GV Health	**TITLE:**	**Clinical Trial Standard Operating Procedure 14: Hosting a Regulatory Inspection, Sponsor or HREC Initiated Audit**	
Document Type:	Procedure	**Approved by:**	Research Management and Governance Committee
Directorate:	CMO + Medical Services	**Section:**	Research
Author/Prepared by:	Usman Tahir	**Position:**	Clinical Trials Coordinator

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Document Details

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Name:	Research Management and Governance (RM&G) Committee
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1. INTRODUCTION AND BACKGROUND:

Regulatory inspections and sponsor initiated audits may be scheduled periodically at investigational sites to review protocol compliance and adherence to International Conference on Harmonisation Good Clinical Practice (ICH GCP), during or after the completion of a study. Human Research Ethical Committees (HREC) occasionally inspect investigational sites during a study to ensure study participant safety and ethical guidelines are being followed.

2. OBJECTIVE:

To describe the procedure and activities for facilitating a regulatory inspection, sponsor or HREC initiated audit.

3. SCOPE:

This SOP applies to the Principal Investigator and all members of the study team including satellite site staff as required.

4. OWNERSHIP AND RESPONSIBILITY:

The Principal Investigator and GV Health study team within each department are responsible for the preparation, conduct and follow-up of inspections/audits.

5. ABBREVIATIONS AND TERMS:

Please refer to GV Health Standard Operating Procedure (SOP) - Abbreviations and Terms for full supporting glossary of terms.

6. PROCEDURE:

The site may be notified about an impending inspection/audit by the sponsor to the Principal Investigator or the study team. Upon notification the following procedures will be followed:

6.1 Pre-Inspection/Audit Activities

- The study team will maintain a professional relationship with the specific regulatory authority, sponsor or HREC conducting the inspection/audit.
- The GV Health study team coordinating the clinical trial in conjunction with the Principal Investigator is responsible for reviewing all documentation (investigator site files and participant folders) to ensure they are complete.
- The GV Health Principal Investigator will nominate a GV Health study team member to act as the inspection/audit representative and will be responsible for coordinating preparations.

6.2 Inspection/Audit Conduct

- The Principal Investigator and appointed GV Health representative, will be present during the opening and closing of the inspection/audit to briefly introduce and conclude the process and to be available to discuss any questions or findings with the inspector/auditor.
- The inspector/auditor must be accompanied at all times.

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- Meeting minutes will be taken by the representative to document any comments or observations made by the inspector/auditor.
- The meeting minutes will be reviewed by the study team so as to assist with inspection/audit responses.
- Original documentation and records may be provided during the inspection/audit process on request. No documentation of any kind may be retained by the inspector/auditor.
- The GV Health Clinical Trial SOPs will be provided to the inspector/auditor, upon request.

6.3 Inspection/Audit Closeout Activities

- The closeout meeting will be attended by the Principal Investigator or delegate and appropriate representatives from the GV Health study team.
- The closeout meeting is an opportunity to clarify and discuss any findings raised during the inspection/audit with the inspector/auditor(s).
- The GV Health study team will meet to discuss and evaluate the inspection/audit meeting minutes and outcomes after the closeout meeting.
- Any findings will be disseminated by the Principal Investigator to the relevant staff members who will collectively develop an appropriate action plan addressing the findings where required.

6.4 Reporting Obligations

- Any inspection/audit outcomes should be reported via Ethics Review Manager (ERM) to notify the Research Governance Officer (RGO) for informing the organisation.

7. MONITORING COMPLIANCE AND EFFECTIVENESS

Compliance with this SOP will be monitored as part of the GV Health monitoring and audit process. Any queries concerning the effectiveness of this SOP identified during the GV Health monitoring process or through use will be addressed and may result in the requirement to update the SOP.

KEY ALIGNED DOCUMENTS

GV Health procedure:

- GVH_CT-SOP-Abbreviations and Terms

KEY LEGISLATION, ACTS & STANDARDS:

National Safety and Quality Health Service (NSQHS) Standards:

- Standard 1: Clinical Governance

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REFERENCE(S)

ICH. (2016). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

National Clinical Trials Governance Framework and User Guide, Australian Commission on Safety and Quality in Health Care. (2022). Safetyandquality.gov.au. https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide

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