

Standard Operating Procedure

WRITING A RESEARCH PROTOCOL TO GOOD CLINICAL PRACTICE

SETTING	Trustwide
FOR STAFF	Research staff with the responsibility for writing research protocols to be sponsored by University Hospitals Bristol and Weston NHS Foundation Trust (UHBW).
ISSUE	To provide guidance to researchers about the required content of a research protocol

SOP number	SOP 004	SOP Version	2.0
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Document History

Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
Original Policy	1.0	28/JUL/2015	17/AUG/2015	Diana Benton	Diana Benton
19/AUG/2015	1.1	19/AUG/2015	14/SEP/2015	Genna Nicodemi	Diana Benton
22/DEC/2015	1.2	22/DEC/2015	16/MAR/2016	Jess Bisset	Diana Benton
28/NOV/2016	1.3	28/NOV/2016	23/DEC/2016	Jess Bisset	Diana Benton
12/JAN/2018	1.4	12/JAN/2018	12/FEB/2018	Trusha Rajgor	Jess Bisset
23/JUL/2020	1.5	21/JUL/2020	24/SEP/2020	Katharine Wale Sandra Mulligan	Elinor Griffiths
13/JAN/2021	1.6	13/JAN/2021	15/NOV/2021	Katharine Wale	Jess Bisset
FEB/2023	1.7	16/FEB/2023	01/APR/2023	Lucy Riddolls	Jess Bisset
AUG 2023	1.8	02/AUG/2023	03/AUG/2023	Elinor Griffiths	Jess Bisset
JUL 2025	2.0	11/JUL/2025	24/OCT/2025	Katrina Hurley Sandra Mulligan	Diana Benton

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.
1.5	Minor updates and clarifications as part of biennial review.

1.6	Update to the references section
1.7	Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment.
1.8	Minor updates and clarifications as part of biennial review and inclusion of reference to UHBW protocol template for non CTIMPs
2.0	Major update including reference to UHBW protocol template for non CTIMPs, inclusion of CIMDs and ATIMPs and several other clarifications throughout the document

1. Introduction

A study protocol is a document which describes how a piece of research will be conducted. It is a version-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, including the sponsor, Chief Investigator (CI) and the funder.

For ease of approval and amendments, other essential documents which support robust management of the research such as the Patient Information Sheets (PIS) and Informed Consent Forms (ICF) should be created as standalone documents. In some circumstances they may be appended to the Protocol; however, this is not recommended where UHBW are sponsor.

2. Purpose

The purpose of this document is to describe how a study protocol should be written in accordance with Good Clinical Practice (GCP) so that it is compliant with the Medicines for Human Use (Clinical Trials) Regulations 2004 (and subsequent amendments) and Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002). Consequently, this SOP principally focuses on the requirements for a protocol of a clinical trial of an investigational medicinal product (CTIMP), an Advanced Investigational Medicinal Product (ATIMP) or Clinical Investigation of a Medical Device (CIMD). However, many areas covered will also be relevant for protocols of non-CTIMPs.

3. Scope

In Scope: Protocols for studies sponsored by UHBW.

Out of scope: Protocols for studies sponsored by organisations other than UHBW

4. Responsibilities

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

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

5. Abbreviations and Definitions

Abbreviations	
ATIMP	Advanced Therapy Investigational Medicinal Product.
CI	Chief Investigator
CIMD	Clinical Investigation of a Medical Device
CTIMP	Clinical Trial of an Investigational Medicinal Product
HRA	Health Research Authority
ICF	Informed Consent Form
GCP	Good Clinical Practice
MDR	Medical Device Regulations
PIS	Patient Information Sheet
R&D	Research and Development
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust

6. Procedure

- A protocol is required when applying for UHBW sponsorship. It may be required as part of a grant application, but often a grant application form would not be detailed enough for a research protocol so the protocol is usually written after successful award of the grant. In some instances the protocol may be written at the same time as grant preparation.
- The protocol should be written by the CI or a delegated member of the research team.

6.1 Protocol document templates

- All protocols for CTIMPs to be sponsored by UHBW should pay due regard to 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.
- For non-CTIMPs, much of the content of the documents from the HRA website will also be relevant to non-CTIMP protocols, However, UHBW has developed a template protocol that can be used for non-CTIMP studies that are not purely qualitative (*TMPL_123 UHBW Protocol Template for non CTIMPs* and see also the accompanying guidance *GD_040 Guidance for UHBW Protocols for non-CTIMPs*) and this should be considered in the first instance. There is also a separate HRA protocol template for qualitative studies that can also be adapted for certain non-CTIMP studies. UHBW supports their use as a basis for writing protocols for all non-CTIMP research to be sponsored by the Trust (. Further information on writing protocols can also be found on the [R&D website](#).

