Gloucestershire Hospitals
NHS Foundation Trust

SOP 29: Writing a protocol

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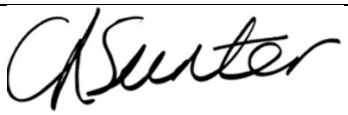
Version:	4.0	
Author:	Chantal Sunter	
Reviewed by Trust Senior Responsible Officer for RIG:	Noel Peter 21/05/2026	
Implementation date of current version:		25/06/2026
Date of Review:		25/06/2029

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, Innovation& Genomics 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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 RIG website:

https://www.gloshospitals.nhs.uk/about-us/get-involved/support-our-trust/research-our-hospitals/

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
2.1	Updating of website links, reformatting and addition of appendix 1 detailing protocol content	31/01/2022
3.0	Removal of SOP categories and change of reference codes Insertion of appendix 1 non-CTIMP protocol template Deletion of protocol template for CTIMPS and direction to use the HRA template for CTIMPS only Changed R&D to R&I	03/01/2024
4.0	R&I department name updated to RIG. Updated terminology to align with update to UK Clinical Trial Regulations. References updated	25/06/2026

This SOP will be reviewed every three years unless changes to any relevant legislation require otherwise

Related Documents:

SOPs:
SOP 23: Urgent Safety Measures SOP 24: Project Review Process – Research Projects SOP 25: Modifications SOP 27: Obtaining Sponsorship for non-CTIMP and CE Marked Medical Device Research Studies

Glossary

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
HRA	Health Research Authority
ICH GCP	International Conference for Harmonisation of Good Clinical Practice
IMP	Investigational Medicinal Product
MHRA	Medicines and Healthcare products Regulatory Agency
RIG	Research, Innovation & Genomics
REC	Research Ethics Committee
TMF	Trial Master File

Contents

1. Introduction, Background and Purpose

The purpose of this SOP is to describe how a study protocol should be written to Good Clinical Practice (GCP) standards so that it is compliant with the UK Clinical Trial Regulations and the UK Policy Framework for Health and Social Care Research.

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: Researchers preparing or reviewing protocols for Clinical Trial of Investigational Medicinal Products (CTIMPs), non-CTIMPs, medical device trials and all other research studies.
- Staff involved with reviewing research project proposals that will be sponsored by the Trust, for the Research, Innovation and Genomics (RIG) Project Review Group. Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) does not currently sponsor CTIMPs

3. When this SOP should be used

This SOP should be used when preparing protocols for all CTIMPs. It should also be followed for all research proposals that are not CTIMPs, some requirements specific to CTIMPs will not apply for other research proposals.

4. Procedure

4.1 Protocol template

4.1.1 All protocols for CTIMPs, non-CTIMPs and those that fall within the scope of the relevant Medicines and Medical Devices regulations should be based on the following templates and guidance produced by the Health Research Authority (HRA)

(a) CTIMP protocol guidance and a template, available here: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/

and also

(b) Guidance on the design of participant information sheets and consent forms, available here: http://www.hra-decisiontools.org.uk/consent/

4.1.2 Qualitative Research Projects

Protocols for qualitative research projects should follow the HRA protocol guidance and template; qualitative-protocol-development-tool.docx (live.com). The guidance and templates for participant information sheets and consent forms linked in 4.1.1 (b) above should be used for qualitative projects too.

The template found in appendix 1 can be used for studies that do not fall under the regulation mentioned above.

4.2 Protocol Development

Researchers are encouraged to get in touch with RIG (ghn-tr.rigprojectreview@nhs.net) at an early stage to ensure they can provide appropriate signposting and support. RIG SOP 24: Project Review and SOP 27:

Obtaining Sponsorship provide details of the RIG review process for research projects and the process for gaining Trust agreement to sponsor.

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

- Chief Investigator (CI)
- Other Key Investigators
- Statistician
- Pharmacy Contact or IMP Specialist
- 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
- When developing the protocol the researcher should ensure they have Patient and Public Involvement (PPI), and have considered Equality, Diversity & Inclusion (EDI) within their proposed protocol. RIG can provide advice and support on this (contact ghn-tr.rigprojectreview@nhs.net)
- Commercial supporters of the research
- Representative of the Sponsor

For all interventional research the protocol should also consider the SPIRIT 2025 Guidelines (Standard Protocol Items: Recommendations for Interventional Trials www.**spirit**-statement.org/).See appendix 2 for standard protocol layout.

