Department	Research & Development
Title of SOP	Protocol design SOP for HUTH-sponsored CTIMPs
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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, 16.10.12	J Pacynko & J Illingworth	Original SOP approved by R&D Committee on 15.10.12
Version 2, 23.11.15	J Pacynko	Weblinks up-dated Hyperlinks removed as no longer work New HRA protocol guidance and template used
Version 3, 17.02.21	S Moffat	SOP changed to new format Weblinks updated

Please note for definitions of acronyms refer to Appendix 2 of Management of SOPs. Refer to Appendix 3 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-huth-sponsored-ctimps/

1 Introduction, background and purpose

1.1 The protocol is a document that describes the objectives, design, methodology, statistical considerations and organisation of a trial. The protocol usually also gives the background and rationale for the trial (ICH GCP 1.44, UK CT reg 2 (1).

1.2 Every clinical trial requires a protocol which forms a contract between the investigator and Sponsor. It is therefore important that the protocol is signed off by the Chief/Principal Investigator and Sponsor representative (usually the R&D Manager).

1.3 The clinical trial **must be** conducted in accordance with the protocol (UK CT reg 29 (a). The Sponsor needs be alerted straight away if the protocol requires a change or clarification because it is the Sponsor's responsibility to decide whether an amendment is substantial or non-substantial and which approvals are required if the amendment is substantial. See Amendments SOP for details of the process.

1.4 The purpose of this SOP is to describe how the protocol should be prepared for clinical trials sponsored by Hull University Teaching Hospitals NHS Trust.

2 Who should use this SOP

2.1 This SOP should be used by:

- All research staff involved with HUTH-sponsored CTIMPs – Chief/Principal Investigator, other study medics, research nurses, project managers, clinical trial co-ordinators, data managers, administrators etc.
- Clinical trials pharmacy staff – technicians and pharmacists.
- All HUTH R&D staff.
- Research staff involved with HUTH-sponsored non-CTIMPs may find this SOP a useful guide, although the SOP will need to be adapted for the non-CTIMP study.
- Research staff involved with clinical trials sponsored by an external organisation where the Sponsor has no SOP for the protocol. HUTH R&D SOPs are defaulted to in this case.

3 Preparation of the protocol

3.1 The Chief/Principal Investigator will be asked to email a draft protocol and 'request for sponsorship' form to R&D at the earliest opportunity in order to start the request for sponsorship process. See R&D GCP SOP 05 Sponsorship of HUTH CTIMPs for the full process.

3.2 The Protocol Summary template in Appendix 1 can be used by investigators to provide an initial draft outline of the protocol. It is also useful to put this summary towards the front of the protocol for a quick reminder of the protocol design.

3.3 Once it is established whether the study is a CTIMP or non-CTIMP, R&D will send to the Chief/Principal Investigator the CTIMP or non-CTIMP protocol guidance and template for HUTH-sponsored trials in order to finalize the protocol. **These are available from the HUTH R&D QA team.**

3.4 The protocol guides are intended to help researchers with points to consider for the content of protocols. The guides indicate the information that should be included in a protocol and cover methodology considerations and requirements specified under Good Clinical Practice (ICH GCP section 6).

3.5 Each section of the protocol guide should be considered carefully. **It is a condition of sponsorship that the protocol guides are adhered to and it is the expected standard for Trust R&D approval.**

3.6 The CTIMP protocol guide and template has been taken from the Health Research Authority (HRA) website - see link below. We have added to this guide wording in red font which is specific for HUTH-sponsored CTIMPs and which should be cut and pasted into the protocol. The red wording has been developed to ensure compliance with the UK CT Regs and ICH GCP, but where it does not reflect the investigator's practice the wording should be revised accordingly.

3.7 Using the HRA's protocol guide will prevent queries raised by the Ethics Committee and MHRA and delays obtaining approvals. https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/

3.8As part of trial set-up, investigators will need to read the R&D GCP SOPs (standard operating procedures) to be aware of their responsibilities as investigators. These SOPs are instructions on how to set up and conduct HUTH-sponsored CTIMPs and are available on the HUTH R&D GCP SOPs webpage at: https://www.hey.nhs.uk/research/researchers/gcp-sops-for-huth-sponsored-ctimps/

3.9 The protocol, patient information sheet, consent form, GP letter and CRF must have a version number and date within the header or footer. See the R&D GCP SOP 01 – Version Control.

3.10 It is advisable that investigators contact a statistician in the early stages of developing their protocol. The HYMS Statistical Consultancy Service is free. Email research@hyms.ac.uk for advice on how to book an appointment with a statistician.

3.11 As a minimum, the Chief/Principal Investigator, Sponsor and Statistician (if involved) should sign off the protocol. The Chief/Principal Investigator signs to agree to conduct the study according to the protocol, the Sponsor representative signs to confirm that Hull University Teaching Hospitals NHS Trust agrees to sponsor the study and the Statistician signs to confirm that the statistics section is correct.

3.12 It is highly recommended that the protocol contains a schedule of assessments in the form of a table with study visits along the top row and investigations/procedures down the left hand column. It is then clear at a glance what study investigations are performed at which visit. This is a good training tool for those involved with the study. An example table is in Appendix 4 at the end of the HRA protocol guide.

3.13 Likewise it is recommended that a flow chart or schematic diagram of the trial design and procedures is present in the protocol which at a glance shows the treatment options and the patients' possible pathways along the study.

3.14 If the study is a randomized controlled trial, it is recommended that the CONSORT website is consulted when compiling the protocol (Consolidated Standards of Reporting Trials http://www.consort-statement.org/).

4 Review of the protocol

4.1The Chief Investigator will be asked to send the final draft protocol and sponsorship request form to the QA Manager or Monitor for review and decision on sponsorship. Any comments regarding the protocol will be sent back to the investigator for resolving. This helps prevent modifications to the protocol and submission of an amendment after the study has started. See R&D GCP SOP 05 Sponsorship of HUTH CTIMPs.

5 Implementation

5.1Implementation of this SOP will conform to the process outlined in R&D SOP 01Management of SOPs.

Appendix 1

Protocol Summary

Title	
Chief/Principal Investigator	
Planned sponsor	
Planned funder	
Background	
Phase	1, 2, 3 or 4
Planned number of sites	
Design	Number of arms, randomised, placebo-controlled, open label, single-blind, double-blind, parallel design, cross-over.
Aims	
Primary objectives	
Secondary objectives	
Population	
Target accrual	
Duration patient in trial	Duration in treatment phase: Duration in follow-up:
Inclusion criteria	
Exclusion criteria	
Randomisation	
Trial treatment	
Investigations	
Definition of end of trial	
Statistical summary	