



SOP 19: Periodic Reporting to Regulatory Authorities

SOP reference:	SOP 19	
Version:	4.0	
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	26/03/2026	
Implementation date of current version:	30/04/2026	
Date of Review:	30/04/2029	

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

gloshospitals.nhs.uk/about-us/get-involved/support-our-trust/research-our-hospitals/standard-operating-procedures-sops/

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.

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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	09/02/2017
2.0	Rebranding to GHNHSFT, updating of contact details and reference documents	31/03/2018
3.0	Updated SOP title Removal of Urgent Safety measures information into a new separate SOP Removal of end of trial report as this information is contained within SOP TD 04 End of Trial Procedures for both sponsored and hosted trials Added information regarding submission to HRA Information regarding devices Removal of appendices Inserted information about a shortened DSUR Removal of SOP categories and change of reference codes	22/11/2023
4.0	Amendment of SOP title. Updating department name from R&D to RIG Removal of annual progress reports, addition of guidance for QSRs. Removal of detailed guidance on DSURs. Updated introduction.	30/04/2026

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

Related Documents:

SOPs	
SOP:05	End of Trial Procedures – Close Down
SOP 20	Adverse Event and Reaction Safety reporting
SOP 23	Urgent Safety Measures

Glossary

CAG	Confidentiality Advisory Group
CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
DSUR	Development Safety Update Report
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
ISF	Investigator Site File
MHRA	Medicines and Healthcare Products Regulatory Agency
PS	Professional Services
QSR	Quarterly summary report
REC	Research Ethics Committee
RIG	Research, Innovation and Genomics
RSI	Reference Safety Information
SARs	Serious Adverse Reactions
TMF	Trial Master File

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1. Introduction, Background and Purpose

After a research study has received all necessary approvals for it to proceed, various bodies and organisations require to be kept informed of its progress. In many (but not all) cases, progress or safety reports must be submitted to regulatory bodies including the Medicines and Healthcare Products Regulatory Agency (MHRA). The procedures for reporting will vary depending on the type of study.

The purpose of this SOP is to describe the requirements for periodic/scheduled reporting during a study for studies sponsored by Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT). For guidance on responsive safety reporting within studies please see SOP 20: Adverse Event and Reaction Safety reporting or SOP 23: Urgent Safety Measures as appropriate. End of trial reporting is discussed in SOP:05 End of Trial Procedures – Close Down

2. Who should use this SOP

This SOP should be used by all staff involved in research studies sponsored by GHNHSFT, and the Professional Services (PS) team within the GHNHSFT Research, Innovation and Genomics (RIG) Department.

3. When this SOP should be used

This SOP should be used when the Trust is sponsoring a research study to ensure all periodic reporting requirements are completed.

4. Annual Safety reporting - CTIMPs

Annual safety reports are required to be submitted, by the sponsor, their legal representative or the Chief Investigator (CI,) for all CTIMPs as described in the

Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. The annual report required is known as a Development Safety Update Report (DSUR) and will be submitted to the MHRA. The DSUR will list all worldwide Suspected Serious Adverse Reactions (SSARs) in the reporting period, i.e. both expected and unexpected and will summarise any issues affecting safety of participants.

GHNHSFT does not currently sponsor CTIMPs, and therefore full details on annual safety reporting for CTIMPs has not been included within this SOP. Further details can be found on the [MHRA website](#) if required.

For studies hosted within GHNHSFT and where the CI is an employee of the Trust, it will be expected that responsibility for annual reporting sits with the external sponsor or their representative. This should be confirmed by CI and RIG PS team during study set-up.

5. Reporting in Clinical Investigations for Medical Devices

For clinical investigations requiring MHRA approval, quarterly summary reports (QSR) are required to provide an update on the latest overall safety profile for the investigation. For UK only studies, the first QSR should be submitted one quarter after the first participant has been treated. Guidance on QSRs can be found on the [MHRA website](#).

The QSRs should be submitted, with an updated copy of the SAE spreadsheet, via the [MORE platform](#) (the MHRA portal). The responsibility for submitting these reports, either device manufacturer or GHNHSFT as sponsor, will be agreed contractually prior to commencement of the study.

All QSRs and related correspondence or documents should be stored in the Trial Master File (TMF).

6. Progress Reports (all studies)

The requirement to submit annual progress reports to the REC was removed in 2024 for studies that have received a final opinion from any REC in the UK. For research requiring only HRA approval there is also no requirement to provide progress reports.

All studies that have been approved by Confidentiality Advisory Group (CAG) are required to submit an annual review report. This must be submitted to the Confidentiality Advice Team via email using the [report template](#). The annual review report should be submitted by the CI for review at least four weeks before the approval expires (i.e. no later than 11 months following the final approval date). The report should be copied to the RIG Professional Services Team (ghn-tr.glos.riprofessionalservices@nhs.net) for their records.

7. References:

[Safety and progress reports \(CTIMPs\) procedural table - Health Research Authority](#)

MHRA guidance on safety reporting: [Clinical trials for medicines: manage your authorisation, report safety issues - GOV.UK](#)

[The Medicines for Human Use \(Clinical Trials\) \(Amendment\) Regulations 2025](#)

Progress Reports: [Progress reports - Health Research Authority](#)

CAG Annual Review Report Template: [CAGSF6-Annual-review-template-v4_1_05Mar25.docx](#)

MHRA Reporting in Clinical Investigations: [Clinical investigations for medical devices - GOV.UK](#)

MHRA Quarterly Summary Reports guidance:
[QSR Template Guidance v2.pdf January 2026 3.pdf](#)