Standard Operating Procedure

WRITING A RESEARCH PROTOCOL TO GOOD CLINICAL PRACTICE

SETTING Trustwide

AUDIENCE Research staff with the responsibility for writing research protocols to be sponsored by UHBristol.

ISSUE To provide guidance to researchers about the required content of a research protocol

QUERIES Contact R&I department : Ext 20233 or research@uhbristol.nhs.uk

SOP number	SOP 004	**SOP Version**	1.4
Effective Date	12/FEB/2018	**Review Date**	12/FEB/2020

Document History

Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
Original Policy	1.0	28/JUL/15	17/AUG/2015	Diana Benton	Diana Benton
19/AUG/2015	1.1	19/AUG/15	14/SEP/2015	Genna Nicodemi	Diana Benton
22/DEC/15	1.2	22/DEC/15	16/MAR/2016	Jess Bisset	Diana Benton
28/NOV/16	1.3	28/NOV/16	23/DEC/2016	Jess Bisset	Diana Benton
12/JAN/18	1.4	12/JAN/18	12/FEB/2018	Trusha Rajgor	Jess Bisset

Version Number	Reason for change
Original V1.0	New SOP
1.1	Minor changes to incorporate consultation feedback
1.2	Minor update to standard wording
1.3	Updates to standard wording and minor clarifications
1.4	Insert SOP into new SOP template, removal of appendices to become standalone templates and minor updates and clarifications to wording.

1. Introduction

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 (CI) and the funder. Documents such as the Patient Information Sheets (PIS) and consent forms may be appended, along with other documentation which supports robust management of the research.

2. Purpose

The purpose of this document is to describe how a study protocol should be written to Good Clinical Practice (GCP) so that it is compliant with the Medicines for Human Use (Clinical Trials) Regulations 2004 (and amendments). Consequently, this SOP principally focuses on the requirements for a protocol of a clinical trial of an investigational medicinal product (CTIMP). However, many areas covered will also be relevant for protocols of non-CTIMPs.

3. Scope

In Scope: Protocols for studies sponsored by UHBristol.
Out scope: Protocols for studies sponsored by organisations other than UHBristol.

4. Responsibilities

The CI is responsible for writing or overseeing the writing of the protocol in consultation with appropriate staff and for ensuring that the protocol is written in accordance with the relevant legislation and UHBristol guidance.

The sponsor representative in R&I is responsible for reviewing the protocol and providing advice on research governance.

5. Abbreviations and Definitions

Abbreviations	
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
HRA	Health Research Authority
ICF	Informed Consent Form
GCP	Good Clinical Practice
PIS	Patient Information Sheet

6. Procedure

- A protocol may be required as part of a grant application (if applying for funding) and will be required when applying for UHBristol sponsorship.
- The protocol should be written by the CI or a delegated member of the research team.
- All protocols for **CTIMPs** to be sponsored by UHBristol must be based on the templates and guidance produced by the HRA (unless agreed otherwise in advance). Protocol templates and guidance on the design of Patient Information Sheets (PIS) and Informed Consent Forms (ICFs) can be found on the HRA website.
- The protocol for **CTIMPs** must contain a CI signature page for the approved protocol and any subsequent amendments to the protocol (unless agreed otherwise in advance).
- Much of the content of the documents from the HRA website will also be relevant to **non-CTIMP** protocols. UHBristol supports their use as a basis for writing protocols for all research to be sponsored by the Trust. Sections only relevant to CTIMPs can be omitted where irrelevant in these cases.
- For UH Bristol sponsored research, it is a requirement that the standard wording provided in *GD_004 UHBristol suggested standard wording for IMP protocols* and *GD_005 UHBristol suggested standard wording for Non-IMP protocols* is used unless alternative wording is agreed in advance. In some cases, the HRA template also contains suggested standard wording. UHBristol standard wording must be used in preference, or in addition to HRA

standard wording. It is the responsibility of the CI to ensure that wording used is not in contradiction of any of UHBristol's research SOPs.

- The protocol should be appropriately version controlled with minor amendments updated with an increased minor version number (e.g. v1.2) and major amendments updated with an increased major version number (e.g. v2.0).
- As part of the UHBristol sponsorship process, the protocol will be reviewed as described in *SOP_002 Sponsorship* to ensure that wording within the study protocol corresponds to the standard wording in *GD_004* and *GD_005* and relevant sections of the IRAS application form.
- If the protocol needs to be amended after regulatory and ethical review, then please refer to *SOP_019 UH Bristol sponsored research amendments*.

7. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&I) and will be available on the R&I website.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP_007 Research Training*.

8. Related documents

- ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996) http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf
- EU COMMISSION DIRECTIVE 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:091:0013:0019:en:PDF
- Statutory Instrument 1031: The Medicines for Human Use (Clinical Trials) Regulations 2004 http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf
- GD_004 UHBristol suggested standard wording for IMP protocols
- GD_005 UHBristol suggested standard wording for Non-IMP protocols
- SOP_002 Sponsorship
- SOP_007 Research Training
- SOP_019 UH Bristol sponsored research amendments