North Bristol NHS Trust

Standard Operating Procedure

Writing a Protocol for CTIMPs

REFERENCE:	RI/QMS/SOP/008
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Document Version History

VERSION NUMBER	EFFECTIVE DATE	REASON FOR CHANGE
1.0	01-03-12	Removed reference to NBT acting as co-sponsor
2.0	09-07-12	SOP renamed, updated in line with new template and recoded from ISOP-B10
3.0	08-02-16	Inclusion of reference safety information, data management and quality control sections

Adapted with the kind permission of University Hospitals Bristol NHS Foundation Trust

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT CHECKING IT IS THE LATEST VERSION

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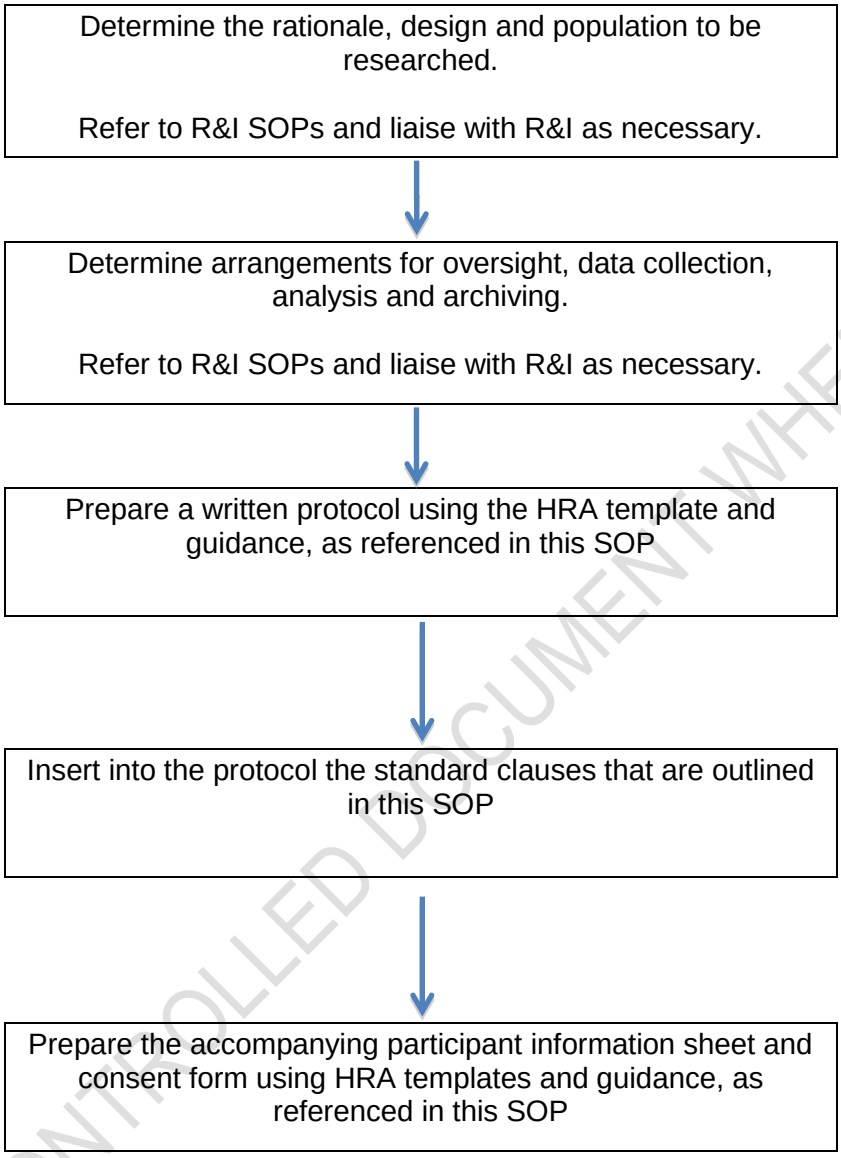
i. SOP Flowchart



1. PURPOSE AND SCOPE

The purpose of this SOP is to describe how a study protocol should be written to ICH GCP 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.

