Gloucestershire Hospitals
NHS Foundation Trust

SOP 16: Managing MHRA Inspection

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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	14/02/2017
2.0	Rebranding to GHNHSFT and updating contact details	31/03/2018
3.0	Updated web address, Added a glossary Reformatted, amended contents page, Corrected typographical errors, Addition of NIHR Learn link Removal of SOP categories and change of reference codes	30/10/2023
4.0	Update of department name from R&D to RIG. Renewal period set at three years. Timeline added for dossier. Governance oversight updated. References and appendices added.	12/02/2026

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

Related Documents:

- All SOPs

Glossary

CAPA	Corrective and Preventative Action
CI	Chief Investigator
CRF	Case Report Forms
CRO	Contract Research Organisation
CTIMP	Clinical Trial of Investigational Medicinal Product
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
GOG	Governance Oversight Group
ICH-GCP	International Conference for Harmonisation of Good Clinical Practice
ICT	Inspection Coordination Team
IMP	Investigational Medicinal Product
MDCI	Medical Device Clinical Investigations
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
PS	Professional Services
SOPs	Standard Operating Procedures
RIG	Research, Innovation and Genomics
TU	Trials Unit

Contents

1. Introduction, Background and Purpose

This SOP relates specifically to Clinical Trials of Investigational Medicinal Products (CTIMPs) and Medical Device Clinical Investigations (MDCIs), which are subject to regulatory inspection by the Medicines and Healthcare Products Regulatory Agency (MHRA) under the UK Clinical Trial Regulations. The purpose of inspection is to assess compliance with the law and is concerned with both the validity of the study data and the protection given to study participants.

ICH GCP defines inspection as 'The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records and any other resources that are deemed by the authority(ies) to be related to the clinical trial and that may be accessed at the investigator site, at the sponsor's and/or service provider's (including CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies)'

The MHRA may review and evaluate a facility (systems-based inspection) and /or an individual trial (for example, a participating site as part of a broader inspection of a multi-site trial's co-ordinating organisation) during either a routine GCP inspection or a "for cause" inspection. A routine inspection is as the name implies; a "for cause" inspection is a triggered inspection conducted in response to information that has raised concerns with a clinical trial (e.g., suspicion of significant regulatory non-compliance, scientific misconduct, fraud or serious breaches). In rare circumstances there may be little or no warning for a triggered inspection.

The majority of MHRA GCP inspections (either systems-based or trial specific) are carried out under the risk-based compliance programme. The MHRA risk assesses each organisation and prioritises inspections for organisations considered to be the highest risk. They will also randomly select a small number of organisations in the medium and low-risk categories for routine risk-based inspections. Particular attention is given to sites that sponsor CTIMPs and MDCIs; however, host sites and parts of organisations providing CTIMP/MDCI services may also be inspected.

A systems-based inspection may include any part of the organisation and any aspect of its operations that have a bearing on CTIMP/MDCIs. Most inspections will include a combination of staff interviews, document reviews and facilities visit. Example processes that may come under scrutiny include regulatory submissions, laboratories, investigational medicinal product (IMP) management, contract management, project management, trial-file management, quality assurance, training, computer systems, monitoring, pharmacovigilance, medical advisors, data management, statistical analysis, report writing, archives and the management of investigator teams.

The MHRA will verify how these processes work in practice to ensure that:

- robust procedures are in place
- the rights, wellbeing and safety of trial participants are protected
- the trial is conducted in accordance with UK Clinical Trial Regulations and the principles of GCP
- trials are conducted in accordance with their approved protocol
- appropriate Standard Operating Procedures (SOPs) are in place and that these are clearly documented and adhered to
- trials have all the necessary approvals prior to commencing – including ethics committee, MHRA and any specific approvals that may be relevant such as that relating to use of ionising radiation.
- local process of checking the above and existence of formal approval on behalf of the organisation by the RIG Office. Along with version control of trial documentation.
- adequate pharmacovigilance is in place

This SOP outlines the procedures necessary to prepare for, host and participate in a MHRA inspection.

2. Who Should Use This SOP

This SOP applies to Chief Investigators (CIs), Principal Investigators (PIs), all members of Research, Innovation and Genomics (RIG) teams and departments

supporting, coordinating or participating in CTIMPS or MDCIs, sponsored or hosted by GHNHSFT

3. When this SOP Should be Used

This SOP should be referred to in preparation for a regulatory inspection.

4. Procedure(s)

For Trust systems-based inspections, the Senior Member of the Trust with the responsibility for RIG is the MHRA's initial contact point.

Should any member of staff be directly notified of any other MHRA inspection planned to take place within the Trust (e.g., by a study Sponsor, CRO, or directly by the MHRA) they should inform the Senior Member of the Trust with the responsibility for RIG and the RIG Professional Services (PS) Team immediately via email (ghn-tr.glos.riprofessionalservices@nhs.net).

