Department	Research & Development
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This page details the version history and the main changes made for each new version.
The new changes are in red font

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.

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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 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.

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

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

1.6 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.

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.

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.

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
- 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 amendments

Substantial and non-substantial (minor) amendments

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

4.2 Make sure that the Sponsor amendment reference number and the Sponsor amendment date is entered correctly in Section 1 of the Amendment Tool.
e.g. **SA 001 (substantial amendment) or MA 001 (minor amendment/non-substantial amendment)**

4.3 Number amendments using whole numbers in numerical order.

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

4.5 If the amendment needs to be modified due to Ethics or MHRA requests then keep the same amendment number but add the word 'modified' and the date the Amendment Tool was completed, ensuring the question in the "Project Type" section "Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a modified amendment (i.e. a substantial amendment previously given an unfavourable opinion)?" is answered "Yes".
e.g. **Amendment 3 (modified), 18.05.15.**

4.6 Do not number the amendment 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 amendment number.

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

Refer to R&D GCP SOP 08 Amendments for details of the amendment process.

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

5 Implementation

- Implementation of this SOP will conform to the process outlined in R&D SOP 01 Management of SOPs.