Research Governance Standard Operating Procedure 13 – Archiving and destruction

Document details		
Version	V1.1 24/04/2026	
Effective from	28/04/2026	
Review date	28/04/2028	
Owner	Research Governance (research-governance@bristol.ac.uk)	
Originally Prepared by	Matt Hewson, Research Quality Officer (matt.hewson@bristol.ac.uk)	
Reviewed by	Rachel Davies, Research and Human Tissue Manager and Acting Co-Head of Research Governance (rachel.davies@bristol.ac.uk)	
Approved by	Rachel Davies, Research and Human Tissue Manager and Acting Co-Head of Research Governance (rachel.davies@bristol.ac.uk)	DocuSigned by: RDavies 02D95A1AC05945F...
Superseded documents	V1.0	

Document history						
Version	Review date	Reviewer	Section(s) Amended	Updated version	Approver	Effective date
V1.0	23/04/2026	Emily Avent	Reference to the Clinical Trials Regulation updated.	V1.1	Rachel Davies	28/04/2026

Table of Contents

1. Glossary

Terminology is explained in the Research Governance Glossary, the most recent version of which can be found **on the Research Governance webpages.**

2. Background

This SOP serves two main functions. First, it describes how members of the RGT should review those parts of a study documentation, including the protocol, consent forms and participant information sheets, concerned with archiving and destruction of essential study documentation (typically, at least the trial master file (including documents contained in electronic form), investigator site file, consent forms and participant medical records) prior to study Sponsorship. The essential documents are those which, in the language of the **UK Clinical Trial Regulations**: "enable both the conduct of the clinical trial and the quality of the data produced to be evaluated; and [...] show whether the trial is, or has been, conducted in accordance with the [...] relevant requirements".

Secondly, this SOP provides guidance on how members of the RGT should respond to queries about archiving and destruction from study teams. It does so by explaining both the legal requirements around document archiving and destruction for CTIMPs, proportionate archiving and destruction procedures for non-CTIMPS. It provides information on how members of the RGT can and should authorise destruction of study documents once the archiving period has passed.

Good quality archiving processes are important, among other reasons, because they enable the reconstruction of a trial during an audit, and facilitate the market approvals of new medications.

This SOP therefore ensures that Sponsored studies are compliant with regulations set out in the **Medicines for Human Use (Clinical Trials) Regulations 2004** as amended by the **Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025** with the principles in the **UK Policy Framework for Health and Social Care Research** and, where applicable, **NHS Records Retention** policy.

3. Scope

This SOP is about two things: the review of protocols and other study documentation by members of the Research Governance Team prior to Sponsorship, to ensure their archiving procedures are documented, compliant with relevant regulations, and proportionate; and the handling of researcher or site queries concerning archiving and destruction. The SOP does not cover specific operational details around archiving or destruction; these should typically be referred to the relevant School, Faculty or site process, so long as these processes are followed in a manner consistent with the principles described in this SOP and the associated regulatory requirements.

This SOP is concerned with the archiving of research *records*; for instance, the trial master file, CRFs, site files, and other non-anonymised information, whether paper or electronic. Research *data,* the anonymised output of the study, should typically be shared openly and widely, in line with University Policy (unless other requirements prohibit this). More information can also be found at data.bris.ac.uk.

Similarly, retention and destruction of *relevant* or *bodily* material (rather than records or data concerning relevant or bodily material) is out of scope; the **RG SOP 23 – Managing a human tissue study** should be consulted before the destruction of any relevant or bodily material.

3.1 TMFs and ISFs

For studies with one or more Research Sites, separate to the central trial team, the study records encompass both a Trial Master File, which will be maintained centrally; and one or more Investigator Site Files, which will be maintained by the Research Sites.

A TMF should contain the original versions of all key documents relating to the setup, approval and the central conduct of the study (this may include documents in electronic form). ISFs should contain copies of relevant approvals and instructional documents along with local records relating to staff (e.g. training and delegation logs), participants and study conduct.

Though stored separately over the course of the study, ISFs are notionally subsections of the TMF. They should be retained at site until the formal closure of a study, including the resolution of any queries generated before or during that process. Once the study is closed and all queries are resolved, ISFs should be archived along with the TMF, and for the same period.

4. Responsibilities

This SOP is primarily for the **RHTM**s and **RGO**s, both in their review of study documentation prior to IRAS submission and eventual Sponsorship, and in the answering of queries from researchers and research sites.

5. Procedure

5.1 Study review

The **RGT member** should ensure that the protocol clearly states the intentions of the research team with respect to their archiving, retention and eventual destruction of records. The intentions documented in the protocol should be consistent not only with any legal or regulatory requirements, but with the record retention policy in the school or faculty of the CI, or the research sites. They should, moreover, be practical and proportionate – commensurate with both the study risk and the various costs attached to records management. The **RGT member** should also ascertain that the study team have assigned funds for the proper archiving and storage of records within their research grant. Where this has been overlooked, the study team should be asked to make arrangements for this.

