
Great Western Hospitals NHS
NHS Foundation Trust

**Standard Operating Procedure:**

# Study Close Down

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## 1. BACKGROUND

Trial close-out is the act of ensuring that all clinical trial related activities have been appropriately reconciled.

Close-out is integral to the quality of a trial and is designed to ensure that all essential documents are in place should the trial data need to be queried or inspected in future and the reason for the close out should also be documented. ICH GCP guidelines define study documents to be filed after completion or termination of the trial.

## 2. PURPOSE

The purpose of this SOP is to detail the procedure for closing down clinical trials of investigational medicinal products (CTIMPs) and non-CTIMPs in which we are a participating site.

## 3. APPLICABLE TO

This SOP is for all staff working on research at the Trust. The responsibility for the close out process lies with the Principal Investigators for trials hosted by the Trust and can be delegated by the PI to the R&I Department who will ensure this process is completed in a timely manner.

## 4. PROCEDURE

This SOP begins when the study terminates. The definition of the end of a trial should be described in the protocol (and any subsequent amendments). In the majority of trials, the completion will be the date of the last patient's last visit (LPLV) or the completion of any follow-up monitoring and data collection described in the protocol.

The protocol should also state the circumstances or events which may determine an early termination date. These events may include:

- Safety concerns
- Poor participant reaction/tolerance to study intervention
- Poor recruitment
- Sponsor's decision
- Investigator's decision

The R&I Manager also reserves the right to consider early closure of a study and will liaise with the Sponsor should the need arise.

*An example of this could be as follows*:

R&I Manager made aware of long term issue within the Pharmacy department which will impact on capacity and capability to be able to continue to deliver the Study.

As soon as the PI or any study personnel are informed of study closure, the research team will ensure that all data required by the protocol are recorded and that all essential documents are filed.

The PI or delegate to ensure that all data queries have been completed and any equipment loaned / provided by the sponsor has/will be returned.

The study team must then also notify the R&I office who will update the study status and;

- Ensure any Honorary Contract or Letters of Access are terminated
- Update the status of Patient Alerts on Electronic Medical Records to capture the change from 'Clinical' to 'Admin' Alert (we will no longer need to be advised of patient admission but we do need to ensure medical record retention)
- Ensure all finance is up to date.
- Arrange for archiving of study documentation

For some trials, the trials office/sponsor may send a representative to the site to complete a final close down visit to confirm that all procedures have been completed correctly prior to archiving of study documentation.

The essential documents will be retained in accordance with our Archiving SOP.

A member of the research team will inform pharmacy and any other support department of the study closure. It is the responsibility of each service support department to ensure they close-down in accordance to the study's procedure and forward any files/documents to R&I for archiving.

The research team should send a copy of the formal notification of study closure received from the sponsor to the R&I office.

5. SUPPORTING DOCUMENTS

SOP (005) Archiving

http://ichgcp.net/8-essential-documents-for-the-conduct-of-a-clinical-trial