Gloucestershire Hospitals
NHS Foundation Trust

# Initiating Research 03 – Writing a protocol

## IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research & Development Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the R&D website:

http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

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| **SOP reference:** | IR03 | |
| **Version:** | 2.0 | |
| **Author:** | Janet Forkes | |
| **Reviewed by Associate Director of R&D** | Julie Hapeshi<br>27/03/2018 | |
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| **Date of Review:** | 01 / 12 / 2018 | |

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

## Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

| Version | Details of Change | Date Implemented |
|---|---|---|
| 1.0 | Original SOP | 01/02/2017 |
| 2.0 | Rebranding to GHNHSFT, updating of contact details and reference documents | 31/03/2018 |
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This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

## Contents

## 1. Introduction, Background and Purpose

The purpose of this SOP is to describe how a study protocol should be written to GCP standards so that it is compliant with the Medicines for Human Use (Clinical Trials) Regulations 2004 (and amendments).

A study protocol is a document which describes how a piece of research will be conducted. It is a controlled document which describes a range of activities including, but not limited to the background, rationale, design, population to be researched, oversight, data collection, analysis and archiving of a study.

Details of the stakeholders in the research should be documented, to include the sponsor, chief investigator and the funder.

Documents such as the participant information sheets and consent forms may be appended, along with other documentation which supports robust management of the research.

## 2. Who should use this SOP?

This SOP should be used by investigators and research team members involved in CTIMPs sponsored by The Trust. However, it is also relevant for researchers preparing protocols for non-CTIMPs.

## 3. When this SOP should be used

This SOP is applicable when preparing protocols for all CTIMPs that are sponsored by the Trust.

## 4. Procedure

### 4.1 Protocol template

4.1.1 All protocols for CTIMPs to be sponsored by the Trust must be based on the following templates and guidance produced by the HRA (unless agreed otherwise in advance):

(a) CTIMP protocol guidance and a template, available here: www.hra.nhs.uk/about-the-hra/consultations-calls/closed-consultations/protocol-guidancetemplate-use-clinical-trial-investigational-medicinal-product-CTIMP-consultationuse/#sthash.S6fI8FDk.dpuf

(b) Guidance on the design of participant information sheets and consent forms, available here: www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-andparticipant-information/#sthash.m682P3Eu.dpuf

### 4.1.2 Non-CTIMP Research Project

All Trial Teams developing a Non-CTIMP research project should also use the HRA templates with all references to the IMP and MHRA, and any other non-relevant sections removed.

## 4.2 Protocol Development

The Protocol should be developed in collaboration with key contributors to the research project. These can include (and are not limited to):

- CI
- Other Key Investigators
- Pharmacy Contact or IMP Specialist or Statistician or Laboratory or sample specialists or collaborators
- Members of any proposed Trial Steering Committee/Data Monitoring Committee or Trial Review Committee
- Members of the funding awarding body
- Commercial supporters of the research
- Representative of the Sponsor ( as accountable on the delegation log in R&D SOP IR01)

The Protocol should be version controlled. The final version of the protocol must be reviewed, amended as necessary and approved by the appropriate clinical trial development team including at the minimum, the CI, the trial statistician and the trial pharmacist (if a CTIMP).

Where GHNHSFT is the Sponsor the following wording should be incorporated into the relevant sections of the protocol:

| Protocol Section | Standard Wording |
|---|---|
| Details of Sponsor | Gloucestershire Hospitals NHS Foundation Trust, R&D Department , Floor 1 , Leadon House, Gloucestershire Royal Hospital, Great Western Road, Gloucester, GL1 3NN<br>Trust Headquarters, Alexandra House, Cheltenham General Hospital, Sandford Road, Cheltenham, GL53 7AN |
| Study Medication | *In addition to a description of study medication, doses, regimen, etc:*<br><br>Study medication will be stored and dispensed by the trial site's pharmacy department in accordance with Good Clinical Practice, Good Manufacturing Practice and pharmacy department SOPs. |
| Safety Reporting | Adverse events will be recorded and reported in accordance with North Bristol NHS Trust's Safety Reporting SOP.<br><br>*In this section, events can be identified that may be excluded from expedited reporting because they are commonly associated with the clinical procedures taking* |

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| | *place; these should be agreed with the sponsor prior to submission to REC. Identify reference documents used to justify this decision e.g. product information. Please refer to SOP on Safety Reporting: R&D SOP Ph02 for further information.* |
| Monitoring & Audit | The study will be monitored in accordance with GHNHSFT's Monitoring SOP R&D SOP MR04. All trial related documents will be made available on request for monitoring and audit by GHNHSFT, the Research Ethics Committee and for inspection by the Medicines and Healthcare products Regulatory Authority or other licensed bodies. The monitoring plan will be developed and agreed by the sponsor. |
| Data Handling & Protection | The database and randomisation system will be designed so as to protect patient information in line with the Data Protection Act 1998. Trial staff will ensure that the participants' anonymity is maintained through protective and secure handling and storage of patient information at the trial centres (as relevant). All documents will be stored securely and only accessible by trial staff and authorised personnel. Data will be collected and retained in accordance with the Data Protection Act 1998. |
| Storage of Records | Study documents (paper and electronic) will be retained in a secure location during and after the trial has finished. All essential documents, including patient records and other source documents will be retained in accordance with GHNHSFT's Archiving SOP, R&D SOP TD05 following the end of a study. Where electronic records are in use, Trust policy will be followed. |
| Indemnity | This is an NHS-sponsored research study. For NHS sponsored research HSG(96)48 reference no.2 refers. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. |
| Authorisations | The study will be performed subject to favourable opinion/authorisation/permission from all necessary regulatory and other bodies. This includes but is not limited to REC, MHRA, HRA, NHS Trusts. |
| Research Governance Statement | This study will be conducted in accordance with: - The Medicines for Human Use (Clinical Trials) Regulations 2004 - International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines – UK Policy Framework for Health and Social Care Research v3 2017 |

The final version of the protocol to be sent for regulatory approval must be signed and dated by the CI. It is then kept in the TMF for Trust Sponsored CTIMPs and Non-CTIMP research projects

For all interventional research the protocol should follow the SPIRIT 2013 Guidelines (Standard Protocol Items: Recommendations for Interventional Trials www.**spirit**-statement.org/ ).

For the efficacy of research projects review the COMET Initiative website (http://www.comet-initiative.org/) for the standardised Core Outcome Measures in Effectiveness Trials

## 4.3 Protocol amendments

Any change of the protocol will constitute an amendment either substantial or non-substantial. The Sponsor will confirm whether the change is substantial or not. For managing amendments including urgent safety measures refer to the HRA website.

Changes must be reviewed and approved by the appropriate personnel e.g. CI, pharmacy advisor, statistician, etc.

## 5 Related SOPs

R&D SOP IR 01 Sponsorship
R&D SOP TD 02 Training
R&D SOP TD 03 Informed Consent
R&D SOP TD 05 Archiving
R&D SOP PH 02 Safety Reporting