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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 5: Clinical Trial Feasibility and Start-Up

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

The International Council for Harmonisation (ICH) of Good Clinical Practice (GCP) outlines the requirement of clinical trial conduct to ensure high scientific, ethical and financial standards are maintained throughout the course of the clinical trial. As such sites must assess all clinical trial protocols against an agreed set of criteria before undertaking clinical trial conduct.

All clinical trials taking place at Bendigo Health must undergo a thorough feasibility assessment to determine protocol validity, site ability to comply with protocol requirements, ability to recruit the proposed participant population, current clinical trial portfolio, competing clinical trials and the registration landscape.

2. Objective

To describe the procedure of clinical trial feasibility and start-up undertaken at Bendigo Health.

3. Scope

This standard operating procedure (SOP) applies to all clinical trials conducted by Bendigo Health.

4. Ownership and Responsibility

The Principal Investigator (PI) is responsible for obtaining the appropriate approvals prior to commencement.

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 Potential Clinical Trials

All potential clinical trials undergo feasibility and site selection review process prior to acceptance:

- On receipt of the protocol and supporting documentation, the relevant department reviews the clinical trial in collaboration with the PI and the clinical trial research manager (or equivalent).

- An assessment is commenced identifying current services across the organisation and additional services/supplies required to facilitate protocol requirements. Recruitment projection is determined and evaluated to best support the proposed participant population.
- The department team leader will review the functionality of the protocol and forecast resources to facilitate the clinical trial.

Site selection and qualification:

- When a clinical trial has been deemed feasible a site qualification visit may be performed between sponsor/contract research organisation (CRO), PI and relevant department/s. The purpose of this visit is to evaluate the site's ability to perform the clinical trial in accordance with the study design and protocol.
- Attendees may include sponsor/CRO representative(s), PI, associate investigators (AIs) or department's study team, as indicated and available.
- A facility tour is conducted during the qualification visit to confirm required equipment, space and services are satisfactory to facilitate the clinical trial protocol and all storage of clinical trial supplies and materials are secure with limited access.
- The sponsor/CRO representative should provide copies of relevant clinical trial materials to attendees prior to qualification visit.
- The PI will confirm that the relevant department has the ability to recruit the proposed number of participants within the protocol specified time frame.
- On request, relevant department will provide the sponsor/CRO representative with appropriate documentation to support site qualification.
- Relevant department study members will provide the sponsor/CRO representative(s) with information on departmental clinical trial practices including responsibilities of clinical trial personnel. (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 4.2).
- The SiteDocs Core Documents module may be temporarily shared with the sponsor/CRO representative for the retrieval of core items.

6.2 Clinical Trial Start-Up

The sponsor/CRO representative will inform the department whether the feasibility and site selection was successful. Once this written confirmation has been received the clinical trial start-up process will commence.

The following documents are completed and collected prior to the site initiation visit (SIV) in collaboration with the relevant department study team and sponsor/CRO representative, as outlined in *SOP 10: Essential Document Management for Clinical Trial Research* (see Related Documents):

- Investigator and department study team's abbreviated CV. All CVS must be signed and dated. CVs remain current for two years after the date.
- Investigator and department study team's ICH GCP certification.
- Statement of Investigator (1572), as required.

- Financial disclosure forms (FDF), as required.
- Site specific vendor's accreditation (as listed on 1572).
- Site qualification survey(s) as required (i.e. imaging and EMR capabilities).

Before the site can be initiated and commence recruitment the following approvals must be received:

- Ethical approval.
- Governance approval.
- Regulatory authority acknowledgement (Therapeutic Goods Administration (TGA) via Clinical Trial Notification (CTN) or approval via the Clinical Trial Exemption (CTX)), where appropriate.

6.3 Site Initiation

All approvals and all clinical trial supplies (i.e. ISF), laboratory manual, central sample kits and central imaging manual etc.,) should be received at site prior to the SIV. After the SIV concludes the sponsor/CRO representative will confirm that the site is activated and is ready to commence recruitment.

The *Site Signature and Delegation of Duties Log* will be completed at SIV when the study team have been suitably trained by the sponsor/CRO.

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
SOP 10: Essential Document Management for Clinical Trial Research
Template: Site Signature and Delegation of Duties Log
Template: Clinical Trials Investigator Curriculum Vitae

12. Amendment History

Version	Date	Amended By	Details of Amendment
2	20-Dec-2021	Dr Rani Watts	Minor administrative amendment only