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** | 1.8 |
| **Effective Date** | 03/AUG/2023 | **Review Date** | 03/AUG/2025 |

**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 |

| 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 |

## 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, 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 to Good Clinical Practice (GCP) so that it is compliant with the Medicines for Human Use (Clinical Trials) Regulations 2004 (and subsequent 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 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** | |
|---|---|
| **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 |
| **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 and this is usually written after successful award of the grant.
- The protocol should be written by the CI or a delegated member of the research team.
- 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.
- CTIMPs 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). The CI signature in the IRAS form also provides further evidence of approval I. Approval of subsequent amendments for UHBW sponsored CTIMPs is evidenced by completion of the sponsor amendment assessment form. The sponsor's sign off of the protocol is evidenced through its processes for sponsorship and greenlighting.
- Much of the content of the documents from the HRA website will also be relevant to non-CTIMP protocols, and there is 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 research to be sponsored by the Trust (Sections only relevant to CTIMPs can be omitted where irrelevant in these cases). However, UHBW has 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). Further information on writing protocols can also be found on the R&D website.
- For UHBW sponsored research, it is a requirement that the standard wording provided in *GD_004 UHBW suggested standard wording for IMP protocols* and *GD_005 UHBW 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. 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 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).
- As part of the UHBW 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 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.

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*.

| | |
|---|---|
| **REFERENCES** | 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<br>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://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:091:0013:0019:en:PDF<br>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<br>The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 https://www.legislation.gov.uk/uksi/2019/744/contents/made?view=plain |
| **RELATED DOCUMENTS AND PAGES** | GD_004 UHBW suggested standard wording for IMP protocols<br>GD_005 UHBW suggested standard wording for Non-IMP protocols<br>SOP_002 Sponsorship<br>SOP_007 Research Training<br>SOP_019 UHBW sponsored research amendments<br>TMPL_123 UHBW Protocol Template for non CTIMPs<br>GD_040 Guidance for UHBW Protocols for non-CTIMPs<br><br>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/ |
| **AUTHORISING BODY** | Trust Research Group |
| **SAFETY** | N/A |
| **QUERIES AND CONTACT** | Research & Development (R&D) department on 0117 34 20233 or research@uhbw.nhs.uk |