UNIVERSITY OF WARWICK

STANDARD OPERATING PROCEDURE 20

Closing Research Study Recruitment Sites

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Revision Chronology:	**Effective date:**	**Reason for change:**
5.0	04 Feb 2026	Minor clarifications around provision of data to sites (inc. signposts to guidance). Updates to flow and style to improve readability. Added reference to trigger for archiving at all sites, definition of trial conclusion and the requirement to collect details of contact at trial location for sponsor to record in order to notify of destruction. Added a note about change in terminology from 'site' to 'locations' into the definitions section. Re-branded to new template.
4.0	08 Nov 2023	Addition of PIC closure and adaptations for sites with limited scope of activity Changes to order and flow of the text
3.0	21 Oct 2021	Biennial review: Updated references to current templates and guidance docs. Minor updates to text and formatting.
2.1	16 Aug 2019	Biennial review: Title change and change to new format. Minor amends to text throughout.
2.0	21 Mar 2017	Biennial review: Title change and change to new format. Text amended throughout to detail site closure procedures and to remove references to end of study regulatory requirements.
1.4	30 Jul 2014	Biennial review: Web links updated and minor text amends for clarification.
1.3	28 May 2012	Biennial review: Format changes to comply with SOP 1. Web links updated. New section 3.3.5 added. Templates added.

1.2	22 Feb 2010	Biennial review: Clarification of responsibilities for reporting end of study and submission of final reports. Addition of information on temporarily halting a study.
1.1	30 Jan 2008	Biennial review: Format change. Update of web-links.
1.0	Mar 2006	

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CONTENTS

1 Purpose and Scope

This SOP outlines procedures for Chief Investigators (CIs), Principal Investigators (PIs), and sponsors for closing research study recruitment sites, including Participant Identification Centres (PICs). It applies to all staff involved in study management.
This SOP covers only site closure, not overall study closure. End-of-study requirements are detailed in the Study Closure Roadmap. Additional guidance on notifying authorities, sending summary reports, and archiving essential documents can be found in:

- **SOP 5 Part 3** – Communication with Approval Bodies
- **SOP 6** – Amendments to Approved Study Documents
- **SOP 23** – Archiving

2 Acronyms

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
GP	General Practitioner
HRA	Health Research Authority
IMP	Investigational Medicinal Product
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
OID	Organisation Information Document
PI	Principal Investigator
PIC	Participant Identification Centre
QA	Quality Assurance
REC	Research Ethics Committee
R&IS	Research & Impact Services
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TMF	Trial Master File (also known as study master file)
TMG	Trial Management Group (also known as study management group)
WCTU	Warwick Clinical Trials Unit

3 Definitions

CI	An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre study.
Investigator	A person responsible for the conduct of the study at a site. If a study is conducted by a team of individuals at a study site, the investigator is the leader with responsibility for the team and may be called the Principal Investigator (PI).
Investigator Location (site)	Current clinical trial regulations refer to **"investigator location"** to reflect the range of settings in which trial activities may be conducted. However,

	within this SOP and associated procedures, the term **"investigator site"** is retained where appropriate (including within established acronyms and documentation) and should be considered synonymous with **"investigator location"** as defined in the regulations.
Multicentre Study	A study conducted according to a single protocol but at more than one location, and therefore, carried out by more than one investigator.
Particiapnt Identification Centre (PIC)	NHS/HSC organisations that process personal data to identify potential research participants, in accordance with sponsor's instructions. Potential participants are then directed elsewhere without undertaking any further research activity for that study.
Trial Conclusion	The conclusion of the trial is the point at which all trial activities have permanently ended at all investigator locations, in accordance with the protocol. This normally means: • The last subject's last visit has occurred • No further trial-related interventions or assessments are planned • The trial is no longer ongoing anywhere This is the trigger point for archiving at each trial location.

4 Background

Comprehensive study close-down is essential to ensure all data and documentation are current, approved, verified, and complete, supporting future audits or inspections.

Closure of recruitment sites must be formally managed to confirm that essential documents and requirements (e.g. study drug management) are addressed, documented, and ready for archiving.

A site is considered 'closed' once all study-related activities (excluding dissemination of results) are reconciled and complete. If a site closes early (e.g. due to poor recruitment, safety concerns, or resource issues), all required closure activities must still follow standard procedures.

5 Responsibilities

CI or delegate	• Ensure all required site closure activities have been arranged and completed. This can be delegated to appropriately trained members of staff.

PI or delegate* **Where recruitment has been instigated via a GP practice, the lead GP or their delegate will be the responsible person.*	• Ensure all required site closure activities are completed. • Implement ongoing requirements for archiving and support for audit/inspection readiness. • Where long-term follow-up continues for an extended period, duties may be delegated to an alternative non-clinical staff member, subject to sponsor agreement. • Ensure any adaptations are justified in documentation.
Sponsor or delegate	• Notify the REC, MHRA (where applicable) and other relevant bodies if an approved site is closed or withdrawn from the study prematurely. • Contact sites at the end of the retention period to give permission to destroy the ISF. *There is no requirement to notify the MHRA regarding routine closure of active sites at the conclusion of a study.*
Study statistician	• Provide input by confirming data lock and resolution of all data queries to inform when site closure can go ahead.

6 When

Site closure procedures should be discussed by the TMG, adhere to a study closure plan if applicable and be implemented as soon as it is practicable when the end of the study activities have been reached or where early termination is necessary. Site closure usually occurs after the final data lock. A template study closure plan is available to support with all tasks relating to closure of a trial, including closure of sites **– T78 – Study Closure Plan Template**.

