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 7: Hosting a Regulatory Inspection, Sponsor- or HREC-Initiated Audit for Clinical Trial Research

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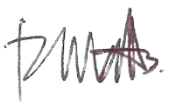
	Final revisions by:	Approved on behalf of the Interdisciplinary Research Steering Committee by Chair:
Name	Dr. Rani Watts	Dr. Angela Crombie
Position Title	Clinical Trials Research Manager	Director of Research and Innovation
Signature		
Date	20-Dec-2021	20-Dec-2021

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1. Introduction and Background

Regulatory inspections and sponsor-initiated audits may be scheduled periodically at investigational sites to review protocol compliance and adherence to International Council for Harmonisation (ICH) of Good Clinical Practice (GCP), during or after the completion of a study.

Human Research Ethics Committees (HRECs) occasionally inspect investigational sites during a study to ensure study participant safety and ethical guidelines are being followed.

2. Objective

To describe the procedure and activities for facilitating a regulatory inspection, sponsor or HREC-initiated audit.

3. Scope

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

4. Ownership and Responsibility

The PI, Department Manager and study team are responsible for the preparation, conduct and follow-up of inspections/audits.

The Department Manager or appointed study team member will provide the key contact for the inspection/audit.

5. Glossary of Terms

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

6. Procedure

The site may be notified about an impending inspection/audit by the sponsor to the PI or the study team. Upon notification the following procedures will be followed:

6.1 Pre-Inspection/Audit Activities

- The study team will maintain a professional relationship with the specific regulatory authority, sponsor or HREC conducting the inspection/audit.

- The study team coordinating the clinical trial in conjunction with the PI is responsible for reviewing all documentation (ISFs and participant folders) to ensure they are complete.
- The PI or the Department Team Leader will nominate a study team member to act as the inspection/audit representative and will be responsible for coordinating preparations.
- The site will notify the commercial sponsor of the planned audit.

6.2 Inspection/Audit Conduct

- The PI and an appointed study team member will be present during the opening and closing of the inspection/audit. The inspector/auditor will briefly introduce and conclude the process and to be available to discuss any questions or findings with the study team.
- The inspector/auditor must be accompanied at all times.
- Meeting minutes will be taken by the representative to document any comments or observations made by the inspector/auditor.
- Original documentation, records and electronic audit trails may be provided during the inspection/audit process on request. No documentation of any kind may be retained by the inspector/auditor.
- A suitable space for undertaking the inspection/audit will be provided.
- This document, *SOP 7: Hosting a Regulatory Inspection, Sponsor- or HREC-Initiated Audit for Clinical Trial Research*, will be provided to the inspector/auditor upon request.

6.3 Inspection/Audit Closeout Activities

- The closeout meeting will be attended by the PI and/or an appointed study team member.
- The closeout meeting is an opportunity to clarify and discuss any findings raised during the inspection/audit with the inspector/auditor(s).
- The PI and/or an appointed study team member will meet to discuss and evaluate the inspection/audit action items and outcomes.
- Any findings will be disseminated to the Department Director, Department Manager and PI who will collectively develop an appropriate action plan addressing the findings, where 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 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 the 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
Template: Site Signature and Delegation of Duties Log
Template: Study Team Training Log

12. Amendment History

Version	Date	Amended By	Details of Amendment
2	10-Nov-2021	Jasmine Gillingham Dr Rani Watts	• Revisions in line with amendments to those made by the Parkville Precinct Clinical Trial Unit • Minor administrative amendments