brighton and sussex medical school

Brighton and Sussex University Hospitals NHS Trust

This is a controlled document
Any printed versions of this document will be classed as uncontrolled

End of a Research Study for non-CTIMPs

SOP Reference:	**SOP/RD/009**
Version Number	**Final V 3.0**
Date:	**10th May 2016**
Effective Date:	30 July 2016
Review by:	29 July 2018.

Author: Justine Boles **Designation:** Senior Trial Manager Brighton & Sussex University Hospitals NHS Trust	**Signature**	**Date**
	J Boles	30 June 2016
Authorised By: Scott Harfield **Designation: Head of** Research and Development Brighton and Sussex University Hospitals NHS Trust.		30/6/16

Version	Date	Reason for Change
3.0	10th May 2016	Any reference to CTIMP studies removed – the CTU SOP must now be referred to for BSUH sponsored CTIMP studies. Additional details relating to the close out process added, Archiving SOP split into 2 (sections 4.4 and 6.0)

1.0 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures to be undertaken when BSUH sponsored Research Studies other than CTIMPs (Clinical Trial of Investigational Medicinal Product) end. All CTIMP studies sponsored by BSUH will be managed by the Brighton and Sussex Clinical Trials Unit (BSCTU) and the End of Study CTU SOPs will be followed for CTIMP studies from the date of effectiveness of this SOP onwards.

2.0 Introduction

Close out is defined as the process of ensuring that all research study related activities are appropriately managed, reconciled and reported at the end of a study in accordance with the protocol, SOPs, Good Clinical Practice (GCP) and the Research Governance Framework.

Close out is integral to the quality of a study and is designed to ensure that all necessary documents are in place and that data is complete, must it be necessary for the study documentation to be retrieved or audited in the future.

3.0 Responsibilities

Sponsor

Approvals to close the study and to ensure that the results are published / disseminated appropriately.

Chief Investigator (CI)

Notifying the Research Ethics Committee (REC) of the end of a research study.

Submission of the clinical study/final report to the HRA and the sponsor.

Notifying local Research & Development departments for sites of the end of a study as well as any other relevant parties such as the funder.

Ensuring completeness of the Trial Master File, including filing a copy of the database (printed or on CD/DVD) and the final statistical analysis report.

Providing a copy of the publication to the sponsor.

Notifying the sponsor of the End of Study.

Archiving of the study documentation.

4.0 Procedure

4.1 Recruitment Closure

Recruitment closure must be planned and agreed with the study teams.

Relevant organisations involved in the study (e.g. funders etc.) must be notified of the closure to recruitment.

An official confirmation of recruitment closure must be sent to each site at the appropriate time.

Relevant study registries such as ISRCTN, ClinicalTrials.gov and study websites must be updated to confirm recruitment closure.

The Central Portfolio Management System must be updated.

4.2 Formal notification to the Research Ethics Committee (REC) and other bodies

At the end of a research study, the CI must notify the REC that gave them a favourable opinion that the study has ended. This must be done using the NRES Declaration of the End of a study form available on the HRA (Heath Research Authority) website:

http://www.hra.nhs.uk/resources/during-and-after-your-study/end-of-study-notification-studies-other-than-clinical-trials-of-investigational-medicinal-products/

This must be done within 90 days of the end of the study.

A final report/clinical study report must be submitted with 1 year of the end of the study. There is no standard format for this but must include as a minimum, whether the study achieved its objectives, what the main findings were and the arrangements for publication/dissemination of the research.

A copy of both the Declaration of End of Study form and a copy of the final study report must also be provided to the sponsor by emailing: Sponsorship.Approvals@bsuh.nhs.uk. Any other relevant parties must also be notified e.g. funders.

4.3 Closure of a participating investigational site(s)

For each site, the following tasks must be completed before official study closure:

- All data entry onto the CRFs must be complete and queries must be resolved.
- If applicable, the final Electronic Data Capture (EDC) output must be printed or saved onto a CD/DVD and filed in the ISF.
- All Serious Adverse Events must be fully documented, and any unresolved adverse events followed up where required,
- All laboratory documentation must be collated with the main Investigator Site File and shipping/destruction of samples completed as required.
- The Declaration of the end of a study form, including evidence of notifying local R&D department must be added to the ISF.
- Any unused study-related supplies and materials must be retrieved, returned, or authorised for destruction where required.

- All sections of the ISF must be collated ready for archiving.

Close out visits may need to be carried out by the monitor, if required, according to the study Monitoring Plan.

Once the site can be closed, a formal site closure notification will be sent to the investigator to confirm that the site is closed and that study related documents can be archived.

A study close out approval form must also be completed.

4.4 Overall Study Closure

Once all the data from sites has been received and no more queries remain, a copy of the database must be sent for analysis according to the protocol.

A copy of the database sent for analysis must be filed in the TMF.

Once analysis has been completed, approval to archive may be sent to study sites.

A statistical analysis report must be prepared and a copy filed in the TMF. Publications will be prepared according to the protocol.

Publications must be prepared by the CI or delegate, and authorship agreed, where applicable, ensuring that BSUH is credited as sponsor. A copy must be provided to the sponsor.

Dissemination of findings to participants must be agreed and actioned, as recommended by the Health Research Authority (HRA). Consideration should also be given to dissemination of the results to the study teams involved.

The TMF must be updated with all results, including the final report, statistical reports and publications, where applicable, prior to archiving.

Once all actions are complete, a request to officially close the study must be sent to the Research Governance and Quality Assurance Committee and approval to archive will be provided.

Archiving may then be carried out according to SOP/RD/004 and SOP/RD/033.

4.5 Early Termination of a Study

A study may be terminated earlier than the planned closure date as a result of recommendations from the sponsor; e.g. as a result of poor recruitment or safety issues.

In this case, REC must be notified within 15 days of the date of termination by submitting the NRES declaration of the end of a study form from the HRA website.

There must be clear documentation in the TMF about the decision to terminate a study early and communication to sites must be provided in an organised manner.

This documentation must include a clear justification and rationale for the decision made by the appropriate personnel, which provides the evidence basis for the early termination.

Participants who are still active in the study must be notified of the study closure with reasons. A communication must be prepared by the CI or Trial Steering Committee with an agreed, unambiguous message to be disseminated by site staff. REC approval is not required but advice may be sought if the information provided is particularly sensitive or distressing.

Other standard procedures for closing a study must be followed.

5.0 Training

This is a 'read and understand' SOP. Please note that the R&D department discourages the retention of hard copies of SOPs and can only guarantee that the most up-to-date version is on the Trust website.

6.0 Cross Referenced SOPs

SOP/RD/004 Archiving Paper Trial Documents for BSUH as a Research Site
SOP/RD/033 Archiving Paper Trial Documents for BSUH as a Sponsor

7.0 References

Health Research Authority, 'End of Study and Beyond' http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/ (accessed 17-June-2014)