4.1 Actions on notification of MHRA Trust Systems Inspection

When the Trust Site receives notification of MHRA inspection, the Senior Member of the Trust with the responsibility for RIG (or their delegate) should be immediately informed. The Senior Member of the Trust with the responsibility for RIG will inform the Chief Executive of the Trust along with additional senior management, as appropriate, and the RIG Professional Services Team. The Senior Member of the Trust with the responsibility for RIG (or their delegate) will establish as soon as possible, and lead, an Inspection Coordination Team (ICT), to act as the primary contact throughout the inspection process, to coordinate all departments and personnel and keep senior management informed.

The ICT will generally be made up of senior members of the RIG department and representatives of other involved departments, which, for a whole system inspection typically may include:

- Pharmacy

- Laboratories
- Information & technology (IT)
- Radiology
- Facilities (in relation to equipment maintenance)
- Medical records
- Archive Facility

4.2 The Inspection Dossier & Arranging Inspection Date

As part of the notification from the MHRA that the organisation has been chosen for inspection under the routine risk-based inspection programme, dates will be given between which the inspection is likely to take place. A request for information, in the form of a GCP inspection dossier and a clinical trials spreadsheet, will also be made. This information should be provided to the MHRA within 30 days of the advance notice email date. This dossier should include:

- a list of clinical trials
- organisation charts
- standard operating procedure (SOP) lists
- contact details
- overview of facilities
- external service providers e.g. Cobalt Health
- clinical trials activities

Templates for the GCP inspection dossier, the clinical trials spreadsheet and a dossier checklist are provided by the MHRA.

The ICT will co-ordinate collection of documents for the dossier. All RIG staff and Trust research staff are required to respond in a complete and timely manner to requests for information from the ICT. Once complete the dossier will be submitted electronically to the MHRA: GCP.Inspectiondossier@mhra.gov.uk.

The dossier will help the inspector in developing an overview of the Trust prior to the inspection, and will assist in defining the inspection scope and developing the inspection plan.

The inspection plan will specify the areas to be visited and trials to be examined in detail, with slots for interviewing individual investigators or teams (either in person or by teleconference). The Senior Member of the Trust with the responsibility for RIG (or their delegate) will liaise with MHRA to agree the final inspection plan and inspection dates; there may be some limited leeway for negotiation on dates to accommodate holidays or other commitments. However, all investigators or other staff required for interview should appreciate that this leeway is limited, and they must make every effort to make themselves available as required for this statutory inspection.

4.3 Prior to the inspection

When the final inspection plan is available, all investigator teams and support departments to be visited, will be individually informed. This notification will include the contact details of the Lead Administrator identified for the inspection (see Section 4.3.3). The ICT will notify Sponsors and TUs which of their trials have been selected for inspection, as applicable.

All staff should be aware that the plan may be changed during the inspection so that other trials, or other departments, are brought into its scope. As such, a Trust wide communication will be issued so that all research teams and support departments are aware of the inspection dates and are aware that they may be called upon to make themselves available to the inspectors during that time.

4.3.1 Documentation

All research teams, support departments and RIG Professional Services team are aware that their study documentation should *always* be inspection ready. However, teams may take the opportunity to review their files to ensure that they are in a position to provide the required documentation in a timely fashion during the inspection. Additional consideration should be given to any requirement to review electronic data.

Any documentation required to be obtained from the Archive facility should be notified to the Trust's Research Archivist as soon as possible.

Documentation to be inspected may include:

- Trial Master Files / Investigator Site Files / Pharmacy Files
- Contracts
- Staff training records, job descriptions and CVs
- Organisational charts
- SOPs [Note: RIG SOPs will be made available to Inspectors on the website but any Sponsor or Study-Specific SOPs will need to be provided by the investigator team. Support departments may also need to provide their SOPs]
- Computer system validation documents
- Case Report Forms (CRFs)
- Source documentation (e.g., Health Records including access to electronic systems, x-rays, lab reports) (with regard to access to e-medical records see SOP 35)
- Patient Information Sheets and Informed Consent Forms
- Laboratory/radiology procedures
- Equipment maintenance and calibration servicing routines
- Pharmacy drug accountability records and e-prescriptions
- Temperature records for IMP and research samples

4.3.2 Training

It is appreciated that the prospect of a MHRA inspection can be daunting for those involved. The RIG team can arrange /provide training sessions for staff or NIHR Learn can be accessed for an online course, to ensure staff are suitably prepared for an inspection,

4.3.3 Practical arrangements

The Senior Member of the Trust with the responsibility for RIG (or their delegate) with the support of the ICT will:

1. Identify administrative support for the inspection – a Lead Administrator and at least two assistants. They will be full briefed and provided with an annotated inspection programme showing their tasks during all phases of the inspection.

