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 1: Preparation, Approval, Review and Issue of SOPs Related to Clinical Trial Research

| | |
|---|---|
| Version No: | 2.0 |
| Effective Date: | 23-Nov-2021 |
| Supersedes: | 01-Sep-2020 |
| Review Date: | 23-Nov-2023 |

| | 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 | 23-Nov-2021 | 23-Nov-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

Bendigo Health has a duty to ensure that all clinical trials conducted within the hospital comply with the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) requirements. A key component of this is adherence to Standard Operating Procedures (SOPs).

ICH GCP defines SOPs as "Detailed written instructions to achieve uniformity of performance of a specific function." (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) sec. 1.55)

SOPs must be clear, concise, of common style, format and content, available where and when needed and be subject to a system of document control.

## 2. Objective

To describe the procedure for the preparation, approval, distribution, document control, revision and review process of Bendigo Health SOPs related to clinical trial research.

## 3. Scope

SOPs are written when the need for a standardised procedure is identified. Amendments to existing SOPs will be in response to changes in regulatory requirements, clinical practice or when deficiencies are noted.

## 4. Ownership and Responsibility

The Interdisciplinary Research Steering Committee will be responsible for the development, maintenance and continuous improvement of the Bendigo Health SOPs related to clinical trial research.

The Department of Research and Innovation will maintain responsibility for the final SOP approval.

## 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 Identifying the Need for an SOP

The Department of Research and Innovation at Bendigo Health will review current clinical trial-related practices and determine if a new SOP is required prior to its development and will also be responsible for reviewing current implemented SOPs to confirm that they are relevant and reflect best practice.

### 6.2 Development of SOPs

SOPs are generated to document a defined policy or procedure.

The SOP developer will be a member of the Clinical Trials Sub-Group who has experience in the relevant SOP subject matter.

The developer in consultation with the Department of Research and Innovation at Bendigo Health will ensure the SOP meets the following requirements:

- Title
- Version control
- Developer and approver signatures
- Introduction and background
- Objective
- Scope
- Ownership and responsibility
- Glossary of terms
- Procedure
- Dissemination and implementation
- Monitoring compliance and effectiveness
- Review and updating
- Reference(s)
- Related document(s)
- Amendment history.

All sections of the template must be completed and adhere to the following:

- SOPs require version control to ensure that individuals are using the correct version, as outlined in *SOP 9: Clinical Trial Research Document Version Control* (see Related Documents). A version number will be assigned to each approved and finalised SOP by the Department of Research and Innovation at Bendigo Health.
- SOPs are required to be easily interpreted and acted upon in the intended manner. They must be written in a style that is logical, step-by-step and unambiguous.

- The SOP may reference other SOPs by number; this reference will not include the version number.
- Individuals or groups responsible (referred to by role only) for the given practice documented in the SOP are to be identified and their responsibility in relation to the procedure outlined.
- SOPs may reference generic forms, checklists or templates required in the step of a procedure, but these will not be attached to the SOP.

### 6.3 SOP Approval and Signature

The Clinical Trials Sub-Group and the Interdisciplinary Research Steering Committee will review the final draft SOP and when satisfied the revised document will be signed by the designated approver.

The SOP will be effective from the date of the approver's signature on the original document.

### 6.4 SOP Review Cycle

A review date will be set for two years post approval date. When an SOP is nearing its review date, the Clinical Trials Research Manager will review the SOP. The Director of Research and Innovation will determine whether it is still current, requires revision, or should be withdrawn.

Should an SOP require revision, the Clinical Trials Research Manager in consultation with the appropriate stakeholders will make revisions.

### 6.5 SOP Withdrawal

An SOP may be withdrawn due to a significant change in current practice, requirement to incorporate another process or task from one SOP into another SOP, or for other reasons.

Recommendations to withdraw an SOP will be considered by the Clinical Trials Sub-Group, with final decision to be made by the designated approver.

### 6.6 Training

A list of core SOPs per job title/role will be defined. Training on all SOPs will be documented electronically and will be required to be undertaken upon approval or commencement of position.

### 6.7 Archiving/Retention

All obsolete SOPs will be withdrawn and an electronic archive will be maintained. Archived SOPs will be retained for a period of 15 years following withdrawal as outlined in *SOP 11: Archiving Clinical Trial Research Documents* (see Related Documents).

## 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 trial 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 through the 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 Trials Sub-group.

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

## 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)

*Clinical Trial Research SOPs Glossary of Terms*
*SOP 9: Clinical Trial Research Document Version Control*
*SOP 11: Archiving Clinical Trial Research Documents*

## 12. Amendment History

| Version | Date | Amended By | Details of Amendment |
|---|---|---|---|
| 2 | 01-Oct-2021<br>23-Nov-2021 | Jasmine Gillingham<br>Dr. Rani Watts | Minor administrative amendments |