GV Health	**TITLE:**	**Clinical Trial Standard Operating Procedure 06: Site Initiation**	
Document Type:	Procedure	**Approved by:**	Research Management and Governance Committee
Directorate:	CMO + Medical Services	**Section:**	Research
Author/Prepared by:	Dr Ainsley Robinson	**Position:**	Clinical Trials Coordinator

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Name:	Research Management and Governance (RM&G) Committee
Position:	Chair RM&G Committee
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1.0	12 Nov 2020	16 June 2023	Dr Ainsley Robinson Research and Ethics	Reviewed and updated to v2.0

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1. PURPOSE:

To describe the procedures related to site initiation of a clinical trial at all sites.

2. SCOPE:

This Standard Operating Procedure (SOP) applies to all Goulburn Valley Health (GV Health) employees, visiting health professionals, contractors, any external researchers, consultants, and volunteers who propose to undertake, administrate, review and/or govern human research involving GV Health patients/participants and staff. All study personnel involved in the clinical study must operate within their scope of practice.

3. PROCEDURE:

3.1. Site Initiation

3.1.1. Prior to Initiation of the Study, the Investigator must:

- Mutually agree with the Sponsor a scheduled date, time, and location for the Study Initiation Visit at the participating site to ensure the site is prepared to commence the study. In the case of a teletrial, this may be at the Primary Site only, or could include (remotely) the Satellite Site/s as determined by the study complexity by the Sponsor/Principal Investigator (PI).
- Review all study related documentation and be familiar with the Investigational Product (IP) and Protocol.
- Ensure that all relevant staff involved with the study, (Associate Investigator (AI), pharmacist, Clinical Trial Coordinator, and others as appropriate, including trial related staff at a Satellite Site), have been advised of the meeting and are able to attend either in person or via videoconference.
- Be in possession of all required approvals and authorisations to conduct the research project.
- For teletrials, ensure a Supervision Plan, that documents the manner and frequency of supervision to be undertaken with other trial staff, especially those new to the role, and, where relevant, trial related staff at a Satellite Site, is in place. A Supervision Plan is to be created by the Primary Site for each Satellite Site.
- For teletrials, identify a Satellite Site under the Teletrial Model should only be initiated when a potentially eligible participant is identified.

For further guidance refer to Appendix 1: Example Initiation Checklist.

3.1.2. During the Initiation Visit, the Investigator must ensure the following are available and/or addressed:

- Study Master File (SMF) containing all required essential documents and review arrangements for organising and maintaining study files. (Satellite Site Study File (SSSF) in the case of the Principal Investigator initiating a Satellite Site).

- A list of all study personnel attending the initiation meeting on an attendance log/Training Log with full name, signature, date and the method attended i.e. in person or via videoconference.
- Original, signed and dated CV of all study personnel involved in the study at the site and any Satellite Sites for which the Investigator has responsibility.
- Other documents such as, financial disclosures, Training Logs, medical licenses, and other essential documents as per Sponsor requirements.
- A contact list with names and contact details of all study personnel from all sites including Satellite Sites, Sponsor and independent third-party service providers is available.
- Timeline for shipment, delivery and receipt of IP and other study related supplies to site.
- A laboratory manual, where applicable, clearly defining sample handling instructions and processes, shipping procedures, documentation handling, contact list of all laboratories involved and any other laboratory activity to be undertaken during the course of the trial.
- A pharmacy manual clearly defining any activity linked to the handling or the Investigational Medicinal Product (IMP)/Investigational Medical Device (IMD).
- Any specialised equipment required will be available throughout the period of the trial, e.g. centrifuge, freezer, etc.
- The electronic Case Report Form (eCRF), completion guidelines and that they are accessible by all sites.
- Training in all aspects required by the Protocol is recorded on Training Log.
- Archiving of study records at the end of the study.
- Subsequent training for staff not in attendance at the Initiation Visit. Such initiation training can be conducted remotely where feasible. It is critical however, that this training is undertaken and documented before they commence activities in the study.
- Supervision Plan for teletrials.
- For each teletrial, the above steps must be repeated for each Satellite Site to be established under the Primary Site.