2. Will ensure that rooms are booked for the inspection:

- One for the inspectors' use, for document review and report writing etc.; this should, if possible, be located near the Lead Administrator's office and photocopying/printing facilities.
- A room for temporary storage of documentation relevant to the inspection – near the Lead Administrator's office.
- Room/s for interviews - near the inspectors' room / Lead Administrator's office.
- A larger room for the opening and closing meetings.
- Specific room bookings as required, for programmed interviews of larger groups of people or in support departments.

3. Arrange the room furnishings appropriately including:

- In all rooms remove or lock away all unpublished material including organisational specific documentation of any kind.
- In the inspectors' room provide:
  a. A desk for each inspector
  b. A telephone
  c. Sufficient desk/table space to hold a significant number of files that may be accumulated for document review sessions
  d. A side table for refreshments
- Outside the door of the inspectors' room provide a small table with 'in' and 'out' trays
- In the room assigned for document storage, provide sufficient empty lockable storage cabinets – number to be determined and according to the volume of documentation in the trials in the planned inspection programme
- Procure equipment for the inspection, including:
  a. Visitor name badges for use by the inspectors when in the Trust (see SOP 30 – Workplace visitors)
  b. Equipment needed, if applicable, to access any electronic documents (access to be arranged as per SOP 35 - Electronic Health Records Document Sharing)
  c. Equipment or sufficient notebooks for staff taking notes in the interview sessions

d. Document logging sheets for use by the Lead Administrator

e. Arrange catering requirements for the duration of the inspection

4.3.4 Location of documentation for inspection

Documentation for trials on the inspection programme will be relocated temporarily so the material is to hand for inspectors' document review sessions, which may take place at various stages of the inspection, between interview sessions.

As soon as possible after investigator teams or support departments are notified that their trial is on the inspection plan, they should email the Lead Administrator (details will be on the notification) to give an estimate of the amount of space their trial documentation will need in the temporary storage facility.

All investigator teams / support departments are responsible for ensuring all their trial files and documents are brought to the Lead Administrator to be placed in the temporary storage facility before the start of the inspection. This should be done at latest on the last working day prior to the inspection. Files relating to less active trials are requested to be moved earlier, if possible, to assist the Lead Administrator. If, for more active trials, it is essential to keep some material until the actual inspection day, this should be discussed with the Lead Administrator.

The Lead Administrator is responsible for keeping a log of all files in temporary storage and for putting a numbered labelling system in place (e.g., file 1 of 5) and for labelling all filing cabinet drawers/shelves.

4.4 On the Day(s) of Inspection

On the first, and every subsequent day of the inspection the Lead Administrator or a designated assistant should meet the inspectors at the organisation's main reception desk. S/he should check the inspectors' photo identification cards and give them organisation visitor name badges for use while on the premises as detailed in SOP 30 – Workplace Visitors

The ICT will ensure that arrangements are in place for the inspectors to be escorted by a member of staff whenever they move around the organisation.

4.4.1 Opening Meeting

The inspectors are likely to hold an opening meeting to explain the purpose of their visit and outline the plan for the inspection. The Senior Member of the Trust with the responsibility for RIG (or their delegate) will be responsible for inviting relevant members of the organisation to attend; this invitation list will include the Chief Executive and other members of senior management as deemed appropriate, members of the ICT, and members of any investigator teams or support department staff involved in the inspection.

4.4.2 Interview Sessions

All members of staff must present themselves for inspection interviews in a timely manner. If unforeseen and urgent matters prevent this, they should contact the Lead Administrator immediately to reschedule at the earliest possible convenience.

The ICT will ensure that arrangements are in place for all interviews to be attended by a 'scribe', who will take notes of the interview. These notes will be retained by the RIG PS team, and may be used for debriefing staff after the inspection and/or for making improvements to clinical trial practice and procedure in the Trust.

Staff should note the following guidance in relation to inspection interviews:

- If an interviewee does not understand the question and/or the context s/he should ask the inspector for clarification
- The interviewee should restrict their answer to the questions posed
- An interviewee may request to consult relevant SOPs or guidance documents during the interview in order to provide the required information
- If the interviewee realises (either during or after the interview) s/he has provided erroneous information, then s/he should immediately correct this and have this noted by the inspector
- If an interviewee decides that a question is outside their area of expertise or authority, they may request time to consult others

4.4.3 Providing documents for the inspectors

The Lead Administrator is responsible for managing provision of documents and copy documents to the inspectors.

