GVHealth	**TITLE:**	**Clinical Trial Standard Operating Procedure 01: Standard Operating Procedure Creation, Implementation and Revision**	
Document Type:	Procedure	**Approved by:**	Research Management and Governance Committee
Directorate:	CMO + Medical Services	**Section:**	Research
Author/Prepared by:	Dr Ainsley Robinson	**Position:**	Research Governance, Ethics, and Trial Support Coordinator

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Document Details

Document Title:	Clinical Trial Standard Operating Procedure 01: Standard Operating Procedure Creation, Implementation and Revision
Document ID:	GVH_CT-SOP-01
Version Number:	3.1
Effective Date:	10 September 2024

Document Approval

Name:	Research Management and Governance (RM&G) Committee
Position:	Chair RM&G Committee
Date:	10 September 2024

Amendment History

Version	Effective Date	Review Date	Author(s)	Amendment Details
1.0	12 Nov 2020	16 June 2023	Dr Ainsley Robinson	Reviewed and updated to v2.0
2.0	16 June 2023	22 March 2024	Usman Tahir, Research and Ethics	Reviewed and updated to v3.0
3.0	22 March 2024	10 September 2024	Dr Ainsley Robinson	Changes to text to reflect review period of 3 years and RM&G Committee as approving body. Updated to v3.1.

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1. PURPOSE:

To document the procedure for the creation and implementation of new Standard Operating Procedures (SOPs) and review of existing SOPs according to the principles of International Council for Harmonisation of Technical requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice (and requirements of the Integrated Addendum to this Guideline published by the Therapeutics Goods Administration (TGA)) (ICH GCP E6 (R2)), the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research 2007 (updated 2018), and the National Clinical Trials Governance Framework (NCTGF).

2. SCOPE:

This SOP applies to any individual delegated the task of writing, reviewing, approving, or distributing a clinical research SOP on behalf of Goulburn Valley Health (GVH). This applies in all instances when a need is identified to either create a new SOP or modify an existing one. Authors of SOPs should have experience of the area covered by the SOP and be authorised to create or modify these.

3. PROCEDURE:

3.1. Initiating the Creation of a New SOP or Revision of an Existing SOP

3.1.1. All GVH researchers may:

- Identify the need for a new SOP or a deficiency or an improvement in an existing SOP and suggest appropriate modification.
- Notify the GVH Research and Ethics Unit in writing and discuss this need with the SOP number and title in the subject header.

3.1.2. GVH Research and Ethics Unit will:

- Assess and verify the need for a new or revised SOP.
- Use the provided template in Appendix 1 and assign a document ID number, version number, and version date for all new SOPs or assign a sequential version number to modify an existing SOP.
- Draft the new or modify the existing SOP and distribute to relevant stakeholders for review and comment.
- Maintain a record of the review process by using the tracked changes feature with a file naming paradigm.
- Incorporate relevant comments and if required redistribute to relevant stakeholder for second review.
- If necessary, repeat above 2 steps until a final version is ready for approval.
- Update the front-page identifier box and/or amendment history box as necessary, ensuring the 'SOP effective date' and 'SOP review by date'.

3.2. Approval and Authorisation of the SOP

3.2.1. GVH Research and Ethics Unit will:

- Arrange for approval and authorisation of the final SOP by the Research Management and Governance (RM&G) Committee, GVH.

- Ensure the amendment history field is completed.
- File the final approved (in writing) new/amended SOP electronically as a PDF file and follow procedure for controlled document upload to Prompt and post Prompt document on the GVH website.
- Securely store the final, approved, new/amended master SOP.
- Once the authorised SOP has been approved, any changes can only be made by following the steps outlined in this SOP.

3.3. Training, Implementation, Distribution of the New or Revised SOP

- All relevant stakeholders should be notified of the new/updated SOP.
- Training is to be recorded as per GVH_CT-SOP-03 Site Staff Qualifications, Training Records and Capability.

3.4. Review

- Review of this SOP is due in three years after the effective date and/or when it is required. The time between SOP authorisation and the effective date may be reduced in special circumstances (e.g. urgent situations where procedures must be implemented immediately).
- An earlier review date is permitted where necessary (e.g. changes to legislation, changes to GVH or National Mutual Acceptance (NMA) policy and procedures).

3.5. Superseded SOPS

- GVH Research and Ethics Unit will notify relevant stakeholders of updated SOPs where required.
- The preceded SOP shall be removed from Prompt and the GVH website.

ABBREVIATIONS AND TERMS:

Please refer to GVH_CT-SOP-Abbreviations and Terms.

KEY LEGISLATION, ACTS & STANDARDS:

National Safety and Quality Health Service (NSQHS) Standards:

- Standard 1 Clinical Governance

KEY ALIGNED DOCUMENTS:

GV Health procedure:

- GVH_CT-SOP-03 Site Staff Qualifications, Training Records and Capability

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REFERENCES:

ICHGCP.NET, Good Clinical Practice. (2019). Ichgcp.net. https://ichgcp.net/

National Clinical Trials Governance Framework and User Guide, Australian Commission on Safety and Quality in Health Care. (2022). Safetyandquality.gov.au. https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-clinical-trials-governance-framework-and-user-guide

National Health and Medical Research Council (NHMRC). (2018). National statement on ethical conduct in human research (2007) - updated 2018, NHMRC. National Health and Medical Research Council. https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

APPENDICES:

Appendix 1: Standard SOP Template

Contributors to the document

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Document Owner:	Dr Md Rafiqul Islam	Director of Research	Research and Ethics
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Committee:	Executive Committee – Safety, Quality & Performance		
	Research Management and Governance Committee		

Appendix 1: Standard SOP Template

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1. PURPOSE:

2. SCOPE:

3. PROCEDURE:

3.1. Sub-Heading

3.1.1 Sub-heading

3.2. Sub-Heading

ABBREVIATIONS AND TERMS:

KEY ALIGNED DOCUMENTS:

REFERENCES:

APPENDICES:

Footer of the SOP is to note:
Due for Review date