END OF TRIAL STUDY REPORTS

Research & Development

Standard Operating Procedure End-of-Trial Study Reports for West Hertfordshire Hospitals NHS Trust Sponsored and Hosted Clinical Trials

SOP Number : SOP-22-06	**Effective Date:** October 2021
Version Number: v06	**Review Date:** 2 - 3 years

1.0 BACKGROUND

This document sets out the procedures to be followed by all West Hertfordshire Hospitals Trust (WHHT) staff who are involved in the close-down, termination, suspension or final reporting of research studies and clinical trials.

It aims to provide clear guidance on how patients, staff and trial related documentation is managed during close-out so as to ensure compliance with the Trust's Information Governance Policies, the Data Protection Act (2000), and the Research Governance Framework (2005).

2.0 PURPOSE

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

3.0 APPLICABLE TO

Any relevant Trust employee involved with CTIMP clinical research sponsored or hosted by WHHT 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, the Research & Development Steering Group (RDSG) & Data Managers.

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 including transparency requirements. The CI/DI should ensure for WHHT 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. (see SOP-14)

5.2.1 End-of-Trial Notification to the MHRA

The CI/DI is responsible for submitting an "End-of-Trial Notification form" to the Medicines and Healthcare products Regulatory Agency (MHRA),the Research Ethics Committee (REC) and the R&D Office within 90 days of the end-of-trial. (see SOP-08)

5.2.2 Early Termination of the Trial

If the trial closes before the expected date, then the CI/DI is responsible for completing and submitting an "End-of-Trial Notification Form" to the MHRA, REC and the R&D Office within 15 days of the end-of-trial, explaining the reasons for early termination. (see SOP-08)

5.3 End-of-Trial study report

The CI/DI is responsible for submitting an End-Of-Trial Study Report to the MHRA within 12 months of trial having ended.

Guidance on the structure and content of an Investigational Medicinal Product (IMP) trial report is available at the MHRA and HRA websites.

5.4 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 End-of-Trial study report has been submitted. Please see the HRA website for more detail on the transparency requirements we must adhere to: Make it Public: transparency and openness in health and social care research

Clinical trial documents should not be archived until the End-of-Trial study report has been submitted. (see SOP-17 and SOP-21)

6.0 RELATED DOCUMENTS

- SOP-08- Role of the CI, Pharmacy, Nuclear Medicine and R&D
- SOP-14- Writing Research Protocols
- SOP-17- Archiving
- SOP-21- Trial Closure

- Make it Public: transparency and openness in health and social care research

7.0 APPENDICES

Appendix 1 - Definitions

8.0 VERSION HISTORY

Revision Chronology:		
Version Number	**Effective Date**	**Reason for Change**
SOP-22-06	**October 2021**	1. Change from general Standard Operating Procedures (gSOP) to SOP 2. Removal of the '10.0 Agreement' from the template - all agreement signatures will be collated on a new 'SOP Signature Sheet Document' 3. Addition of Transparency requirements 4. Other minor changes and clarifications of terms following review
gSOP-22-05	**October 2017**	Minor amendments following review
gSOP-22-04	**01/10/2015**	Minor amendments following review
gSOP-22-03	**22/05/2014**	Minor amendments following review
gSOP-22-02		SOP modified for implementation at ENHT/WHHT.
gSOP-22-01 (MVCC)		SOP modified for implementation at MVCC

9.0 AUTHORSHIP & APPROVAL

Author

Signature  **Date** 28/10/2021

R & D Steering Group Approval

Signature  **Date** 28/10/2021

Appendix 1: Definitions

Chief Investigator (CI)
The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI. For Trust sponsored trials, the CI had been delegated the pharmacovigilance responsibility for identification, recording and reporting of safety events, including submission of Development Safety Update Reports (DSURs) to the MHRA and REC.

Clinical Trial
A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. A Study Type.

Clinical Trial of Investigational Medicinal Product (CTIMP)
A clinical trial that is within the scope of the UK Medicines for Human Use (Clinical Trials) Regulations 2004. An investigation in human subjects, other than a non-interventional trial, intended: a) to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products, b) to identify any adverse reactions, or c) to study absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of those products.

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

The Medicines & Healthcare products Regulatory Agency (MHRA)
The MHRA is the competent authority for the UK in relation to the Directive 2001/20/EC and the Clinical Trials Regulations, and for Medical Devices, the competent authority in relation to the Medical Devices Regulations 2002.