

Standard Operating Procedure:

Ethics and Governance with Teletrials

**SOP Number: TT-SOP-06**

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| Approved by: | VCCC Teletrials Steering Committee |

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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Description generated with very high confidenceviccompcancerctr**

Introduction and Background

All clinical trials taking place within (SITE) are conducted in compliance the clinical trial protocol that has received prior ethical and governance approval. (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 1996, sec. 2.6)

1. Objective

To describe the procedure for obtaining ethical and governance approval for new and existing clinical trials.

1. Scope

This SOP is applicable to the study team and external providers engaged in the conduct of (SITE) clinical trials, including the study team at all Teletrial satellite sites.

1. Ownership and Responsibility

The principle investigator is responsible for ensuring ethical and governance approval is obtained for new and existing clinical trials prior to commencement. The administrative process of ethical and governance submissions may be undertaken by a member of the study team or an external provider where required.

1. Glossary of Terms

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

1. Procedure

6.1 New Clinical Trial Submission

New clinical trials being considered by SITE will undergo a feasibility process prior to ethics and governance submission as outlined in (SITE) TT-SOP-05: Clinical Trial Feasibility and Start-Up with Teletrials (see Related Documents).

Once the clinical trial has received feasibility acceptance, (SITE) may engage the services of an external provider to facilitate the administrative process of ethical and governance submission on behalf of the principal investigator.

After receiving ethical and governance approval, the study team performs quality checks on the documents to ensure International Conference on Harmonisation Good Clinical Practice (ICH GCP) compliance.

Local HREC guidelines are followed.

For a Teletrial, the primary site will be responsible for submitting and receiving ethics approval. A governance application must be submitted to each satellite site and follow the local processes for review and approval.

6.2 Existing Clinical Trial Amendment Submission

(SITE) may engage the services of an external provider to facilitate the administrative processes of ethics and governance submission on behalf of the principal investigator. The principal investigator and the study team review changes and provide feedback on the implementation of the amendment.

After receiving ethical and governance approval, the study team performs quality checks on the documents to ensure ICH GCP compliance.

Local HREC guidelines are followed.

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 Document(s)

SITE TT-SOP-Glossary-of-Terms

SITE TT-SOP-05: Clinical Trial Feasibility and Start-Up