

University of Hertfordshire

COMPLETING A CASE REPORT FORM- SPONSORED/CO-SPONSORED

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for Completing a Case Report Form in University of Hertfordshire Sponsored/Co-Sponsored Clinical Trials

SOP Number: gSOP-41-01	Effective Date: 26 th April 2018
Version Number: 1.0	Review Date: Every 3 years (or as required)

1.0 BACKGROUND

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

This Standard Operating Procedure (SOP) describes procedures to be followed by all UH staff who record data for the purpose of research in University of Hertfordshire Sponsored/co-sponsored clinical trials. Where there are potential conflicts between different collaborating organisations' SOPs, project level working instructions should be developed, to determine precedence.

2.0 PURPOSE

- To define the CRF completion process for UH sponsored/co-sponsored clinical trials.
- To provide guidance for the management of trial related data and therefore ensure that all data is collected, verified and analysed to assure that trial data is accurate.

3.0 APPLICABLE TO

Any UH employee involved with the collection and management of data for clinical research including, but not limited to: Chief Investigators (CI), Principal Investigators (PI), Research Managers, Statisticians, Trial Managers and Data Managers.

“ICH GCP guidelines state that only appropriately qualified individuals should supervise trial data handling, verify the data and conduct the statistical analyses (ICH 5.5)”.

4.0 RESPONSIBILITIES

The Chief Investigator (CI) or delegate and Trial Co-ordinator is responsible for the design and development of CRFs. The CI is also responsible for ensuring that there are adequate CRFs for use in the study in all participating sites. Instructions should be given to all participating sites on how to complete the CRFs to ensure data is collected in a standardized fashion. A CRF completion guide may be useful in a multicentre study.

5.0 PROCEDURE

5.1 CRF Completion and Retention

5.1.1 Case Report Forms (CRFs) are the usual data collection tool used in a clinical trial and are essential for quality assurance and control. The CRFs can be either in paper format (pCRF) or an electronic CRF (eCRF). The procedures outlined below apply to both CRF formats.

5.1.2 The CRF should be completed by an appropriate individual delegated the responsibility by the Chief Investigator/Principal Investigator and recorded on the study delegation log.

5.1.3 All staff completing the CRFs should have adequate training to ensure minimal corrections required. For multicentre studies a CRF guidance document is recommended to assist sites with accurate CRF entry.

5.1.4 To complete pCRFs, always use black ballpoint pen. **Do not use pencils.**

5.1.5 Ensure that the CRF contains only anonymised data unless it is specified in the protocol that CRFs are source documents and that patient names can be collected.

5.1.6 The CRF should be completed in a timely manner using source documents (i.e. medical notes) unless the protocol states that the CRF can be the original site of recording. Ensure that all entries are legible.

5.1.7 Do not leave CRF pages blank. If data are unavailable then the annotations not done (N/D), not applicable (N/A) or unknown (U/K) should be recorded as appropriate.

5.1.8 Do not create additional fields on the CRF i.e. Only provide information which is asked for. Do not use ‘post it’ notes within CRFs to include additional information.

5.1.9 Corrections should be made by crossing through the incorrect entry with a single line so that the original entry is still readable. Enter the correct data. Initial and date the correction. Never use correction fluid or obliterate entries made on the CRF.

5.1.10 The CRF should be reviewed for accuracy and completeness by the Investigator or an appropriately delegated individual and signed off before the CRF data is entered onto the statistical database.

5.1.11 The UH sponsored study CRFs will be subject to source data verification monitoring (see SOP-12) to ensure the data collected is accurate and verifiable and that the safety of patients is maintained. The level of monitoring will be decided by the Sponsor and detailed in the study monitoring plan.

5.1.12 The Monitoring report will identify any changes which are required to the CRF. The CRF corrections should be made by the research team within the defined timelines of the monitoring report.

5.1.13 CRFs should be stored in a secure location during the course of the study and archived when the study has finished.

5.1.14 Once the participant has finished their study treatment and the CRF has been completed they should be sent to the study's delegated data manager. The data manager should then check the CRF for missing or incomplete responses and if found, queried with the investigator and recorded.

6.0 RELATED DOCUMENTS

- gSOP-12 Monitoring
- gSOP-15 Designing a CRF
- gSOP-40 Data management overview

7.0 APPENDICES

- Appendix 1 - Definitions

8.0 VERSION HISTORY

Revision Chronology:		
Version Number	Effective Date	Reason for Change

9.0 AUTHORSHIP AND APPROVAL

Author

Signature

Date

Vice Chancellor (Research & Enterprise) Approval

Signature

Date

10.0 AGREEMENT

Please detach and retain within your training files

I have read and understood the contents and requirements of this SOP (SOP-41-01) and accept to follow UH policies implementing it.

Recipient

Signature:Date:

Name & Position:

Appendix 1: Definitions

Chief Investigator

A Registered Physician, Dentist, Pharmacist or Registered 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 Authorisation (CTA)

Regulatory approval issued by a Competent Authority to conduct a clinical trial within a Member State.

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).

Investigational Medicinal Product (IMP)

A pharmaceutical form of an active substance or placebo being tested, or used as a reference in a clinical trial. This includes a medicinal product which has a marketing authorisation but is, for the purpose of the trial -

- Used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation,
- Used for an indication not included in the summary of product characteristics under the authorisation for that product,
- Used to gain further information about the form of that product as authorised under the authorisation

Non-Substantial Amendment

Minor changes to the original REC application, to the protocol, or any other supporting documentation that will NOT affect to a significant degree;

- The safety or physical or mental integrity of the subjects of the study;
- The scientific value of the study;
- The conduct or management of the study.
- The quality or safety of any investigational medicinal product used in the trial

Principal Investigator (PI)

A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host site.

Substantial Amendment

Amendments to the original REC application, to the protocol, or any other supporting documentation that is likely to affect to a significant degree:

- The safety or physical or mental integrity of the subjects of the study;
- The scientific value of the study;
- The conduct or management of the study;
- The quality or safety of any investigational medicinal product used in the trial

The Medicines & Healthcare products Regulatory Agency (MHRA)
UK Competent Authority responsible for regulation of clinical trials.