

Standard Operating Procedure:

Delegation of Duties with Teletrials

**SOP Number: TT-SOP-04**

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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 |
| 1.0 | 03 October 2018 | Hannah Cross | New |
| 1.1 | 13 September 2019 | Alana Donaldson | Addition of term local laboratory staff from list of staff indirectly involved in trial conduct. |

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.

**viccompcancerctr.org**

**DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION.**

1. Introduction and Background

As mandated by the International Conference on Harmonisation Good Clinical Practice (ICH GCP) all study team members performing clinical trial related tasks are required to be qualified to do so by education, training and experience. Study team members must be adequately delegated and supported in order to perform their duties. The principal investigator is responsible for the supervision of all study team members and retains overall responsibility for the conduct, delegation and training on protocol and clinical trial related requirements.

1. Objective

To describe the procedure for delegating clinical trial related duties undertaken by members of the study team.

1. Scope

This SOP applies the principal investigator and to all members of the study team, including study team members at any teletrial satellite site.

1. Ownership and Responsibility

The principal investigator is responsible to ensure all study team members have the necessary expertise and experience in order to successfully perform the task(s) delegated to them.

1. Glossary of Terms

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

1. Procedure
2. Delegation of Duties

Prior to performing any clinical trial related tasks, initial training will be performed as outlined per (SITE) -TT-SOP-03: Clinical Trial Training with Teletrials (see Related Documents), either by the principal investigator or delegate (self-directed learning tool or sponsor/clinical research organisation (CRO) trainer). Once appropriately trained, duties will be delegated by the principal investigator as documented on the (SITE) Delegation of Duties Log (see Related Documents). For teletrials these are further expanded upon in the trial supervision plan.

The principal investigator is responsible for ensuring the (SITE) Delegation of Duties Log is maintained and current.

The (SITE) Delegation of Duties Log includes:

* Full name, signature and initials of study team member.
* Delegated role(s), per the specified role key.
* Start and end date of delegated role(s).
* Principal investigator’s signature confirming delegation.

The (SITE) Delegation of Duties Log will be utilised for all new clinical trials coordinated by (SITE). The original (SITE) Delegation of Duties Log will be kept at site for the duration of the study and archived with the investigator site files at the completion of the study. A certified copy will be presented to the sponsor on request.

1. Staff Indirectly Involved in Trial Conduct

Staff at the SITE (listed below, but not limited to) who as part of their routine practice complete a procedure (i.e. vital signs, Electrocardiography (ECG), venepuncture or imaging) on a patient who may also be participating in a clinical trial will not be considered part of the study team. As such they are not required to undertake clinical trial education, training and delegation.

* Clinicians,
* Specialist nurses,
* Nurses,
* Local laboratory staff,
* Ophthalmologists,
* Radiologists,
* Pathologists and
* Technicians.

The principal investigator is responsible for the oversight and interpretation of the results provided from the above mentioned staff and the required actions.

1. Departmental Responsibilities

Departments within the precinct may have clinical trial related duties (i.e. intravenous investigational product administration) assigned to them by the principal investigator. A named person will assume responsibility for the conduct of such activity on behalf of the department and as such will be delegated this task on the delegation of duties log. The named person will be required to undertake appropriate protocol training relevant to the undertaken activity.

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)

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

1. Related Document(s)

(SITE) TT-SOP-Glossary-of-Terms

(SITE) TT-SOP-03: Clinical Trial Training

(SITE) Delegation of Duties Log