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Version control will be managed through the Department of Research and Innovation.

The Department of Research and Innovation, in collaboration with the Cancer Centre Clinical Trials Unit, has developed a series of standard operating procedures (SOPs) designed to facilitate good clinical trials practice and compliance with applicable regulatory requirements for clinical trial research at Bendigo Health. These SOPs are based on those developed by the Parkville Cancer Clinical Trials Unit (PCCTU) who have kindly granted permission for adaptation and use at Bendigo Health.

SOP 4: Clinical Trial Research Delegation of Duties

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	Final revisions by:	Approved on behalf of the Interdisciplinary Research Steering Committee by Chair:
Name	Dr. Rani Watts	Dr. Angela Crombie
Position Title	Clinical Trials Research Manager	Director of Research and Innovation
Signature		
Date	20-Dec-2021	20-Dec-2021

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

1. Introduction and Background

As mandated by the International Council for Harmonisation (ICH) of Good Clinical Practice (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 (PI) is responsible for the supervision of all study team members and retains overall responsibility for the conduct, delegation of duties and training on protocol and clinical trial related requirements.

2. Objective

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

3. Scope

This standard operating procedure (SOP) applies to the PI and to all members of the study team.

4. Ownership and Responsibility

The PI is responsible for the overall conduct of the clinical trial. They are responsible for supervising and ensuring all study team members have the necessary expertise and experience in order to successfully perform the task(s) delegated to them.

5. Glossary of Terms

Please refer to Bendigo Health's *Clinical Trial Research Standard Operating Procedures Glossary of Terms* for a full supporting glossary.

6. Procedure

6.1 Delegation of Duties

The PI has overall responsibility for all clinical trial duties and is not required to delegate themselves to individual tasks on the *Site Signature and Delegation of Duties Log* (see Related Documents).

Prior to performing any clinical trial related tasks, initial training will be performed as outlined in *SOP 3: Clinical Trial Research Training* (see Related Documents), either by the PI or delegate (for example, a self-directed learning tool or sponsor/CRO trainer).

Once appropriately trained, duties will be delegated by the PI as documented on the *Site Signature and Delegation of Duties Log* (see Related Documents).

The PI is responsible for ensuring the *Site Signature and Delegation of Duties Log* is maintained and current in both the eISF and the ISF.

The *Site Signature and Delegation of Duties Log* must include:

- Full name, signature and initials of study team member
- Delegated role(s) as per the specified role key
- The start date of delegated role(s)
- The end date, to be entered upon cessation of either the study or the study team member's role in the clinical trial - whichever occurs first
- PI's signature confirming delegation

The original *Site Signature and Delegation of Duties Log* will be kept at site for the duration of the study and archived with the ISFs at the completion of the clinical trial. A copy will be presented to the sponsor upon request.

6.2 Staff Indirectly Involved in Trial Conduct

Staff within the organisation (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. Such staff includes:

- Clinicians
- Specialist nurses
- Nurses
- Laboratory staff
- Ophthalmologists
- Radiologists
- Pathologists
- Technicians
- Allied health staff

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

6.3 Delegation of Responsibility During a PI's Absence

When the PI takes a period of extended leave (considered to be greater than 6 weeks and less than 12 months), they will temporarily delegate their responsibilities to an investigator who has the necessary expertise and experience to act as PI in their absence. This role will be documented in

the *Site Signature and Delegation of Duties Log* as acting PI. Where the acting PI was previously delegated as a sub-investigator, their original delegation will be ended.

The acting PI assumes all responsibility for the clinical trial, delegated for the duration of the PI's absence and ensure the appropriate qualification and training for any newly delegated study team member(s).

6.4 Change of Principal Investigator

If there is a permanent change to the PI, the *Site Signature and Delegation of Duties Log* will be ended and a new *Site Signature and Delegation of Duties Log* will be started. New delegation will document the change of PI and their acceptance of the role and responsibility.

7. Dissemination and Implementation

The Department of Research and Innovation at Bendigo Health is responsible for the dissemination and implementation of the Bendigo Health SOPs related to clinical research. Any content updates will be tabled at the Clinical Trials Sub-Group and the Interdisciplinary Steering Committee meetings. Content updates will be accompanied by relevant promotions and training.

Approved SOPs will be published on the Bendigo Health intranet and available through the SiteDocs portal. SOPs will be made available in hard copy format upon request to: clinicaltriasresearchsupport@bendigohealth.org.au.

Any updates to the existing approved SOPs will be disseminated internally, and will be effective immediately.

8. Monitoring Compliance and Effectiveness

SOP compliance will be monitored as part of the Bendigo Health SOP monitoring and audit process, initiated by Clinical Trials Sub-group.

Any queries concerning the effectiveness of the SOP identified during the Bendigo Health monitoring and audit process or through use will be escalated to the Interdisciplinary Research Steering Committee to advise.

9. Review and Updating

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

10. Reference(s)

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) (2016).

11. Related Document(s)

SOP Glossary of Terms

SOP 3: Clinical Trial Research Training

Template: Site Signature and Delegation of Duties Log

12. Amendment History

Version	Date	Amended By	Details of Amendment
2	11-Nov-2021	Jasmine Gillingham Dr. Rani Watts	• Revisions made in line with amendments to those made by the Parkville Precinct Clinical Trial Unit; • Minor administrative amendments