Humber Health Partnership

Version Control SOP

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AI update statement: This Standard Operating Procedure (SOP) was reviewed and updated with the assistance of an Artificial Intelligence (AI) tool. The AI output was used to support drafting and editing only; all content was verified, amended where required, and approved by the document owner/author in accordance with the Trust's document control and governance requirements.

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Hull University Teaching Hospitals NHS Trust
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This page details the version history and the main changes made for each new version.

Version Log		
Version number and date	**Author**	**Details of significant changes**
Version 1, 04.03.11	J Pacynko	Original SOP approved by R&D Committee on 04.03.11 by global email. R&D Committee reviewed SOP on 24.02.11, but meeting not quorate.
Version 2, 02.02.15	J Pacynko	Links up-dated Minor clarifications made in red type.
Version 3, 28.01.21	S Moffat	SOP changed to new format Addition of HRA to 1.4 in Section 1, page 4 Hyperlinks removed from the Amendment SOP in 2.5, Section 2, page 5 and in 3.8, Section 3, page 6.
Version 4, 14.12.22	S Moffat	New Section 3 added – Version control of GCP forms, page 5. Now Section 4 - Version control of amendments ● Page 6 – sub heading changed to both Substantial and non-substantial amendments as the Amendment Tool is used for both. Removal of paragraph for non-substantial amendment ● Line 4.2, page 6 –wording changed from Substantial Amendment Notification Form to Amendment Tool. ● Line 3.5, page 6 – wording changed from Substantial Amendment Notification wording to Amendment Tool wording.
Version 5, 30.04.2026	L Cox	1. Introduction & Purpose • Added wording to incorporate ICH E6(R3) principles, including Quality by Design (QbD), proportionality, and protection of critical-to-quality (CTQ) factors. • Added requirements for documenting the rationale for document changes and ensuring decisions are risk-based. • Added expectations for data governance, including integrity, traceability, and secure handling of documents. 2. Version Control of Study Documents • Added requirement to document the impact of changes on participant safety, data integrity, operational feasibility, and CTQ factors. • Added expectations for metadata, audit trails, system validation, and secure digital document management. • Strengthened wording on traceability and auditability of document histories. 3. Version Control of GCP Forms (R&D QA Only) • Expanded “Reason for changes” to include assessment of impact on CTQ factors, participant safety, and data integrity.

		• Added requirements for validated electronic systems, including access controls and audit trails. • Added wording to clarify oversight and approval responsibilities in line with R3. 4. Version Control of Modifications • Added requirement to document the rationale for each amendment, not just the description of changes. • Added requirement to assess and document the impact of amendments on CTQ factors, participant safety, and data integrity. • Added requirement to update the risk assessment when amendments introduce operational or methodological changes. 5. Implementation • Added requirement for staff training on ICH E6(R3) principles. • Added expectations for continuous improvement, including periodic evaluation of version control processes. • Added wording to ensure ongoing oversight and alignment with evolving regulatory guidance. • Trust name changed from Hull University Teaching Hospitals NHS Trust (HUTH) to Humber Health Partnership (HHP- Hull University Teaching Hospitals NHS Trust and Northern Lincolnshire and Goole NHS Foundation Trust).

Contents List

Please note for definitions of acronyms refer to Appendix 1 of Management of SOPs. Refer to Appendix 2 of Management of SOPs for the standards to which clinical trials that investigate the safety and/or efficacy of a medicinal product are conducted.

All the HUTH R&D GCP SOPs are available at:
https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/

1 Introduction, purpose and who should use this SOP

1.1 Clinical trial documents such as the protocol, patient information sheet, informed consent form, GP letter and amendments must be given a version number and date when the document was completed.

1.2 Version control of trial documents enables staff and patients to use the up-to-date version at all times.

1.3 Good version control of trial documents will help to demonstrate that the trial has been conducted according to the UK Clinical Trial Regulations and GCP.

1.4 Version control processes must support the identification, protection and maintenance of critical-to-quality factors throughout the clinical trial lifecycle. Document changes must be proportionate to the risks, complexity and nature of the trial, and the rationale for each change must be recorded to demonstrate risk-based, quality-focused decision-making. Version control activities must also support robust data governance, ensuring data integrity, traceability, and secure management of both paper and electronic documents.

1.5 All users of clinical trial documents must use the most recent version that has been approved by the MHRA and/or REC, HRA and Trust R&D.

1.6 The purpose of this SOP is to describe the method of version control for study documents and amendments.

This SOP is relevant to all research staff, clinical trials pharmacy staff and R&D staff.

1.7 This SOP is defaulted to for hosted trials if the external sponsor does not have an SOP in place for version control.

2 Version control of study documents

2.1 The following documents must be given a version number and date:

- Protocol
- Patient information sheet and other information sheets
- Informed consent form
- GP or hospital consultant letter
- Adverts
- Patient study card
- Case report forms
- Substantial amendments

- Study prescriptions
- Study medication labels

2.2 Number the document using whole numbers in numerical order. Do not number the document 1.1, 1.2, 1.3 or 1a, 1b, 1c or 1A, 1B, 1C etc since this has frequently led to errors in the sequence of numbering and confusion in the past.