2. DEFINITIONS/ABBREVIATIONS

CTIMP	Clinical trials of Investigational Medicinal Products
HRA	Health Research Authority
ICH GCP	International Conference on Harmonisation guidelines for Good Clinical Practice
NBT	North Bristol NHS Trust
R&I	NBT Research & Innovation Office
MHRA	Medicines and Healthcare Products Regulatory Agency
NBT	North Bristol NHS Trust
SOP	Standard Operating Procedure
Sponsor	The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research

3. WHO SHOULD USE THIS SOP

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

4. WHEN SHOULD THIS SOP BE USED

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

5. PROCEDURE

5.1 **Protocol template**

All protocols for CTIMPs to be sponsored by NBT 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 on the HRA website (www.hra.nhs.uk).

(b) Guidance on the design of participant information sheets and consent forms, available on the HRA website (www.hra.nhs.uk).

5.2 **Protocol wording**

Where NBT is the Sponsor of the CTIMP, the following wording should be incorporated into the relevant sections of the protocol:

Protocol Section	Standard Wording
Details of Sponsor	North Bristol NHS Trust, Research & Innovation, 3rd Floor, Learning & Research Building, Southmead Hospital, Westbury-on-Trym, Bristol, BS10 5NB
CI and Research Team Contact Details	Enter the Chief Investigator's contact details, including correspondence address and emergency contact details. Include contact details for relevant/key members of the research team
Study Medication	*In addition to a description of study medication, doses, regimen, etc:* 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. *In this section, events can be identified that may be excluded from expedited reporting because they are commonly associated with the clinical procedures taking place; these should be agreed with the sponsor prior to submission to HRA. Identify reference documents used to justify this decision e.g. product information. Please refer to SOP on Safety Reporting: Clinical Trials of Investigational Medicinal Products (CTIMPs) (RI/QMS/SOP/013) for further information.*
Reference Safety Information (RSI)	The following will be used as the Reference Safety Information (RSI) during the course of this trial: • Summary of Product Characteristics for XX (name of IMP)/Investigator Brochure for XX (name of IMP)/other document (delete and amend as appropriate) If there are any updates made to the document described above, these will be reviewed by the Chief Investigator and Sponsor and a joint decision made whether the updated document will be submitted to the MHRA for use as the RSI in the trial.
Data Management	*The protocol should refer to the Data Management Plan (DMP) which will give specific information regarding the management of the data during and at the end of the trial. Please refer to SOP on*

	Data Management (RI/QMS/SOP/017) for further information.
Monitoring, Audit and Inspection	The study will be monitored in accordance with North Bristol NHS Trust's Monitoring SOP. All trial related documents will be made available on request for monitoring and audit by North Bristol NHS Trust, the HRA 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.
Quality Control	Where applicable, a random sample of x% (at least 10%) of CRFs will be checked, by the trial research team or R&I monitor, against entries within the database and with the source data for quality purposes. The percentage checked will be increased if a significant error rate is found. The data from the first patient recruited at a new site will be reviewed. This may include consent records, safety data and primary endpoint data.
Data Handling & Protection	The database and randomisation system will be designed so as to protect patient information in line with (i) the Data Protection Act 1998 until 24 May 2018, and (ii) the General Data Protection Regulation, as from time to time amended from 25 May 2018. 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 relevant data protection legislation.
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 North Bristol NHS Trust's Archiving SOP 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 MHRA, HRA, NHS trusts.
Research	This study will be conducted in accordance with:

Governance Statement	• The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments • International Conference for Harmonisation guidelines for Good Clinical Practice (ICH GCP) • UK Policy Framework for Health and Social Care Research

6. DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the Trust intranet shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP.

The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

7. RELATED SOPS AND DOCUMENTS

- Health Research Authority
  Protocol guidance and template for use in a CTIMP
  www.hra.nhs.uk

- Health Research Authority
  HRA Consent and Participant Information Sheet Preparation Guidance
  www.hra.nhs.uk

- The following NBT documents are available on the R&I website: www.nbt.nhs.uk/research

RI/QMS/SOP/007	Applying for NBT Sponsorship
RI/QMS/SOP/010	Archiving
RI/QMS/SOP/013	Safety Reporting: Clinical Trials of Investigational Medicinal Products (CTIMPs)
RI/QMS/SOP/014	Monitoring