

University of Hertfordshire

END OF TRIAL STUDY REPORTS

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for End-of-Trial Study Reports for University of Hertfordshire
Sponsored/Co-sponsored/Hosted Clinical Trials

SOP Number: gSOP-22-01	Effective Date: 26 th April 2018
Version Number: v1.0	Review Date: 3 years (or as required)

1.0 BACKGROUND

This is a University of Hertfordshire standard operating procedure. UH acknowledges WHHT R&D which has allowed UH to use the SOPs developed by WHHT where possible, modified for local implementation.

This document sets out the procedures to be followed by all University of Hertfordshire (UH) staff who are involved in the close-down, termination, suspension or final reporting of research studies and clinical trials. Where there are potential conflicts between different collaborating organisations' SOPs, project level working instructions should be developed, to determine precedence.

It aims to provide clear guidance on how participants, staff and trial related documentation is managed during close-out so as to ensure compliance with the University' Information Governance Policies, the Data Protection Act, and the UK Policy Framework for Health and Social Care Research (2017).

This SOP is specifically for CTIMPs, however in the absence of a documented procedure can be used as guidance for any other clinical study.

2.0 PURPOSE

To ensure End of Trial Study Reports are submitted for all UH sponsored/co-sponsored or hosted trials in accordance with the protocol, regulatory and Sponsor requirements.

3.0 APPLICABLE TO

Any UH employee involved with clinical research sponsored/co-sponsored or hosted by UH including, but not limited to, Chief Investigators (CI), Principal Investigators (PI), Consultants, Co-investigators, Research Fellows, Clinical Trial Pharmacists, Research Managers, Statisticians, Research Nurses, Allied Health Professionals, Trial Coordinators, CTSNMG & Data Managers.

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4.0 RESPONSIBILITIES

The CI/PI or Delegated Individual (DI) is responsible for the submission of the End-of-Trial Study Report to meet with regulatory and Sponsor requirements. The CI/DI should ensure for UH sponsored/co-sponsored trials that the end of trial is detailed in the approved protocol.

5.0 PROCEDURES

5.1 Definition of the End-of-Trial

The end-of-trial is usually stated in the study protocol. In most cases this will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol.

5.2 End-of-Trial Notification to the MHRA

The CI/DI is responsible for submitting an “Declaration of the end of a clinical trial form” to the Medicines and Healthcare products Regulatory Agency (MHRA), the Research Ethics Committee (REC), the R&D Office and the CTSN within 90 days of the end-of-trial. There are separate forms for use in CTIMPs and all other research. The appropriate forms are available on the Health Research Authority website.

5.3 Early Termination of the Trial

If the trial closes before the expected date, then the CI/DI is responsible for submitting an “End of a Clinical Trial Declaration Form” to the MHRA, REC, the R&D Office and the CTSN within 15 days of the end-of-trial, explaining the reasons for early termination.

5.4 End-of-Trial study report

For CTIMPS: The CI/DI is responsible for submitting a final research report to the MHRA and REC within 12 months of trial having ended.

For non-CTIMPS: a summary of the final research report should be sent to the REC within 12 months of the end of the study.

There is no standard format for final reports for the REC. As a minimum the report should state whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.

5.5 Following submission of the End-of-Trial Study Report to the MHRA and the REC

No further amendments can be made to the study once the “Declaration of the end of a clinical trial form” has been submitted.

Clinical trial documents should not be archived until the final report has been submitted.

6.0 RELATED DOCUMENTS

- gSOP-09 - Amendments
- gSOP-13- Research Applications
- gSOP-14- Writing Research Protocols
- gSOP-17- Archiving
- gSOP-21- Trial Closure

7.0 APPENDICES

- Appendix 1 - Definitions

8.0 VERSION HISTORY

Revision Chronology:		
Version Number	Effective Date	Reason for Change

9.0 AUTHORSHIP & APPROVAL

Author

Signature

Date

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature

Date

10.0 AGREEMENT

Please detach and retain in your training files

I have read and understood the contents and requirements of this SOP (gSOP-22-01) and accept to follow the UH policies implementing it.

<p>Recipient</p> <p>Signature:Date:</p> <p>Name & Position:</p>
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Appendix 1: Definitions

Chief Investigator (CI)

A registered Physician, Dentist, Pharmacist or Nurse who has overall responsibility for the conduct of the trial.

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health outcomes.

Clinical Trial of Investigational Medicinal Product (CTIMP)

A study that looks at the safety or efficacy of a medicine/food stuff/placebo in humans as defined by the Medicines for Human Use Regulations (2004).

Delegated Individual (DI)

An individual delegated by a person of responsibility to carry out their task(s).

The Medicines & Healthcare products Regulatory Agency (MHRA)

UK competent authority responsible for regulation of clinical trials.