Gloucestershire Hospitals NHS Foundation Trust

SOP 13: Monitoring and Oversight of Hosted Research Studies

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol and Western 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 version	03/03/2025

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

Related Documents:

SOPs
SOP 02 Research Documentation and File Management SOP 11 Confirmation of Capacity and Capability

Glossary (if applicable)

C&C	Confirmation of Capacity and Capability
CTIMP	Clinical Trial of an Investigational Medicinal Product
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
GOG	Governance and Oversight Group
PI	Principal Investigator
PS	Professional Services
R&I	Research and Innovation
RPM	Research Portfolio Manager

Contents

1. Introduction, Background and Purpose

Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) has a responsibility for oversight of all research activity hosted within the Trust, and all research which it sponsors, as described in the UK Policy Framework for Health and Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations – see Appendix 4 for references.

Monitoring is an act of overseeing the progress of a study, to ensure that:

- The rights and wellbeing of the subjects participating in the study are protected
- The reported trials data are accurate, complete and verifiable from source documents.
- The conduct of the study is in compliance with the current approved protocol/protocol amendment(s), with Good Clinical Practice (GCP) and with the applicable regulatory requirements

The purpose of this SOP is to describe the risk-based process that will be followed by GHNHSFT Research and Innovation (R&I) team to monitor, and maintain oversight, of research hosted within the Trust.

2. Who Should use this SOP?

This SOP should be followed by all members of the GHNHSFT R&I Department and all members of staff within GHNHSFT who are engaged with research within the Trust.

3. When Should this SOP be used?

This SOP should be used at study set-up to identify the initial requirements for monitoring, if applicable, and throughout the conduct of the study to ensure ongoing robust oversight.

This SOP is applicable to all research studies (both Clinical Trial of an Investigational Medicinal Product (CTIMP) and non-CTIMPs) hosted by the Trust. Studies sponsored by the Trust are not within the scope of this SOP.

4. Oversight of studies delivered outside of R&I Teams

Where a study is to be delivered without the direct involvement of a R&I Delivery Team, this will be flagged on EDGE at study set-up by the member of R&I completing the C&C review using the 'Non R&I Team' option in the 'Research team' form, and also highlighted to the Quality Assurance (QA) Manager within R&I Professional Services (PS) at the start of the set-up process. All studies will be recorded on the 'Hosted study oversight log' on the RDSU drive.

The QA Manager will make an initial risk assessment of the study (see Appendix 1 for risk assessment guide), recorded in the 'Study Set-up' workflow on EDGE. Any study assessed as high risk at this point, will be highlighted as needing input from the R&I Delivery teams and/or R&I Research Doctor. Low or medium risk studies will require a Study-Start visit, as described below. Only studies deemed very low risk will go ahead without a visit.

No CTIMP will be delivered at the Trust without involvement of the R&I Delivery teams or R&I Research Doctor. Should a CTIMP present from a non-R&I team, this will be flagged at set-up, and the study directed to the Research Matron, R&I Research Doctor and R&I Pharmacy Team to discuss support.

For non-CTIMP studies, a Study Start visit from R&I, including a member of the R&I Delivery team, will be performed, to ensure the study team have everything in place prior to starting a study, and processes in place to successfully deliver the study. See Appendix 2 for visit guide. Documentation of this visit will be stored on the study's EDGE record.

Following the visit the study will be risk assessed by the R&I team, indicating any further action or monitoring to be performed, as per Appendix 2.

5. Monitoring of hosted studies

During set-up of hosted studies, the Research Portfolio Manager (RPM), or applicable colleague, completing the Confirmation of Capacity and Capability (C&C) review, will record details of the Sponsor's proposed monitoring plan within the EDGE Study Set Up workflow. The Trust will not routinely monitor any externally sponsored studies that have monitoring in place, or that have been deemed by their Sponsor as not requiring monitoring.

5.1 Escalation

The Trust may decide to monitor, audit or review a hosted study should there be a cause of concern that the study is not being conducted or documented correctly, and the issue has not been resolved by the study Sponsor or where the R&I teams will not have direct involvement in delivery.