Research records, and archives thereof, should meet ALCOA+EA standards; that is: Accurate; Legible; Contemporaneous; Original; Attributable; Enduring (stored securely in a non-degrading format); Available (to those with appropriate access credentials, for instance archivists or auditors).

For CTIMPs, the protocol should state, per the UK **Clinical Trials Regulations,** that research records will be retained for at least twenty-five years.

The protocol should also refer to a trial archiving plan that will detail the practicalities of archiving and destruction, and which details responsible individuals by role.

The **RGT member** should check that the information about archiving processes and timelines of retained information within the protocol is consistent with the information provided to participants in the consent form and participant information sheet. For information on how the consent form and participant information sheet should be produced to ensure valid, appropriate and effective consent, see **SOP 11 - Consent and Participant Information**.

ATIMPs are governed by more stringent regulations. If a researcher proposes an ATIMP, this should be discussed with the **Head of Research Governance**.

Otherwise, for non-CTIMPs (including CIMDs), and with the exception of consent forms for human tissue samples (see below) there are no UK legislative requirements for the archiving of research records. Where the study includes NHS patients, the **NHS Record Management Code of Practice** will apply, and record retention must be sufficiently robust to meet the requirements of the **UK Policy Framework for Health and Social-Care Research**.

In any event, record retention plans must meet the requirements of the University's record retention policies and any applicable policies of collaborating organisations.

The **RGT member** reviewing the protocol should therefore check, in collaboration with the researchers, that:

- Archiving intentions around timeline, storage, medium and policy are clearly and explicitly stated in the protocol, and meet organisational requirements.
- These intentions are proportionate to the nature of the study; the CTIMP standards (see above) are likely to be accepted by the REC, but may be excessive for lower risk studies.
- Where the study involves participants under 16, recruited via the NHS; the research involves an intervention; and the research record is the primary record of that intervention: all research records will be retained until the youngest study participant has reached 25 years of age (or 26 where the participant was 17 at the end of treatment).

Occasionally (for both CTIMPs and non-CTIMPs) the study will be configured in such a way that additional, more stringent requirements apply (for instance, an international study led from a jurisdiction with a longer retention period but Sponsored, in the UK, by the university). In this case, the retention policy should reflect these more stringent requirements.

Where a study involves human tissue samples, it is a legal requirement for samples obtained in the UK, and good practice for imported samples, that consent forms are retained for as long as the samples are held (this retention of personally identifiable information is permissible under data protection legislation because the information is required to comply with the obligations of the **Human Tissue Act**). Where the samples are incoming material to the University, but the consent forms cannot be shared, the *warrant* for the depositor (for instance, legal assurance from the depositor that the consent forms exist) must be retained for at least as long as the samples are. Where the samples are outgoing from the University, but the consent forms cannot be shared, the consent forms must be retained by the University for at least as long as the samples are.

5.2 Responding to archiving and destruction queries

Queries about how long something needs to be retained for

In responding to a request (typically by a site) for permission to destroy research records, the **RGT member** assessing the query should first check what timescales were described in the study documentation approved by the REC (such as the protocol, the IRAS or ethics form, or participant information sheets). In addition, they should check whether any applicable regulatory timescale (described in 4.1 above) or extra-regulatory requirement is in place.

Queries about whether something can be destroyed

In responding to a request (typically by a site) for permission to destroy research records, the **RGT member** assessing the query should first check whether the timescale implemented in the protocol has passed, and whether any applicable regulatory timescale (described in 4.1 above) has passed. For instance, if a site requests permission to destroy CRFs relating to a CTIMP, it would be necessary to check that no marketing authorisations were contemplated or in progress.

If these timescales have passed, the **RGT member** should seek confirmation from the CI that they are happy for destruction to begin. Where the CI is happy for destruction to begin, the **RGT member** should check that they, as Sponsor representative, are also happy for destruction to begin. When both these conditions are satisfied, the **RGT member** responding to the query should confirm that both the Sponsor and CI are happy for destruction to begin with the person who initially raised the request.

Permission to destroy consent forms related to human tissue should only be granted when the corresponding human tissue has been destroyed; the reader should also consult the **RG SOP 23 – Managing a human tissue study**.

Queries about archiving and/or destruction where the study documents are silent

Where it is unclear whether the timescales have passed (for instance, because of limited detail in the protocol), the responsible **RGT member** should follow the process described in the previous paragraph; the decision whether they, as Sponsor representative, are willing to grant permission for destruction should be taken on a case by case basis, and in line with any regulatory and/or organisational retention requirements.

Queries relating to digitisation

If hard-copy originals are to be scanned for digital retention, and the originals destroyed, a 100% quality control process is required – i.e. every scanned page of every document must be checked against the original in order to ensure a complete, legible, accurate copy has been made, before the originals can be destroyed.

6. Related documents

Internal documents

RG SOP 6 – Sponsoring a study

RG SOP 7 – Registering a study

RG SOP 11 – Consent processes

RG SOP 23 – Management of human tissue studies

External documents

The Human Tissue Act 2004

UK Policy Framework for Health and Social Care Research

ICH GCP E6 R3

UK Clinical Trials Regulations

NHS Record Management Code of Practice