3.1.3. At the Conclusion of the Initiation, the Investigator must:

- File the Sponsor's initiation visit report/letter in the SMF.
- Ensure that the staff at the Satellite Site files all communication and documentation in the SSSF.

ABBREVIATIONS AND TERMS:

Please refer to GVH_CT-SOP-Abbreviations and Terms.

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KEY LEGISLATION, ACTS & STANDARDS:

National Safety and Quality Health Service (NSQHS) Standards:

- Standard 1 Clinical Governance

KEY ALIGNED DOCUMENTS:

Nil.

REFERENCES:

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

APPENDICES:

Appendix 1: Example Initiation Checklist

Contributors to the document

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Appendix 1: Example Initiation Checklist

ACTIVITY	YES	NO	N/A	ACTIONS/COMMENTS
ENSURE THE SITE INITIATION MEETING IS SCHEDULED AND ALL RELEVANT STAFF ARE ABLE TO ATTEND				
• PRINCIPAL INVESTIGATOR/COORDINATING PRINCIPAL INVESTIGATOR	☐	☐	☐	
• ASSOCIATE INVESTIGATOR	☐	☐	☐	
• STUDY COORDINATOR	☐	☐	☐	
• SPONSOR OR CRA	☐	☐	☐	
• PHARMACIST	☐	☐	☐	
• OTHER RELEVANT STAFF E.G LABORATORY STAFF	☐	☐	☐	
REVIEW INVESTIGATIONAL PRODUCT (OVERVIEW AND BACKGROUND AS PER INVESTIGATIONAL BROCHURE)	☐	☐	☐	
SHIPMENT RECORDS	☐	☐	☐	
REVIEW AND CONFIRM RELEVANT STAFF (E.G. ASSOCIATE INVESTIGATOR) UNDERSTANDING OF THE:				
• ICH GCP / THE NATIONAL STATEMENT	☐	☐	☐	
• INFORMED CONSENT PROCEDURES	☐	☐	☐	
• ROLES AND RESPONSIBILITIES	☐	☐	☐	
• RECORD KEEPING	☐	☐	☐	
• ETHICS AND GOVERNANCE REPORTING	☐	☐	☐	
• PROTOCOL	☐	☐	☐	
• STUDY PROCEDURES	☐	☐	☐	
• RANDOMISATION PROCEDURES	☐	☐	☐	
• UN-BLINDING PROCEDURES	☐	☐	☐	
• SAMPLING HANDLING PROCEDURES	☐	☐	☐	
• RECRUITMENT TARGET	☐	☐	☐	
• STUDY TIMELINES	☐	☐	☐	
• ARCHIVING PROCEDURES	☐	☐	☐	
• OTHER (SPECIFY)	☐	☐	☐	
REVIEW AND CONFIRM THAT SITE RESOURCES ARE ADEQUATE TO CONDUCT THE TRIAL				

ACTIVITY	YES	NO	N/A	ACTIONS/COMMENTS
REVIEW CONTENTS OF STUDY MASTER FILE TO ENSURE IT COMPLIES WITH TELETRIALS COMPENDIUM				
REVIEW AND CONFIRM SOURCE DOCUMENTATION LOCATION FOR SATELLITE SITES AND COMPLIANCE WITH TELETRIALS COMPENDIUM				
COMPLETE ALL LOGS AS NECESSARY				
• SITE SIGNATURE AND DELEGATION OF RESPONSIBILITIES LOG (DELEGATION LOG)	☐	☐	☐	
• TRAINING LOG	☐	☐	☐	
• OTHER (SPECIFY)	☐	☐	☐	
COLLECT ALL DOCUMENTS AS NECESSARY E.G. CV				