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Standard Operating Procedure:

**Hosting a Regulatory Inspection, Sponsor or HREC Initiated Audit with Teletrials**

**SOP Number: TT-SOP-08**

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| Author(s): | Hannah Cross  VCCC Program Manager |
| Approved by: |  |

**This is a controlled document. It should not be altered in any way without the expressed permission of the developer and the approver.**

**Amendment History**

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| Version | Date | Amended By | Amendment Details |
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Developed by the Victorian Comprehensive Cancer Centre (VCCC) in conjunction with the Parkville Cancer Clinical Trials Unit (PCCTU), based on the Clinical Oncology Society of Australia (COSA) Australasian Tele-trials Model.

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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.

1. Objective

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

1. Scope

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

1. Ownership and Responsibility

The principal investigator, (SITE) Manager, (SITE) Leadership Group, and (SITE) study team are responsible for the preparation, conduct and follow-up of inspections/audits.

The (SITE) Manager or (SITE) Team Leader will provide the key contact for inspection/audit.

1. Glossary of Terms

Please refer to (SITE) TT-SOP-Glossary-of-Terms (see Related Documents) for full supporting glossary of terms.

1. Procedure

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

* 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 (SITE) 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 (SITE) team leader will nominate a (SITE) study team member to act as the inspection/audit representative and will be responsible for coordinating preparations.
  1. Inspection/Audit Conduct
* The principal investigator and appointed representative (including the (SITE) team leader/(SITE) Manager 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.
* 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 (SITE) TT-SOP-Master-list (see Related Documents) will be provided to the inspector/auditor, and upon request all SOPs will be provided.
  1. Inspection/Audit Closeout Activities
* The closeout meeting will be attended by the principal investigator or delegate and appropriate representatives from the (SITE) 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 (SITE) study team will meet to discuss and evaluate the inspection/audit meeting minutes and outcomes.
* Any findings will be disseminated to the (SITE) leadership team, (SITE) Manager and principal investigator who will collectively develop an appropriate action plan addressing the findings where required.

1. Dissemination and Implementation

Approved SOPs will be disseminated electronically by (SITE). SOPs will be made available in hard copy format or electronically upon request. Any updates to the existing approved SOPs will be disseminated internally, and will be effective immediately.

1. Monitoring Compliance and Effectiveness

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

1. Review and Updating

This SOP will be reviewed every three years, or when changes to legislation or working practices that impact upon the content of this document. This SOP may be merged with another SOP if appropriate or removed entirely if it becomes redundant.

1. Reference(s)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (1996). Guideline for Good Clinical Practice E6(R1).

1. Related Documents

SITE TT-SOP-Glossary-of-Terms

Integrated addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)