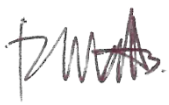
DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION.

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 3: Clinical Trial Research Training

Version No: 2.0
Effective Date: 20-Dec-2021
Supersedes: 01-Sep-2020
Review Date: 20-Dec-2023

	Final revision 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) 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 and training on protocol and clinical trial related requirements.

2. Objective

To describe the procedure for documenting clinical trial training that has been undertaken by members of the study team.

3. Scope

This SOP applies to the PI and to all members of the study team.

4. Ownership and Responsibility

The PI 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.

5. Glossary of Terms

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

6. Procedure

6.1 Initial Protocol Training

Prior to study staff delegation, initial training will be performed by:

- The PI
- Delegate as appropriate to the delegated role (self-directed learning tool or sponsor / Clinical Research Organisation (CRO) trainer)
- Clinical Research Associate (CRA) at either Site Initiation Visit (SIV) or routine monitoring visit

Bendigo Health defines initial protocol training as encompassing the following:

- Current version of the protocol

- Content of the Patient Information and Consent Forms (PICF(s))
- Relevant safety information
- Protocol training materials provided by the sponsor

Initial protocol training, as above, will be documented in the *Study Team Training Log* or, alternatively, in the electronic investigator site file (eISF) by "read and understood" workflow on the protocol document. Individual training records for supporting documents (including PICF or training slides, etc.) are not required.

Training in the eISF requires users to enter their user name and password. This is tracked within the document view by user, status, date and time signed, date and time counter signed. These details cannot be manually updated or changed.

The PI is responsible for countersigning all protocol training. Once appropriately trained, duties are delegated by the PI and documented in the *Site Signature and Delegation of Duties Log*.

Study team members are not required to document training in sponsor mandated portals.

Delegated site personnel that did not attend the SIV may document initial training in one of two ways:

1. Complete the *Study Team Training Log*.
2. The training record can be completed on SiteDocs portal as per Section 6.2.2 of this SOP.

6.2 Protocol Amendment Training

Bendigo Health defines protocol amendment training as encompassing the following:

- Updated versions of the protocol
- Content of the PICF(s), if updated
- Any relevant safety data
- Any protocol training materials
- A summary of changes or tracked changes to the protocol

Protocol amendment training, as above, will be documented in the eISF by 'read and understood' workflow on the protocol document. Individual training records for supporting documents (including PICF, training slides, safety data or tracked changes etc.) are not required.

Training requires users to enter user name and password and is tracked within the document view by user, status, date and time signed, date and time counter signed and cannot be manually updated or changed. The PI is responsible to countersign all protocol amendment training.

The PI is responsible for identifying and implementing required training on amendments to the protocol in a timely manner. To facilitate this, training documents will be available for delegated study team members and training will be completed prior to ethical and governance approval. If any changes occur during the submission process updated training will be performed as required.

6.2.1 Manual Process

The PI or delegate will provide the study team with training materials (i.e. training slides, summary of changes or tracked changes of approved amendment) via email. Upon receipt, study team members will be required to reply to confirm they have read and understood the changes.

The PI will ensure the *Study Team Training Log* is completed to document the relevant training and date of training for all study team members based on their email acknowledgement.

6.2.2 eISF Process

Protocol amendment training, as above, will be documented in the eISF by "read and understood" workflow on the protocol document. Individual training records for supporting documents (including PICF, training slides, safety data or tracked changes, etc) is not required.

Training in the eISF requires users to enter their user name and password. This is tracked within the document view by user, status, date and time signed, date and time countersigned. These details cannot be manually updated or changed. The PI is responsible for countersigning all protocol amendment training.

6.3 Other Amendment Training

Where the PICF is updated due to safety data (without causing a protocol amendment), study team members delegated to obtain informed consent or key roles, such as research nurse or study coordinator, will complete PICF amendment training. The safety amended PICF training will be documented in the eISF by 'read and understood' workflow.

Where the PICF is updated with administrative changes only (without causing a protocol amendment), training is not required. The PI will disseminate the PICFs to the study team. This does not require documentation.

6.4 Other Training Requirements

All study team members are required to have valid ICH GCP training.

Delegated study team members are required to complete training on supplementary trial documents as applicable to the tasks delegated to them. For example:

- Study team members delegated to handle and ship samples are required to complete the relevant training, as outlined in *SOP 8: Handling and Shipping of Biological Substances and/or Dangerous Goods for Clinical Trial Research* (see Related Documents), as necessary.

- Study team members delegated to make entries in, corrections to and sign off the case report form (CRF)/eCRF (as per the *Site Signature and Delegation of Duties Log)* will complete relevant training modules and provide evidence of training, as required.
- Study team members delegated to investigational product (IP) dispensing, accountability, receipt and storage as per the *Site Signature and Delegation of Duties Log* will complete training on the IP or pharmacy manual and any supplementary documents encompassing IP compounding, dispensing or administration.
- Where the protocol mandates procedures outside of routine practice, relevant named person(s) will be delegated on behalf of their department and train on the relevant manuals.

Study team members are not required to undergo nor document training in supplementary trial documents such as:

- Investigational Brochure (IB). The IB is a reference document which informs the protocol.
- Updated versions of the IB are acknowledged by the PI and documented on the IB signature page (if provided by the sponsor and electronically through the SiteDocs portal.
- The PI will disseminate safety data to the study team, including urgent safety data, 'Dear investigator letters' and aggregated reports.

6.5 Staff Indirectly Involved in Trial Conduct

Staff (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
- Laboratory staff
- Ophthalmologists
- Radiologists
- Pathologists and
- Technicians

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

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 Interdisciplinary Research 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 the through SiteDocs portal. The latest SOPs will be made available in hard copy format upon request to: clinicaltrialsresearchsupport@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 the Clinical Trial Sub-group.

Any queries concerning the effectiveness of the SOP identified during the Bendigo Health monitoring and audit process will be escalated to the Interdisciplinary Research Steering Committee for 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 4: Clinical Trial Research Delegation of Duties
Template: Study Team Training Log
Template: Site Signature and Delegation of Duties Log
SOP 8: Handling and Shipping of Biological Substances and/or Dangerous Goods for Clinical Trial Research

12. Amendment History

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