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

The Protocol, and any supporting documents (e.g. consent form) if applicable, 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).

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 Trial Master File (TMF) for Trust Sponsored research projects

4.3 Protocol modifications

Any change of the protocol will constitute a modification either substantial, a modification of an important detail or minor modification. The Sponsor will confirm whether the change is substantial or not, please contact RIG on ghn-tr.researchandinnovation@nhs.net to obtain this advice for Trust sponsored studies. For managing modifications, including urgent safety measures, refer to the HRA website, and RIG SOPs.

Changes must be reviewed and approved by the appropriate personnel e.g., CI, pharmacy advisor, statistician, etc. Those studies which fall within the scope of the relevant Medicines and Medical Devices regulations should have a Trial Management Group led by the CI.

5. References

https://www.ct-toolkit.ac.uk/routemap/trial-planning-and-design/

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/

http://www.hra-decisiontools.org.uk/consent/

www.**spirit**-statement.org/

http://www.comet-initiative.org/

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

UK Policy Framework for Health and Social Care Research - Health Research Authority

Appendix 1: Protocol template for studies not covered by the HRA templates

Please read the accompanying "Guidance for using the Protocol Template for Sponsored Studies (not covered by the HRA templates)" whilst writing your protocol

Guidelines can be found:
https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals/

TITLE PAGE

Full/long title of study	
Short title/study acronym	
Protocol version number /date	
IRAS Number	
ISRCTN/Clinicaltrials.gov number	
Sponsor	Gloucestershire Hospitals NHS Foundation Trust
Sponsor reference number	
Funder name and reference number (if applicable)	
Chief Investigator	
Sponsor Representative	Research, Innovation & Genomics Leadon House Gloucestershire Royal Hospital Great Western Road Gloucester GL1 3NN

1 PROTOCOL VERSION HISTORY

Amendment No. State whether Substantial Amendment (SA) or Non-substantial amendment (NSA)	**Version No.**	**Version Date**	**Brief summary of change(s) and reason for update.**
Initial Application	1.0		Not applicable

2 SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirements.

I agree:

- to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor
- that no activity will commence at participating sites until Sponsor green light is confirmed
- that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:
Signature: Date:

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Name (please print):

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Interventional studies only
Research and Innovation representative as Study Sponsor:
Signature: Date:

..../...../.....

Name (please print):

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Position

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3 KEY CONTACTS

Chief Investigator	
Study Co-ordinator/Clinical Trials Unit	
Sponsor	
Joint-sponsor(s)/co-sponsor(s)	
Funder(s)	
Key Protocol Contributors	
Study Management and Oversight Committees	
Statistician	

4 CONTENTS

5 LAY SUMMARY

6 SYNOPSIS

KEY STUDY INFORMATION	
Study Title	
IRAS Number	
Study Design/Type	
Study Participants	
Planned Sample size	
Planned Study Period	
End of study definition	
Single site or multi-site	
Research Aim(s)	
Research objectives	
Intervention(s) (if applicable)	
Archiving period	
SAMPLES (If applicable)	
DATA	

7 LIST OF ABBREVIATIONS

Abbreviation	Full text
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
ISF	Investigator Site File (This forms part of the TMF)
NHS	National Health Service
PI	Principal Investigator
PPI	Patient and Public Involvement
PIS/PIL	Participant Information Sheet/Leaflet
RCT	Randomised Control Trial
REC	Research Ethics Committee
R&I	Research and Innovation
SMG	Study Management Group
SSC	Study Steering Committee
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

8 FUNDING

Funders	Financial and Non-Financial support given

9 ROLES AND RESPONSIBILITIES

9.1 Role of sponsor and funder

9.2 Study team

9.3 Trial/study management committees/groups and individuals

9.4 Protocol Contributors

10 KEY WORDS

11 BACKGROUND

12 RATIONALE

13 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

13.1 Primary objective

13.2 Secondary objective(s)

13.2.1 Outcome measures/endpoints

13.2.2 Primary outcomes

13.2.3 Secondary outcomes

14 STUDY DESIGN AND SETTING

14.1 Study design

14.2 Study setting

15 PARTICIPANT ELIGIBILITY CRITERIA

15.1 Inclusion criteria

15.2 Exclusion criteria

15.3 Equality, diversity and inclusion considerations

16 STUDY PROCEDURES

16.1 Recruitment

16.1.1 Participant identification

16.1.2 Screening

16.2 Payment

16.3 Informed consent

16.4 Randomisation scheme

16.4.1 Method of implementing the randomisation/allocation sequence

16.4.2 Blinding and Emergency unblinding

16.5 Trial assessments

16.5.1 Baseline data

16.5.2 Follow-up assessments

16.5.3 Qualitative assessments

16.6 Withdrawal criteria

16.7 Clinical samples: collection, storage and analysis

17 ETHICAL AND REGULATORY CONSIDERATIONS

17.1 Research Governance Statement

This study will be conducted in accordance with:

