TO THE
R&I OFFICE.

Archiving Authorised by Principal Investigator

Name: ............................................................ (PRINT)
Signed: ............................................................ Date: ............................................................
EXAMPLE

Archiving LMB Barcode References and Contents

NAME OF STUDY
THE PEANUT STUDY

SPONSOR
UHL

UHL Study Number 02345

REC Reference Number 5416

Destroy Date June 2015

<table>
<thead>
<tr>
<th>BOX NO</th>
<th>LMB BARCODE</th>
<th>CONTENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>329167</td>
<td>CRF's Nos 1-4</td>
</tr>
<tr>
<td>2</td>
<td>329168</td>
<td>CRF's Nos 5-10</td>
</tr>
<tr>
<td>3</td>
<td>329169</td>
<td>CRF's Nos 11-20</td>
</tr>
<tr>
<td>4</td>
<td>329170</td>
<td>Investigator folder or sections of, i.e Approvals, amendments, correspondence</td>
</tr>
</tbody>
</table>
Archiving LMB Barcode References and Contents

Form B (3)

NAME OF STUDY

SPONSOR

PRINCIPAL INVESTIGATOR

UHL Study Number

REC Reference Number

Destroy Date

<table>
<thead>
<tr>
<th>BOX NO</th>
<th>LMB BARCODE</th>
<th>CONTENTS</th>
</tr>
</thead>
<tbody>
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</table>
APPENDIX C
Form C-Request for Research Documentation to be retrieved from Stor-a-file

FORM C: PART 1

Name of person requesting information
Contact telephone number
UHL Study Number/REC Ref
LMB Barcode
Box Reference
For what purpose is the retrieval of information required?

Contact details at site for delivery
Name
Tel:
Full details of location

Name and Full Billing Address for Invoice
Cost Code
Name of Holder (PRINT)
Signature of Holder
Full Billing Address & Contact Telephone Number

Form Completed by (name)
Job Title: Signed:

PLEASE NOTE
FOR PROGRESSION OF THIS FORM THE PI's SIGNATURES IS REQUIRED AND ALL THE ABOVE INFORMATION MUST BE COMPLETED BEFORE BEING SENT TO THE R&I OFFICE.

Retrieval of Archiving Authorised by Principal Investigator
Name (PRINT)
Signed
Date

Form C-Request for Research Documentation to be retrieved from Stor-a-file
Version 7 November 2019
CONFIRMATION OF DOCUMENT(S) TO BE RETURNED AFTER RETRIEVAL

**FORM C: PART 2**

<table>
<thead>
<tr>
<th>LMB Barcode</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

<table>
<thead>
<tr>
<th>UHL/REC Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Date retrieval originally requested on ..................................................

Date box received from Stor-a-file ......................................................

Date R&I contacted on to advise ready for collection ................................

Contact details at site for collection

Name......................................................................Telephone Number

Full details of location for collection..........................................................

......................................................................................................................

**Confirmation box/documents are being returned in full**

Name......................................................................Telephone Number

Signature.................................................................................................

For R&I Office purposes only:-

Date confirmation received from Stor-a-file that collection has been completed ..................
APPENDIX D
Form D – Request for Retrieval of Research Documentation for
Destruction at Expiry of Archiving

FORM D: PART 1

Name of person requesting information

Contact telephone number

UHL Study Number/REC Ref

LMB Barcode

Box Reference

Contact details at site for delivery

Name Tel:

Full details of location

Name and Full Billing Address for Invoice

Cost Code Name of Holder (PRINT)

Signature of Holder

Full Billing Address & Contact Telephone Number

Form Completed by (print name):

Job Title:

Signed: Date:

For R&I Office purposes only:-

Date confirmation received from Stor-a-File that collection has been completed:

Name:

Signature:

Date:

Form D – Request for Retrieval of Research Documentation for Destruction at Expiry of Archiving

Version 7 November 2019

1 of 5
CONFIRMATION OF DESTRUCTION OF PAPER FORMAT RECORDS

FORM D: PART 2

Records Destruction Form

1. Short Study Title: ...........................................................................................................................................

