BU Bournemouth University

BU RDS SOP 001 V1

Title: Archiving Clinical Research Records	
Effective Date: 19/11/2019	Review Date: 19/11/2020
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1. Scope

1.1 This document applies to all researchers and Sponsor staff supporting research projects sponsored or co-sponsored by Bournemouth University and any hosted studies.

1.2 This Standard Operating Procedure (SOP) may also be used by staff from other organisations, with prior agreement.

2. Responsibilities

The *Archive team* is responsible for ensuring the research data is stored securely, retrieved and destroyed appropriately.

The *Chief Investigator (CI)/Researcher* is responsible for ensuring the research data are archived and not destroyed before the agreed date as set-out in the REC application and study protocol. The CI/Researcher must also ensure that data is retained no longer than the conditions set out in the REC application and study protocol, or according to the requirements set out by the funder. They are also responsible for ensuring research data is available for audit or inspection.

The *Sponsor* should ensure that there are sufficient archiving facilities and that there is a suitable named Archivist. They are also responsible for informing the participating organisations of the retention period and as to when documents no longer need to be retained.

The *Principal Investigator (PI) and participating site study team* are responsible for confirming archiving requirements with the study Sponsor prior to the research commencing. Each participating site should log the dates of archive alongside details of the designated Archivist.

3. Procedure

<u>Introduction</u>

3.1 Research documents are those held in the Sponsor's file and the individual site's Investigator Site File (ISF). Both of these records together form the Trial Master File (TMF). All of these records must be archived by the end of the study (i.e. after final publication), however in certain situations a site can contact the Sponsor, in order to

request to prematurely archive their study folders (e.g. if the study was closed early at site due to staff departure, for example).

3.2 Research data and project files may be created in electronic and/or paper form. Some source documents may be held on paper, but some records may be held electronically, such as patient medical records. GCP guidelines address both of these methods.

Archiving

3.3 The retention period for each research project will be documented in the application to the Research Ethics Committee (REC) via the IRAS application form. A favourable opinion must be given by the REC before any study activity takes place. It is *recommended* that non-interventional (observational) studies be archived for 5 years once the site Principal Investigator (PI) has signed the end of study declaration.

The Sponsor may decide to set a longer retention period, for example if the study involves children. This should be decided on a case-by-case basis, and the CI/Researcher should declare this in the study protocol. If the CI/Researcher decides to extend the archiving period then they must first seek agreement from the appropriate body/organisation (e.g. REC, Sponsor and/or funder). Interventional studies and Clinical Trials of Investigational Medicinal Products (CTIMPs) have varying recommended periods of retention (see Appendix document) (Information Governance Alliance (IGA), 2016).

3.4 The Sponsor is responsible for arrangements for archiving; including periods of retention, and this should be agreed and documented between the sponsoring organisation and each participating site at project set-up. The schedule for archiving, alongside the division of responsibility is outlined in each study contract and should be documented in the TMF. The CI/Researcher must determine whether they will archive the participating sites' ISFs alongside the Sponsor file as the TMF, or allocate each site to archive their own study records.

3.5 If the research project involves NHS patients, then their paper medical records should be archived for 5 years after the conclusion of the trial (Statutory Instrument, 2006). Although these guidelines refer to studies involving medicines, it is good practice to follow in non-medicinal/non-interventional projects.

3.6 It is a legal requirement that the Sponsor appoints a named individual (Archivist) within their organisation and gives them the responsibility to archive documents which are, or have been contained in the TMF, alongside Case Report Forms. This staff member is also responsible for ensuring that the documentation is restricted to those appointed individuals and auditors or inspectors. The Sponsor may appoint more than one person to undertake this duty but must ensure that there is clear documentation detailing the appointment(s) and that there is a full training record in support of the responsibility. The aforementioned staff must have a clear legal link to the sponsoring organisation (either through employment or contractual links, or that they are the Sponsor themselves).

Archiving Process

3.7 The designated Archivist and the archive team are responsible for guaranteeing that the research data they are archiving is protected at all times. In accordance with GCP, the archive team must ensure that the study records are protected from the environment (i.e. mould, pests, damp, fire etc.). The archive team are also tasked with ensuring that there is controlled access to the study records along with any request for review, relocation, return requests or removals. Any alterations to the documents must not be carried out without prior permission, and when altered, there should be an audit trail.

3.8 Prior to sending documents for archive, all A4 plastic wallets should be removed as these can stick to paper and remove the ink. Likewise staples and paper clips should be removed as these can rust over time. A full reconstruction of the study should be possible, based on the contents of the archived materials. Case Report Forms should be anonymised.

Archiving Electronic Data

3.9 If the NHS organisation is using purely electronic patient medical records then archiving requirements will need to be discussed with the Trust R&D and their I.T. department. Sites should consider access for monitors and inspectors, and whether any of the data can be isolated for the purposes of inspection, and in the interest of data protection.

3.10 Similarly if the site has used electronic ISFs (e-ISFs) then the metadata of documents loaded into the e-ISF should also be present so that the document can be identified within the system. They should be held on a secure server and files locked in read-only format so they cannot be edited, with restricted access. There should be more than one copy, i.e. be backed up elsewhere. Metadata should be retuned so as to comply with GCP guidelines and the accepted standards such as Dublin Core or DDI. Metadata must contain the following items, as a minimum: creator, date, subject and title (IGA, 2016).

If the site has used paper ISFs but has some documents stored electronically, then these can be transferred to a current storage method (e.g. CD) and archived alongside the study files. The storage method should be password protected and the password stored separately to the medium. Document all processes in the TMF.
Final archived (raw) data may be stored on BORDaR (Bournemouth University Online Research Data Repository). Further guidance available here.

Destruction of Archived Data

3.11 The Sponsor should notify the investigator and participating site team regarding the destruction of research data, in writing, ensuring that the Trust R&D is included in the correspondence.

The essential documents (e.g. protocol, completed consent forms, template study-specific documents etc.) will be retrieved from the designated archiving facility for review by the designated Archivist at the site. The designated Archivist will then notify the

Sponsor in writing once the documentation has been destroyed. The reasons and notice of destruction should be signed by the appropriate authorised person (i.e. Director of Research; or Head of Research).

4. Abbreviations and definitions

CI	Chief Investigator
CTIMPs	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
IRAS	Integrated Research Application System
(e-)ISF	(Electronic) Investigator Site File
PI	Principal Investigator
REC	Research Ethics Committee
R&D	Research & Development (Trust Research Governance)
(e-)TMF	(Electronic) Trial Master File

5. Related documentation and references

Information Governance Alliance (IGA), (2016), Records Management Code of Practice for Health and Social Care – appendix document

libguides.bournemouth.ac.uk. (2018). *LibGuides: Research Data Management*. [online] Available at: http://libguides.bournemouth.ac.uk/research-data-management [Accessed 31 Aug. 2018].

Statutory Instrument, (2006), The Medicines for Human Use (Clinical Trials) Amendment Regulations

6. Archive contact details

Dependent on project – seek guidance by emailing researchethics@bournemouth.ac.uk