Department	Research & Development
Title of SOP	Version control SOP
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Authors:	J H Pacynko and J Illingworth
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Target audience:	Research, pharmacy and R&D staff
Distribution:	HUTH R&D internet Click on GCP SOPs for HUTH-sponsored CTIMPs https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/
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Authorized by		**Sign**	**Date**
R&D Director	Professor Thozhukat Sathyapalan		
R&D Manager	James Illingworth		

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.

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
- Trial Master File forms e.g. the Delegation Log

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 GCP SOP 08, Amendments SOP.

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 amendments

Substantial amendments

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

3.2 Make sure that the **amendment number and date** is entered correctly **in part E.1** of the Notification of Substantial Amendment form.
e.g. E.1 Sponsor's substantial amendment code number, version, date for the clinical trial concerned: **Amendment 3, 19.01.15.**

3.3 Number amendments using whole numbers in numerical order.

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

3.5 If the protocol has been amended enter the new amended protocol version number and date in point **B.4** of the notification of substantial amendment form.

3.6 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 notification of substantial amendment form was modified.
e.g. **Amendment 3 (modified), 18.05.15.**

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

3.8 Do not use the protocol number as the amendment number.

If part E.1 of the substantial 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 GCP SOP 08, Amendments SOP for details of the amendment process.

3.9 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.

Non-substantial amendments

3.10 It is equally important to up-date the version number and date of trial documents that have been amended non-substantially.

3.11 Non-substantial amendments must also be recorded on the Study Tracking Log with brief details of changes and the date when changes were made. This log of non-substantial amendments will be requested by the MHRA during inspections.

5 Implementation

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