When the Inspectors request documentation for review, the Lead Administrator, or an assistant will:

- note the details on a document log.
- obtain the document from the temporary storage facility or request a member of staff in the relevant department to locate it.
- give the document (or a copy of the document) to the Inspectors in the inspectors' room.
- keep a note on the document log of exactly what has been provided or any documents unable to be provided together with a reason.
- return the document to the temporary storage facility as soon as the Inspectors have completed their review. This includes documents obtained directly from departments, which will be returned at the end of the inspection when the temporary storage facility is cleared.

It may be more convenient to use the 'in' and 'out' trays outside the inspectors' room to pick up the inspectors' requests for documentation and leave documents for them to collect. Any confidential documents should be retained securely by the Lead Administrator until they can be handed personally to the requesting inspector.

4.4.4 Debriefing

At the close of each day the Senior Member of the Trust with the responsibility for RIG (or their delegate) may host a debriefing session which all staff who have been involved in the day's inspection activities will be invited to attend. This will be an opportunity to assess progress, discuss unresolved questions, provide outstanding requested information and plan the next day's agenda.

4.4.5 Close out of the inspection

The inspectors will hold a close out meeting at the end of the inspection. The Senior Member of the Trust with the responsibility for RIG (or their delegate) will be responsible for inviting appropriate members of the organisation to attend, in the same way as for the opening meeting. All who are invited are strongly recommended to attend if they can, since this is a valuable learning opportunity for all staff involved in clinical trial work.

The inspectors will provide verbal feedback summarising observations and findings made during the inspection and allow the opportunity to correct any misunderstandings. The grading of the findings at this point is provisional and may be changed by the inspector for the report (see Appendix 1 for description of gradings). The ICT will provide feedback from the close out meeting to research teams as necessary (for example if no team representatives has been able to attend).

4.5 Following Inspection

4.5.1 The Inspection Report

The Inspection report will be received by email and requires a response in the form of a corrective action and preventative action (CAPA) plan. The Senior Member of the Trust with the responsibility for RIG (or their delegate) will coordinate the organisation's response with the support of the ICT. All staff are required to respond to requests for contributions in a complete and timely manner, since the deadline for response set by the inspectors must be met.

The final MHRA Report will be reviewed and signed off by the Senior Member of the Trust with the responsibility for RIG (or their delegate) and those who have contributed responses. The lead inspector may ask for additional clarification from the responses provided, usually providing one opportunity to provide additional information or clarification.

Once the MHRA has reviewed the inspection response and confirmed that the Trust has provided a CAPA plan that is considered acceptable, the inspection will be formally closed. The MHRA will issue a 'GCP Inspection Statement' by email.

If there are critical findings identified, these are referred to the GCP Inspection Action Group (IAG). This is a cross-agency group that oversees all critical findings and decides on the actions to be taken in addition to the review of the CAPA for the critical finding.

4.5.2 Corrective and Preventative Action (CAPA) oversight

The CAPA plan will be reviewed quarterly in the Governance and Oversight Group (GOG) meeting, to ensure that corrective actions are implemented as per the responses on the report. The RIG Professional Services team will be responsible for undertaking this and for preparing and maintaining an appropriate CAPA file. Outcomes from GOG will be reported to the Heads of Service meeting, either for information or escalation.

5. References

NIHR Learn Login Page:
Identity Gateway (nihr.ac.uk)

Good clinical practice for clinical trials - GOV.UK
MHRA: How to show the MHRA you're meeting good clinical practice (GCP) standards and what to expect from an inspection.

Microsoft Word - Guidance for Formulating Responses to GCP Inspection Findings V2 (25-04-22)
MHRA: CAPA guidance

APPENDIX 1: Grading of Inspection Findings

Deficiencies found during inspections are graded at 3 levels: critical, major and other.

Critical

a) Where evidence exists that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that:
   - the rights, safety or well-being of trial subjects either has been or has significant potential to be jeopardised, and/or
   - the clinical trial data are unreliable and/or
   - there are a number of Major non-compliances (defined in (d) and (e)) across areas of responsibility, indicating a systematic quality assurance failure, and/or

b) Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported major non-compliances (defined in (d) and (e)).

c) Where provision of the TMF does not comply with Regulation 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the regulations.

Major

d) A non-critical finding where evidence exists that a significant and unjustified departure from applicable legislative requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed, and/or

e) Where evidence exists that a number of departures from applicable legislative requirements and/or established GCP guidelines have occurred within a single area of responsibility, indicating a systematic quality assurance failure.

Other

f) Where evidence exists that a departure from applicable legislative requirements and/or established GCP guidelines and/or procedural requirement and/or good clinical practice has occurred, but it is neither critical nor major.

APPENDIX 2: MHRA GCP Inspection Process Flowchart

MHRA GCP Inspection Process