University of Hertfordshire UH

Clinical Trials Unit



## University of Hertfordshire Clinical Trials Unit (CTU)

# VERSION CONTROL OF STUDY DOCUMENTS

Standard Operating Procedure for the writing and preparation of study documents for use in Research Studies and Clinical Trials at the University of Hertfordshire

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| **SOP Number:** gSOP-39-03 | **Effective Date: 26th February 2025** |
| **Version Number: 3** | **Review Date:** 3 years (or as required) |

### 1.0 BACKGROUND

This is a University of Hertfordshire (UH) standard operating procedure (SOP). This document defines the procedures for the writing and preparation of study documents for use in research studies and clinical trials at UH. This should be read in conjunction with UPR11 Appendix 5 on standard naming conventions for document titles. Using a document version control system will enable staff to organise files logically and retrieve them effectively and efficiently. It also facilitates shared working on documents.

Where there are potential conflicts between different collaborating organisations' SOPs, project level working instructions should be developed, to determine precedence.

### 2.0 PURPOSE

The document clarifies the requirements for accurate version control of study documents produced for UH sponsored/co-sponsored research studies, to comply with the requirements stated in Appendix C of the Good Clinical Practice guidelines (GCP: 'a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected').

The document aims to provide clear guidance on how to produce correctly version-controlled documentation and how these should be reviewed and updated.

Version control is the process by which different drafts and versions of a document are dated and managed. It provides an audit trail for the drafting and updating of a finalised version of a document. Version control must be used when more than one version of a document exists, or when this is likely to be the case in the future. It is essential that all users of a controlled document use the most up to date version in order to ensure that accurate procedures are being followed at all times.

## 3.0 APPLICABLE TO

This applies to all staff involved in clinical research sponsored/co-sponsored by UH or hosted by UH, including, but not limited to: Chief Investigators, Principal Investigators, Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial Coordinators, Clinical Studies Officers, Data Managers and Students.

## 4.0 RESPONSIBILITIES

- The Chief Investigator (CI), Principal Investigator (PI) or delegate is responsible for the version control of the documents. The CI or academic supervisor must ensure that if they delegate the role of version control to another member of the research team, that they have sufficient knowledge and expertise.

- It is the responsibility of the CI, PI or delegate to circulate the study specific documents to research sites. When a new version of a document is issued to sites, the researcher should obtain written confirmation from the PI at each site that:

    - The updated document(s) have been placed in the site file;
    - The previous version of the document is retained in the site file but is marked as superseded;
    - All staff working on the study are aware of the changes to the document.

- All staff preparing UH sponsored or co-sponsored study documents must comply with the requirements set out in section 5, as well as the UPR on standard naming conventions (see section 6 for related documents).

## 5.0 PROCEDURE

### 5.1 Original Documents

**5.1.1** A document control system shall be used for all study documents. Superseded versions of documents will be appropriately archived.

**5.1.2** For clinical trial documentation, during initial drafting, each successive draft of a document must use a systematic system to ensure it is clear which document is the most recent version. For example, documents could be numbered sequentially from 0.1, 0.2, 0.3 etc. and dated i.e., each draft version becomes a decimal place larger.

**5.1.3** The final original version of the research document should be labelled as Version 1.0 and dated. This version will be submitted for the appropriate approvals and authorisations.

**5.1.4** The version number and date should be added to the end of the file name and within the document, i.e. on the title page and also in the header or footer of each page.

**5.1.5** Procedures should be in place to ensure that in addition to the completed version, each draft version of the document is saved and clearly identified by its file name.

**5.1.6** A copy of each finalised version of a document should be included in the Trial Master File

(TMF).

**5.1.7** Files should clearly indicate document versions that have been superseded so that these documents are not inadvertently used.

**5.1.8** Key trial documents which form the TMF (particularly those in electronic format) must be stored in a protected format to avoid unauthorised or accidental editing. This can be done by restricting access to certain team members or changing the document to a non-editable format such as PDF.

**5.1.9** All versions of a document used during the lifetime of a clinical trial must be kept, to allow replication of the trial. It is recommended that files clearly indicate document versions which have been superseded.

### 5.2 Amendments

**5.2.1** If amendments are necessary following appropriate approvals or authorisations, then subsequent versions of the draft research document should be numbered as 1.1, 1.2, until the version is complete. The finalised version should then be numbered Version 2.0 and dated. If the study document is then substantially amended again during the study, then the version submitted for approval of the amendment will be numbered Version 3.0 and so on.

**5.2.2** If the study document requires only a minor amendment during the study then the version used will increase by a decimal place larger i.e. Version 3.1.

**5.2.3** An electronic hard copy of all final documents and also a tracked changes version (both to be sent to regulatory authorities during amendment process, see g-SOP-09) should be filed in the appropriate area of the TMF and final study documents also filed in the Site Files at all sites actively conducting the study. The tracked changes version can be provided for information purposes to all active study sites.

**5.2.4** As outlined in Section 4 of this document, amended documents must be circulated to all research sites and receipt obtained.

## 6.0 RELATED DOCUMENTS

- gSOP-19: Quality Management System
- UPR-IM11 Records Management and the Archiving and Retention of Prime Documents and Business Records
- gSOP-09 Amendments

## 7.0 APPENDICES

- Appendix 1.0 Definitions

## 8.0 VERSION HISTORY

| Revision Chronology: | | |
|---|---|---|
| **Version Number** | **Effective Date** | **Reason for Change** |
| **2.0** | **March 2022** | Scheduled review |
| **3.0** | **February 2025** | Scheduled review |
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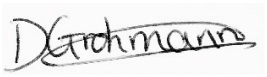
## 9.0 AUTHORSHIP & APPROVAL

**Author** Dominique Grohmann

**Signature**  **Date** 20/05/2024

## Pro-Vice Chancellor (Research & Enterprise) Approval

**Signature** **Date 22/10/2025**

**Signed by Dr Susan Grey, Chair of the Governance of Clinical Studies Group (GCSG), on behalf of the Pro-Vice Chancellor (Research & Enterprise)**

## 10.0 AGREEMENT

**Please detach and retain within <u>your training files</u>**

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**I have read and understood the contents and requirements of this SOP (ref gSOP-39-03) and accept to follow University policies implementing it.**

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| **Recipient** |
| Signature: ……Date: …….. |
| Name & Position: …… |

**Please retain copy of the signed form for your reference in your training file**

## Appendix 1 – DEFINITIONS

**Case Record Form (CRF)** - a printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject".

**Chief Investigator (CI) -** An individual who is responsible for the conduct of the whole project in the UK. 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.

**Continuing Professional Development (CPD) –** A process of setting goals and objectives for development and the charting of progress made against them. Development can be achieved by collection of CPD points allocated to approved training events.

**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).

**Elective** – training which is optional, that is available to any employees and any other staff involved in clinical trials but is not compulsory.

**Good Clinical Practice (GCP) -** as defined in the Regulations.

**International Conference on Harmonisation (ICH) –** Produced a series of guidelines in 1996, E6 being the guideline on Good Clinical Practice, otherwise known as (ICH-GCP).

**Investigational Medicinal Products (IMP) -** means 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 purposes 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, or
- used to gain further information about the form of that product as authorised under the authorisation

**Mandatory** – training which must be completed by all employees and any other staff involved in clinical trials and is therefore compulsory.

**Principal Investigator (PI)** - The investigator responsible for the research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person

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

**The Regulations** - Medicines for Human Use (Clinical Trial) Regulations 2004 transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928.