

2019

HEALTH+MEDICAL RESEARCH

Hosting an audit or regulatory inspection

Standard Operating Procedure



NSW Health

100 Christie Street

St Leonards NSW 2065

(02) 9391 9228

www.health.nsw.gov.au

www.medicalresearch.nsw.gov.au

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1. Purpose

To describe the processes necessary to host an external Good Clinical Practice (GCP) audit or inspection. To ensure that sites conducting clinical trials take appropriate account of the Guidelines for Good Clinical Practice based on sponsor requirements¹.

2. Scope

All clinical trials (except Teletrials)² conducted at NSW Public Health Organisations.

3. Applicable to

The principal investigator (PI) and all site staff.

Research Office staff and Human Research Ethics Committees (HRECs)

Departments supporting clinical trials (e.g. pharmacy, radiology, pathology, information & technology (IT)).

4. Definitions

Refer to SOP-G-01: Glossary of terms.

5. Background

An audit is a systematic and independent examination of trial activities to determine whether a trial is conducted in accordance with applicable requirements. An inspection is similar to an audit in that it is an official review of trial-related activities, but is conducted by a regulatory authority that has rights conferred by regulation (e.g. to enter premises and to request documents). External audits and regulatory inspections and may be scheduled periodically at sites to confirm protocol compliance and adherence to GCP and regulatory requirements.

Routine audits and inspections often include the following components:

- An opening meeting to confirm the purpose of the audit/inspection and to provide introductions and methodology.
- A pre-prepared plan to conduct the audit/inspection. This plan may be revised based on initial findings as the audit/inspection proceeds. Audits/inspections normally include:
 - Interviews: e.g. with the trial team, supporting department staff and research office.

- Document review: including but not limited to source data, case report forms, investigator site files, pharmacy documentation, clinical trial SOPs or policies.
- Facility tours: clinics and supporting departments (e.g. pharmacy, laboratories, radiology, archives).

- Feedback of key findings at a closing meeting.

It is recommended that Research Offices develop a local procedure/work instruction covering specific responsibilities and activities for preparation and conduct of audits and inspections; noting that regulatory inspections normally require more extensive planning and input from the organisation than routinely conducted trial audits. During an audit/inspection, the PI should work with the Research Office in accordance with these local requirements.

Implementing corrective and preventative actions (CAPA)

Deficiencies identified at audit or inspection should be actively managed to ensure continuous improvement (e.g. through the Research Office and clinical governance where applicable). Any PI whose trial is audited should provide a copy of the audit report to the organisation. As part of the requirement for continuous improvement, the organisation should also encourage sponsors to feedback major site deficiencies occurring at its sites. Whether a deficiency is at organisational or trial level, the organisation/PI should ensure the correction of specific deficiencies and where appropriate, the prevention of further deficiencies through the identification of the root cause.

6. Procedure

Principal Investigator (PI)

Have oversight of any audit or inspection of their trial.

Appoint an appropriate team member to coordinate the audit/inspection.

Ensure that all documentation is reviewed and filed appropriately before the audit/inspection.

Any trial team member

Promptly inform the Research Office (and PI) when notification of an audit or inspection is received.

Research Office

¹ All trials must comply with the principles of GCP (Section 2 of ICH GCP (E6 R2) or Clause 4 of ISO 14155) however sponsors submitting data to regulatory authorities will normally require full compliance with ICH GCP (E6 R2) or ISO 14155 GCP Guidelines.

² NSW Health have published an annotated version of these SOPs for sites utilising a Teletrials model.

Liaise with the PI and their audit/inspection co-ordinator as necessary, to prepare and host the audit/inspection in accordance with local policy.

Ensure organisational policies, procedures and work instructions demonstrate that the organisations has processes that are compliant with GCP and applicable regulation.

Audit/ Inspection Coordinator – before the audit/inspection

Establish the scope of the audit/inspection and in liaison with the PI agree a date that allows the PI and other key staff sufficient notice to attend.

Liaise with the PI and if required, the Research Office to organise a suitable work area or office for the auditor/inspector with sufficient space for all requested documents and with access to photocopying facilities.

Ensure site staff have reviewed all trial documentation (including the investigator site file and all source documents).

Collate and provide an inspection dossier, if requested.

PI/Audit Inspection Coordinator – during the audit/inspection

Check the identity card of the auditor/inspector on arrival and ensure the auditor/inspector is accompanied at all times.

Ensure key staff attend the opening meeting.

Make available all trial-related records requested.

Attend to all other requests (e.g. retrieval of additional documents or arrangements for additional staff to be interviewed).

Ensure meeting minutes are taken to facilitate the production of the audit response; including all questions answered and any comments or observations made by the auditor/inspector.

Where the auditor/inspector requests copies of documents to take away, ensure these copies are stamped as confidential and de-identified (inspectors may request copies of un-redacted documents where necessary). Maintain a log of all documents requested.

Ensure all relevant staff attend the closing meeting to receive verbal feedback of the findings and to provide answers to questions or clarifications.

Audit/ Inspection Coordinator – after the audit/inspection

Coordinate the response to each finding and where applicable, prepare the formal response document within any specified timeframe.

Liaise with all relevant staff and the Research Office to facilitate any corrective and preventative (CAPA) actions arising.

Research Office – after the audit/inspection

Have oversight of any corrective and preventative (CAPA) actions arising.

Disseminate audit/inspection findings to relevant staff and use anonymised findings to continuously evaluate and improve research practices and assist in staff training.

7. References

[Therapeutic Goods Regulations 1990](#) sections 12 AB and 12 AC

[ICH GCP \(E6 R2\): Good Clinical Practice Guidelines – Annotated by the TGA](#)

[The National Clinical Trials Governance Framework \(Draft\)](#)

8. Associated documents

None