STANDARD OPERATING PROCEDURE 20
Closing Research Study Recruitment Sites

Version:	V4.0	Effective Date:	07 Nov 2023
Issue Date:	24 Oct 2023	Review Date:	07 Nov 2025
Author:	Jill Wood, QA Manager, Warwick Clinical Trials Unit (WCTU)		
WCTU Reviewers:	Donna Howe, Trial Coordinator, WCTU Amy Arnold, Trial Manager, WCTU		
Sponsor Reviewers:	Mathew Gane, Research Governance & QA Manager, Research & Impact Services (R&IS)		
WCTU approval:	Natalie Strickland, Head of Operations, WCTU		
Sponsor approval:	Carole Harris, Assistant Director, R&IS (Systems & Strategic Projects) & Head of Research Governance		
Review Lead:	WCTU QA Team		

Contents

1. Purpose and Scope 3
2. Definitions 3
3. Background 3
4. Procedure 4
4.1 Responsibilities 4
4.2 When? 4
4.3 How? 4
4.3.1. Early closure of recruitment sites 5
4.3.2. Closure of sites to recruitment only 6
4.3.3. Closure of PIC and other site types 6
List of abbreviations 7
Templates 7

Revision Chronology:	Effective date:	Reason for change:
Version 4.0	08 November 2023	Addition of PIC closure and adaptations for sites with limited scope of activity Changes to order and flow of the text
Version 3.0	21 October 2021	Biennial review: Updated references to current templates and guidance docs. Minor updates to text and formatting.
Version 2.1	16 August 2019	Biennial review: Title change and change to new format. Minor amends to text throughout.
Version 2.0	21 March 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.
Version 1.4	30 July 2014	Biennial review: Web links updated and minor text amends for clarification.
Version 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.
Version1.2	22 February 2010	Biennial review: Clarification of responsibilities for reporting end of study and submission of final reports. Addition of information on temporarily halting a study.
Version 1.1	30 January 2008	Biennial review: Format change. Update of web-links.
Version 1.0	March 2006	

STANDARD OPERATING PROCEDURE 20
Closing Research Study Recruitment Sites

1. Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to detail procedures for Chief Investigators (CI), Principal Investigators (PI) and sponsors for the closure of research study recruitment sites. It is applicable to all staff involved in study management.

This SOP does not cover details on the closure of the study, only the part related to the closure of recruitment sites, including Participant Identification Centres (PICs). Requirements for end of study procedures are outlined in the WCTU Study Closure Roadmap and further information on notification to the authorities of the end of a study, sending summary reports and archiving of essential documents can be found in SOP 5 part 3 'Communication with Approval Bodies', SOP 6 'Amendments to Approved Study Documents' and SOP 23 'Archiving'.

2. Definitions

Chief Investigator (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).
Multicentre Study	A study conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.
Participant 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.

3. Background

Comprehensive study close down is essential to ensure data and documentation are up to date, approved, verified and complete, to facilitate potential future audit(s) and/or inspections. Closure of study recruitment sites, at any time point must be formally managed to ensure all the necessary (essential) documentation for archiving and other requirements e.g., management of study drugs, have been addressed and appropriately handled and documented. It is good practice to prepare a study closure plan. There is a Trial Closure Roadmap available which can be used to aid the production of a plan.

A site may be deemed 'closed' once all study–related activities (not including dissemination of results) at that site are reconciled and/or complete. In circumstances where a site must close early e.g., poor recruitment rates, safety concerns or if there are issues around staff resources and the site cannot support the study properly, all required site closure activities must take place in line with close out procedures at the end of a study.

4. Procedure

4.1 Responsibilities

CI or delegate	Responsible for ensuring all required site closure activities have been arranged and completed. This can be delegated to appropriately trained members of staff.
Principal Investigator or delegate* ***Where recruitment has been instigated via a GP practice, the lead GP or their delegate will be the responsible person.***	Responsible for ensuring all required site closure activities have been completed at their site. Implement any on-going requirements for archiving and for subsequent audit/inspections. Where long-term follow-up will continue for an extended period, it may be agreed for an alternative non-clinical staff member to continue these duties if agreed with study sponsor. Such adaptations should be justified in the risk assessment.
Sponsor or delegate	Notify the Research Ethics Committee (REC), Medicines and Healthcare products Regulatory Agency (MHRA) (where applicable) and any other relevant body if an approved site is closed or withdrawn from the study prematurely. There is no regulatory requirement to notify routine closure of active sites at the conclusion of a study.
Study statistician	To provide input by confirming data lock and resolution of all data queries to inform when site closure can go ahead.

4.2 When?

Site closure procedures should be discussed by the Trial/Study Management Group (T/SMG), 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.

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

4.3 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 T/SMF:

- 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)

Site closure may be conducted by a visit or by written communication depending on what has been agreed and documented in the study monitoring plan or closure plan.

Where a site visit is required, this should be scheduled with the site's PI or their delegate and carried out on a mutually convenient date. If a site closure visit is not required by the monitoring plan/closure plan, a checklist should be provided to the PI (or delegate) with a request to confirm completeness of documentation and appropriate reconciliation activities. To facilitate this process, current versions of study wide essential documentation can be made easily available to the site alongside the checklist. A copy of this list must be returned to the coordinating centre for review and any discrepancies raised with the site until assurances are in place to confirm the ISF is ready for long term retention.

A site closure letter (or email) should be sent to the site to confirm closure once all actions are completed. A template site closure checklist and letters are available on the website alongside this SOP:
T33 – Site closure checklist template
T34 – Site closure letter template

Arrangements for providing information to participants at the end of a study should also be agreed with sites. The HRA have developed guidance to explain how and what information must be provided to participants, their legal representatives, consultees, relatives, or close friends (where applicable) at the end of a study. Further information and links to the full guidance document can be found in SOP 7 'Participant Information & Consent'.

An outline of the results of the study or a copy of the final report should be provided to each participating site when available. For studies where electronic data capture has been used, the coordinating centre will need to make arrangements for the recruiting site to retain a read-only copy of their data set. For WCTU managed studies, this can be facilitated by the WCTU Programming Team.

4.3.1. Early closure of recruitment sites

Depending on the progress of the entire study, it may be necessary to close a site whilst there is on-going 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 T/SMG. 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 The Health Research Authority (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 on-going participants, if required.

Closure should be conducted and documented as per the procedures detailed in section 4.3.

4.3.2. 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 4.3.

4.3.3. 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)*.

List of abbreviations

CI	Chief Investigator
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
T/SMF	Trial/Study Master File
T/SMG	Trial/Study Management Group
WCTU	Warwick Clinical Trials Unit

Templates

T33	Site closure checklist
T34	Site closure letter template