2.3 Date the document with the date that the document is completed.
e.g. **Protocol version 2, 19.01.15 or shortened to protocol v2, 19.01.15**

2.4 The version number and date should either be in the header or footer of the document so that it appears on each page. Electronic documents must also include system-generated metadata where available, supporting traceability and auditability in accordance with expectations for data governance.

2.5 If any changes are made to documents as part of a substantial or non-substantial amendment, the version number and date of the document must be up-dated. Refer to R&D GCP SOP 08 Amendments.

2.6 A clear history of changes made to documents must be kept in order to demonstrate that the trial has been conducted to the UK clinical trial regulations and GCP. The Study Tracking Log is used for this purpose and is available from the HUTH R&D QA team. The history of changes must include the rationale for each modification, including assessment of the impact on participant safety, data integrity, operational feasibility and critical-to-quality factors. Where electronic systems are used, version control must ensure appropriate audit trails, metadata, access controls and system validation to protect data integrity and prevent unauthorised modification.

2.7 Pharmacy documentation (prescriptions, labels, accountability forms etc) will be version controlled according to the pharmacy SOP.

3 Version control of GCP forms (for R&D QA only)

3.1 For changes made to all other document/form templates, other than those listed in paragraph 2.1 the version control process for amended documents must be followed. These documents/forms include the following (please note this list is not exhaustive):

- Trial Master File, Investigator Site File, Pharmacy Site File, Laboratory Site File List of Contents
- Delegation Log
- Study Tracking Log
- Training and Delegation Log
- Contact Sheet
- Adverse Event Form
- Serious Adverse Event Form
- Study Patient List
- Casenote sheets
- Protocol Deviation Log
- Serious Breach Notification
- File Note Templates
- Monitoring Visit Checklists

- Trial Equipment File Note
- Monitoring Plan
- Data Management Plan
- Randomisation Process File Note
- Current Documents Form
- Telephone Contacts
- Medication Accountability Logs

All of the above are saved on \\hri_data3\clinicalgov\Research\GCP SOPs & forms\GCP forms. Electronic storage locations must be access-controlled, secure, and compliant with expectations for data governance, including system validation, audit trails, and protection against unauthorised access or modification.

3.2 A Document Tracking Log must be completed with the following details for each amended document/form:

- The document title.
- The superseded version number and date.
- Details of changes
- Reason for changes - The reason for changes must include an explanation of the impact of the modification on critical-to-quality factors, participant safety, data integrity, and operational processes.
- Current version (after changes made)

The log must be signed by the person making the changes and then sent to another QA team member for approval, this can be done via Docusign.

Each document must have 3 folders set up:

- Current – a Word copy of the approved amended version to be filed in this folder
- Previous – the previous version to be moved to this folder
- Version Control – a sub folder must be created for whichever version the amendment is for e.g. Version 2 and in this a “tracked change” document, the pdf signed Document Tracking Log form and copy of the amended document must be filed.

3.3 The above version control process must also be used when amending the Working Instructions for R&D QA processes.

4 Version control of Modifications

Substantial Modifications, Modifications of an Important Detail and Minor Modifications

4.1 In the past, there has been a large amount of confusion caused by wrong version control of modifications. To avoid this please note the following points.

4.2 Make sure that the Sponsor modification reference number and the Sponsor modification date is entered correctly in Section 1 of the Modification Tool.
e.g. **SA 001 (substantial modification) or MOID 001 (Modification of an Important Detail) or for (Minor Modifications) MA.**

4.3 Number modifications using whole numbers in numerical order.

4.4 Date the modification with the date that you complete the modification form.

4.5 If the modification needs to be modified due to Ethics or MHRA requests then keep the same modification number but add the word 'modified' and the date the Modification Tool was completed, ensuring the question in the "Project Type" section "Is all or part of this modification being resubmitted to the Research Ethics Committee (REC) as a modified modification (i.e. a substantial modification previously given an unfavourable opinion)?" is answered "Yes".

e.g. **Modification 3 (modified), 18.05.15.**

4.6 Do not number the modification 1.1, 1.2, 1.3 or 1a, 1b, 1c or 1A, 1B, 1C etc.

4.7 Do not use the protocol number as the modification number.

If the Notification of modification form is not completed correctly, then the MHRA and Ethics Committee will number the modification in different ways which causes a great deal of confusion when checking whether modification have been approved and whether they were approved before implementing.

Refer to R&D GCP SOP 08 Modifications for details of the modification process.

4.9 The modification number and date, brief details of changes made and dates of submission and approvals of the modification must be completed on the Study Tracking Log.

4.10 The rationale for each modification must also be documented, including assessment of the modification's impact on participant safety, data integrity, and critical-to-quality factors. Where amendments introduce operational or methodological changes, the risk assessment must be updated and documented.

5 Implementation

Implementation must also include training and inclusive of quality-by-design, proportionality, risk-based decision-making, and data governance. Continuous improvement activities must be undertaken to evaluate the effectiveness of version control processes and ensure ongoing compliance with R3 expectations.