Triggers for escalation of oversight/monitoring of hosted studies may include, but are not limited to:

- Personnel:
  - Studies delivered by teams other than R&I Delivery Teams that have been deemed medium/high risk at study-start visit.
- Study:
  - A study failing to recruit or falling far behind its 'recruitment-to-time-and-target' (RTT) figure, flagged during RTT reporting within R&I PS.
  - A study with a large number of issues/errors consistently flagged during external monitoring visits (see 6.1 below) or major findings noted.
  - Concerns raised by member of R&I, Trust staff member, trial participant or member of the public.
  - Concerns raised by an external Sponsor

Where a concern has been raised about a study that cannot be, or hasn't been, resolved by the Sponsor, this should be escalated to the R&I QA Manager or R&I PS Manager. The QA Manager or PS Manager will discuss the issue with the PI, and offer support to resolve. All communication and relevant documentation should be stored on the EDGE record.

Where further input is required, steps taken could include:

a. Where a need has been identified, training can be offered (or support to find suitable training) for relevant staff.
b. Potential support for study delivery from R&I Delivery Teams, or R&I Research Doctor, if not already involved in study.
c. Monitoring visit conducted by member of R&I (template for monitoring included in appendix 3).

PIs will be required to engage with R&I throughout this escalation process, to ensure they are fulfilling their responsibilities of study oversight.

6. R&I Oversight

6.1 External monitoring reports

Reports from all external monitoring visits, whether on-site or remote, should be sent to the R&I Professional Services Team (ghn-tr.glos.riprofessionalservices@nhs.net) and R&I Research Team Lead, if applicable, by the PI or member of the team delivering the study.

Within R&I PS the Assistant RPM will upload the monitoring report onto the study's EDGE record, and record the visits on an access restricted google sheet ('Monitoring Spreadsheet'), giving a summary of the visit and findings. A copy of the monitoring report will also be sent to the R&I QA Manager.

The QA Manager will review received reports. Any issues that require immediate attention will be escalated to Research Matron and/or Professional Services Manager. Otherwise, outstanding actions will be discussed with the relevant study lead or PI, if the study has no R&I delivery team input.

6.2 Quarterly Reporting

An overview of external monitoring will be provided quarterly to the Governance and Oversight Group (GOG) by the QA Manager, with any concerns or trends highlighted, and corrective actions taken, or to be taken, described.

Any concerns reported regarding studies, escalation of monitoring, or review, of hosted studies within the quarter will also be reported to GOG, this will include an overview of any self-monitoring completed or R&I monitoring performed, all actions taken and outcomes. Outcomes from GOG will be reported to the Heads of Service meeting, either for information or escalation.

APPENDIX 1: Risk Assessment Guide

Risk Assessment Guide for Hosted Studies

Low Risk	Medium Risk	High Risk
--	**--**	Clinical Trial of Investigational Medicinal Product (CTIMP)
--	--	Medical Device study
Observational study	Interventional study	Highly invasive interventional study (e.g. surgical technique, radiotherapy)
Not recruiting participants lacking capacity to consent	Experienced team recruiting participants lacking capacity to consent.	Inexperienced team recruiting participants lacking capacity to consent.
Not recruiting participants who are minors	Experienced team recruiting participants who are minors	Inexperienced team recruiting participants who are minors
No Randomisation	Randomisation, with experienced team	Randomisation, with inexperienced team
Simple study schedule/design	Challenging study schedule/design (*risk of protocol non-compliance)*	Very complex study schedule/design (*risk of protocol non-compliance)*
No change from standard care pathway	Minimal change from standard care pathway	Significant change from standard care pathway
Sponsor monitoring plan in place, or deemed by sponsor to be low-risk & not requiring monitoring	Minimal sponsor monitoring plan in place	No Sponsor monitoring in place for study not deemed low risk.

Very Low Risk Studies may include: PIC Site Studies, Staff Surveys, Simple questionnaire study, Study working with data only.