6.2 Chief Investigator (CI) approval of protocol

- All studies require evidence of CI approval of the protocol. This can be in the form of a CI signature in the Protocol itself or CI signature on a separate document (i.e. a separate sign off sheet or e-mail). The CI signature in the IRAS form also provides further evidence of approval.
- CI approval of any subsequent protocol amendments, for UHBW sponsored CTIMPs is evidenced by completion of the sponsor amendment assessment form. (*TMPL_060 CTIMP Amendment Assessment Form for Sponsor*). For non CTIMPs documentary evidence that the CI has approved the protocol amendment can be in the form of an email or signature on the amended Protocol.

6.3 Sponsor approval of protocol

- Where UHBW is sponsor, review of the protocol is undertaken as part of the sponsorship process. In some instances, sponsor signature will be captured on the protocol as evidence of sponsor sign off.
- Sign off of the protocol is also evidenced through UHBW agreement to sponsor the trial and by granting the sponsor 'greenlight as the sponsor approved protocol forms part of the checks required prior to this stage.'
- For UHBW CTIMPs using the HRA 'CTIMP Protocol Development Tool' (<https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/>) direct evidence of the Sponsor's approval of the protocol can also be included in the protocol document. This is not mandatory.
- For UHBW interventional, non-CTIMP studies using *TMPL_123 UHBW Protocol Template for non CTIMPs*, direct evidence of the Sponsor's signature is included in the document.
- Sponsor approval of any subsequent protocol amendments:
 - For UHBW sponsored CTIMPs is evidenced by completion of the sponsor amendment assessment form. (TMPL_060 CTIMP Amendment Assessment Form for Sponsor).
 - For non CTIMPs sponsor approval of any subsequent protocol amendments can be evidenced via email and sponsor representative signature on the HRA amendment tool.

6.4 Additional protocol information

- For UHBW sponsored research, it is a requirement that the standard wording provided in *GD_005 UHBW suggested standard wording for protocols* is used unless alternative wording is agreed in advance (note most CTIMP trials will have protocol templates provided by a registered trials unit and therefore the standard wording may not be applicable in the exact format as per GD_005).. In some cases, the HRA template also contains suggested standard wording. UHBW standard wording must be used in preference, or in addition to HRA standard wording. It is the responsibility of the CI to ensure that the wording used is not in contradiction of any of UHBW'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).
- Draft versions of the protocol written before the first IRAS submission should be numbered v0.1, v0.2 etc. The IRAS submission should begin with version 1.0.
- As part of the UHBW sponsorship process, the protocol will be reviewed as described in *SOP_002 Research Sponsorship* at UHBW to ensure that wording within the study protocol corresponds to the standard wording in *GD_005*, and with relevant sections of the IRAS application form.
- If the protocol needs to be amended after initial regulatory and ethical approval, then please refer to *SOP_019 UHBW sponsored research amendments*.

7. Dissemination and training in the SOP

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

Plan Elements	Plan Details
The Dissemination Lead is:	Research Operations Manager
Is this document: A – replacing the same titled, expired SOP, B – replacing an alternative SOP, C – a new SOP:	A – replacing the same titled, expired SOP
If answer above is B: Alternative documentation this SOP will replace (if applicable):	N/A
This document is to be disseminated to:	All applicable research staff (including R&D)
Method of dissemination:	<p>For major updates to the SOP dissemination will be:</p> <ol style="list-style-type: none"> 1. To Chief Investigators of UHBW Sponsored CTIMPs 2. Research Unit leads across UHBW 3. Head of Research Governance at UoB (where SOP is applicable) <p>All updates (major and minor to the SOP) will be:</p> <ol style="list-style-type: none"> 1. Updated on the trust MyStaffApp 2. Updated on the R&D website/Sharepoint 3. Cascaded in R&D communications
Is Training required:	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 <i>SOP_007 Research Training UHBW</i>

REFERENCES	
	<p>ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996) ICH Official web site : ICH</p> <p>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</p> <p>http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:091:0013:0019:en:PDF</p> <p>Statutory Instrument 1031: The Medicines for Human Use (Clinical Trials) Regulations 2004</p> <p>http://www.legislation.gov.uk/ukxi/2004/1031/pdfs/ukxi_20041031_en.pdf</p>

	<p>The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019</p> <p>https://www.legislation.gov.uk/ukxi/2019/744/contents/made?view=plain</p>
RELATED DOCUMENTS AND PAGES	<p>GD_005 UHBW Standard wording for protocols GD_040 Guidance for UHBW Protocols for non-CTIMPs SOP_002 Research Sponsorship at UHBW SOP_007 Research Training UHBW SOP_019 UHBW sponsored research amendments TMPL_060 CTIMP Amendment Assessment Form for Sponsor TMPL_123 UHBW Protocol Template for non CTIMPs</p> <p>Latest versions of these documents can be found on the Research & Development section of UHBW's website: http://www.uhbristol.nhs.uk/research-innovation/for-researchers/templates-and-sops/</p>
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	<p>Research & Development (R&D) department on 0117 3420233 or research@uhbw.nhs.uk</p>