Closing a site within a multi-centre study may occur at any time due to various reasons including:

- Completion of target recruitment at site or for the whole study
- Failure or prolonged lack of recruitment at a site
- Change of protocol requirements that deems a site unsuitable
- Change or absence of key personnel at a site
- Persistent issues with site e.g., poor data quality, late submission of data, lack of adherence to safety reporting requirements

Any other reason whereby a site is unable to commit to the study.

7 How

Closure of recruitment sites should ensure that the following are resolved and/or up to date and relevant documentation available in the ISF and/or TMF

Site payments
Data queries
ISF documentation
Equipment reconciliation
Investigational Medicinal Product (IMP) accountability (inc. destruction)
Arrangements for archiving and continuing study obligations
Actions raised as a result of monitoring
Record of Serious Adverse Events (SAEs)
Ensure all non-compliances are resolved and closed
Ensure transfer of data has been discussed/arranged
Confirmed with site that archiving period will be initiated upon conclusion of the trial.
Confirmation of role at site that will take responsibility for being notified of destruction by Sponsor.

7.1 Method of Closure

Site closure may be conducted via visit or written communication, as agreed and documented in the study monitoring plan or closure plan.

- **If a site visit is required**
  - Schedule with the PI or delegate on a mutually convenient date.
- **If a site visit is not required**
  - Provide the PI or delegate with a site closure checklist and request confirmation of:
    - Completeness of documentation
    - Appropriate reconciliation activities
  - Make current versions of study-wide essential documents easily accessible alongside the checklist.
  - The completed checklist must be returned to the coordinating centre for review.
  - Address any discrepancies until the ISF is confirmed ready for long-term retention.

7.2 Closure Confirmation

Send a site closure letter or email once all actions are complete.
Templates available:

- **T33** – Site Closure Checklist
- **T34** – Site Closure Letter

7.3 Archiving at site

The Investigator Site File (ISF) must be archived for the same duration as the Trial Master File (TMF). The applicable retention period should be defined in the protocol. Archiving for all investigator locations is triggered simultaneously upon the conclusion of the trial at all locations. At trial close-out, contact details must be recorded for the individual or organisation responsible at each trial location once the retention period expires; where possible, a **role or function** should be recorded in preference to a named individual. This is the responsibility of the Sponsor or their delegate. For studies managed by WCTU, this information should be included in the trial closure plan or provided to the Quality Assurance Team.

7.4 Participant Information at Study End

Arrangements for providing information to participants must be agreed with sites.
Refer to **HRA guidance** and **SOP 7 – Participant Information & Consent** for details on what and how to communicate with participants, legal representatives, consultees, relatives, or close friends.

7.5 Provision of Study Results

- Each site should receive an outline of study results or a copy of the final report when available.
- For studies using electronic data capture, the coordinating centre must ensure sites retain a read-only copy of their dataset.
    - For WCTU-managed studies, this can be arranged by the WCTU Programming Team.
    - Guidance can be found in **G38 – Data Transfer to Sites**.
    - Template emails for communication relating to this are also available: **T76 and T77 – Template Data Transfer to Site.**
- Timing should consider impacts on blinding, publication, or contractual obligations but should occur before site closure.
    - **Dataset content:**
        - Agreed with the TMG
        - Does not need anonymisation (but may not need to return supplementary contact information)
        - Must include all site and participant provided data to allow reconstruction of results

- Additional supplementary information inclusion can be discussed

7.6 Early closure of recruitment sites

It may be necessary to close a site whilst there is ongoing recruitment/participant involvement at other sites.

The CI is responsible for making the decision as to whether a site should be closed and the reason(s) for doing so should be discussed and documented by the TMG. Discussions should involve the PI from the local site. An amendment to document the closure may be required depending on the circumstances. See **SOP 6 Amendments** to Approved Study Documents 'and HRA guidance for further details: **https://www.hra.nhs.uk/approvals-amendments/amending-approval/**

The CI or their delegate must inform the PI and site personnel of the decision and confirm a plan in writing for any ongoing participants, if required.

Closure should be conducted and documented as per the procedures above.

7.7 Closure of sites to recruitment only

In some circumstances, sites may be closed to recruitment but remain open for data collection purposes e.g. Primary Care practices who have assisted with the identification of potential study participants; this would not be considered as being a formally closed site. At the end of the period of relevant study related activities, a letter should be sent to the site to thank them and explain that their direct involvement has ended but it may be necessary for the study team to contact them in the future if any data queries are required. This may also involve a variation of the site agreement depending on the circumstances. R&IS staff should be contacted to arrange contractual amends if required.

Once these activities are complete, closure should proceed as described in section above.

7.8 Closure of PIC and other site types

For PICs and sites where no recruitment took place, closure does not need to involve the site retaining any documentation if the coordinating centre has copies of any screening logs and evidence of any other activities that were undertaken. Where a site has failed to recruit, a file note should be available to explain the situation. In both circumstances it is good practice to confirm closure with a letter to the site in place of a formal closure checklist. It is suggested that where site activity varies in scope (e.g. Primary Care sites), review of the closure templates is undertaken, and amendments made to suit the individual set-up. Where site activity is limited, the minimum suggestion would include local site retention of:

- Organisation Information Document (OID)
- Study protocol
- Local Research & Development Approvals
- Data Collection tool template *(if applicable)*.

8 Templates

T33	Site closure checklist
T34	Site closure letter template
T78	Study Closure Plan Template
G38	Data Transfer to Sites
T76	Template Data Transfer to Site Email (Non-CTIMP)
T77	Template Data Transfer to Site Email (CTIMP)