APPENDIX 2: R&I Study Start Visit – Guide

Study Start Checklist

Study name:		
Local R&I Number:		
PI:		
Sponsor		
Visit Date:		
Visit Location:		
Visit Conducted by	R&I Professional Services:	
	R&I Delivery:	
Present at visit:		

	Comments
PI and relevant team members GCP trained (*within last 3 years)*	
ISF in place	
Localised study documents in place	
Screening plan in place	
Consent process discussed	
Patient study visit logistics discussed	
Source data discussed	
Data collection arrangements discussed	
EDGE access in place, and team aware of requirements *e.g. recruitment/SAEs*	
Details of sponsor monitoring plan	

Ensure team are aware of:

R&I Contact details	
Location of R&I SOPs	
Request to send any monitoring reports or feedback to R&I ***(if applicable)***	
Request to send any significant correspondence from sponsor to R&I ***(e.g. amendments, study closure)***	

Further comments/actions

Risk assessment:		
Study has been assessed by the R&I team and deemed to be *(please indicate)***:**		
LOW RISK	**MEDIUM RISK**	**HIGH RISK**
No further monitoring will be scheduled	No scheduled monitoring required – R&I satisfied Sponsor monitoring sufficient for study	Study will be directed to R&I Research Matron and Research Doctor to discuss support. Study should not proceed until this support is in place.
	Continued oversight required - Follow-up visit will be scheduled …….	

R&I Team members completing visit:	
Signature *(Professional Services):*	
Signature *(R&I Delivery):*	
Date:	

Copy to be sent to PI and uploaded to the study EDGE record

APPENDIX 3: R&I Study Start Visit – Guide

R&I Monitoring Report – Hosted study

Study name:	
Local R&I Number:	
PI:	
Sponsor:	
Visit Date:	
Visit Location:	
Visit Conducted by:	
Present at visit:	

1. Recruitment

Recruitment Target:	
No. of patients screened:	
No. of patients consented:	
No. of patients randomised:	
No. of patients completed:	
No. of patients in follow up:	
Number of withdrawals and reasons:	
Is RTT rate satisfactory?	
Further comments:	

2. Monitoring

Has any external monitoring by Sponsor occurred?	
Detail any issues/concerns raised:	
Have actions been completed/issues rectified?	
Further comments:	

Has any Trust monitoring occurred previously?	
If yes, have actions been completed/issues rectified?	

Further comments:	

3. Site File Review

Is the Investigator Site File maintained to a good standard?	
Further comments:	

4. Participant Review

Participant study number:	
Correct consent process completed & documented?	
Any concerns or issues raised during Source Data Verification?	
Further comments:	

Participant study number:	
Correct consent process completed & documented?	
Any concerns or issues raised during Source Data Verification?	
Further comments:	

Participant study number:	
Correct consent process completed & documented?	
Any concerns or issues raised during Source Data Verification?	
Further comments:	

Continue as needed.

5. Support departments *(if applicable)*

Lab: Have all study samples been handled/processed correctly as per protocol?	
Further comments:	
Pharmacy:	

Have all Pharmacy / IMP arrangements been performed as per protocol?	
Further comments:	

6. Pharmacovigilance *(if applicable)*

No of SAEs:	
No of SARs:	
No of SUSARs:	
Have all events been recorded appropriately and reported as required?	
Were any events identified during monitoring that had not been recorded?	
Further comments:	

7. Deviations or breaches

Have any deviations to study protocol or breaches to guidance/legislation been recorded appropriately and reported as required?	
Were any deviations or breaches identified during monitoring that had not been recorded?	
Further comments:	

8. Overview

Summary of monitoring visit:	
Further monitoring to be scheduled?	
If yes, provide estimate of date:	

9. Actions Required

Action Required	Responsible

R&I Team member completing visit:	
Signature:	
Date:	

Copy to be sent to PI and uploaded to the study EDGE record

APPENDIX 4: References

ICH GCP

ICH: E 6 (R2): Guideline for good clinical practice - Step 5

UK Policy Framework for Health and Social Care Research

UK Policy Framework for health and social care research

Medicines for Human Use (Clinical Trials) Regulations

The Medicines for Human Use (Clinical Trials) Regulations 2004