- The principles of Good Clinical Practice, as set out in the International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines
- The UK Policy Framework for Health and Social Care Research.

17.2 Assessment and management of risk

17.3 Research Ethics Committee (REC) and other Regulatory review & reports

17.4 Regulatory Review & Compliance

The study will be performed subject to favourable opinion/ authorisation/permission or equivalent from all necessary regulatory and other bodies. This includes but is not limited to REC, HRA, NHS Trusts.

17.5 Amendments

17.6 End of study

18 PATIENT & PUBLIC INVOLVEMENT

19 PROTOCOL COMPLIANCE

19.1 Protocol Deviations

19.2 Notification of Serious Breaches to GCP and/or the protocol

20 DATA PROTECTION AND PATIENT CONFIDENTIALITY

21 DATA MANAGEMENT

21.1 Data collection tools and source document identification

21.1.1 Source Data

21.1.2 Source Documents

21.1.3 Case report forms

21.1.4 CRFs as Source Documents

21.2 Data handling and record keeping

The database and randomisation system will be designed so as to protect patient information in line with the General Data Protection Regulation. Study staff will ensure that the participants' anonymity is maintained through protective and secure handling and storage of patient information at the study centres (as relevant) in line with the Ethics approval. All documents will be stored securely and only accessible by study staff and authorised personnel. Data will be collected and retained in accordance with the General Data Protection Regulation.

21.3 Access to Data

21.4 Access to the final study dataset

22 STATISTICS AND DATA ANALYSIS

22.1 Sample size calculation

22.2 Planned recruitment rate

22.3 Statistical analysis plan

22.3.1 Summary of baseline data and flow of patients

22.3.2 Primary outcome analysis

22.3.3 Secondary outcome analysis

22.3.4 Subgroup analyses

22.3.5 Adjusted analysis

22.3.6 Interim analysis and criteria for the premature termination of the trial

22.3.7 Participant population

22.3.8 Procedure(s) to account for missing or spurious data

22.4 Other statistical considerations

22.5 Economic evaluation

23 SAFETY REPORTING

Adverse events will be recorded and reported in accordance with GHNHSFT SOP 19 Periodic Safety Reporting to Regulatory Authorities and SOP 20 Adverse events and reaction safety reporting.

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24 QUALITY ASSURANCE, RISK ASSESSMENT AND MONITORING

24.1 Risk Assessment

24.2 Monitoring, audit and inspection

The study will be monitored in accordance with SOP 13 Monitoring. All study related documents will be made available on request for monitoring and audit by the Sponsor, the relevant Research Ethics Committee and for any other regulatory authorities.

24.3 Peer review

25 INSURANCE AND INDEMNITY

This is an NHS-sponsored research study. 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. Ex-gratia payments may be considered in the case of a claim.

26 FINANCIAL AND OTHER COMPETING INTERESTS

27 FINANCE AND CONTRACTUAL ARRANGEMENTS INCLUDING EQUIPMENT SUPPLY AND INTELLECTUAL PROPERTY

28 PUBLICATION AND DISSEMINATION

28.1 Dissemination policy

28.2 Authorship eligibility guidelines and any intended use of professional writers

29 DOCUMENT STORAGE AND ARCHIVING

Study documents (paper and electronic) will be retained in a secure location during and after the study has finished. All essential documents, including patient records and other source documents will be retained for a period of 5 years following the end of the study. Where study related information is documented in the hard copy medical records – those records will be identified by an alert sticker. Refer to SOP 02 Research Documentation and File Management and SOP 06 Archiving.

30 REFERENCES

31 APPENDICES

31.1 APPENDIX 1 Study Flow Chart

31.2 APPENDIX 2 Schedule of Procedures

31.3 APPENDIX 3 -Data Flow diagram