2. Edge Number ............
   IRAS Ref: .................

3. Site .........................................................

4. Date confirmation received from Sponsor that study archiving period expired  --/--/-----

5. Details of all Records Destroyed

6. Date of Destruction  --/--/-----

7. Confirmation of process of destruction ........................................................................................................

8. CI/ Delegated Individual confirming destruction completion
   Name: ..............................................................................................................................
   Role: ............................................................................................................................
   Signature: ..................................................................................................................
   Date: ..........................................................................................................................
Guidance Document for FORM D PART 2 Confirmation of destruction of paper format documents

Form completion instructions:

1. Short Study title as listed on IRAS application
2. Enter Sponsor assigned EDGE number for the study
   Enter IRAS reference number
3. Site: enter details of site. For multicentre studies a completed form will be required for each
   collaborating centre
4. Enter date of Sponsor email confirming that archiving period is complete. A copy of this email should
   be filed in the archiving section of the Trial Master File/Investigator site file/s
5. Details of all documents destroyed should be listed. For example (paper format)
   - Site File/Trial Master File Volumes 1 to 5.
   - Pharmacy File Volume 1 and 2
   - Case report forms for all subjects (list details).

NB. Where consent for future research is in place, consent forms must be retained for the period
stated within the IRAS application. Anonymised datasets and samples covered by this consent
may be retained.

6. Complete date that all records were destroyed
7. Confirmation of process of destruction e.g. via confidential waste bins/ collection by Universities
   disposal process
8. CI/delegated individual to sign and date form

CONFIRMATION OF DESTRUCTION OF DIGITAL/ELECTRONIC FORMAT RECORDS

Form D – Request for Retrieval of Research Documentation for Destruction at Expiry of Archiving

Version 7 November 2019
Records Destruction Form

1. Short Study Title: .................................................................

2. Edge Number: .............

   IRAS Ref: ..............

3. Site: .................................................................

4. Date confirmation received from Sponsor that study archiving period expired: --/--/--

5. Details of all Records Destroyed:

6. Date of Destruction: --/--/--

7. Confirmation of process of destruction: .................................................................

8. CI/Delegated Individual confirming destruction completion

   Name: ...................................................................................

   Role: ...................................................................................

   Signature: ...........................................................................

   Date: ...................................................................................

R&I Office Use Only:

Name: ................................................................. Signature: .................................................................

Date: ............................................................

Form D – Request for Retrieval of Research Documentation for Destruction at Expiry of Archiving

Version 7 November 2019
Guidance document for Form D PART 3 Confirmation of Destruction of Digital Format Records/Databases

Form completion instructions:

1. Short Study title as listed on IRAS application

2. Enter Sponsor assigned EDGE number for the study
   Enter IRAS reference number

3. Site: enter details of site. For multicentre studies a completed form will be required for each collaborating centre

4. Enter date of Sponsor email confirming that archiving period is complete. A copy of this email should be filed in the archiving section of the Trial Master File/Investigator site file/s

5. Details of all records destroyed should be listed. It is very easy for multiple copies of digital information to exist, therefore it is vital that all various locations that records could be stored, have been considered. The Investigator must ensure that all copies of archived study data held in any format i.e. virtual platforms e.g. Cloud based, APPS or on individual devices, hard drives, cd, usb sticks and computer servers are permanently deleted

NB. Where consent for future research is in place, consent forms/ eConsent must be retained for the period stated within the IRAS application. Anonymised datasets and samples covered by this consent may be retained.

6. Complete date that all records were destroyed

7. Confirmation of process of destruction e.g. storage device securely wiped/CD destroyed / virtual platform records deleted.

8. CI/delegated individual to sign and date form