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SOP 06 Site Initiation

1.1 Purpose

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

1.2 Scope

This Standard Operating Procedure (SOP) applies to all relevant employees including, but not limited to, visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants and staff. All study personnel involved in the clinical study must operate within their scope of practice.

1.3 Procedure

6.1 Site Initiation

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/PI.
- Review all study related documentation and be familiar with the Investigational Product and Protocol.
- Ensure that all relevant staff involved with the study, (Associate Investigator, Pharmacist, Clinical Research 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 is in place, 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. A Supervision Plan is to be created by the Primary Site for each Satellite Site.
- Do not initiate a Satellite Site under the Teletrials Model until such time as a potentially eligible participant population is identified.

For further guidance refer to [Appendix 7 Initiation Checklist Example](#).

Melbourne Centre for Clinical Trials

Standard Operating Procedure

SOP No.: 06

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Written by: National Clinical Trials Project Reference Group



THE UNIVERSITY OF
MELBOURNE

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 in the case of the PI 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 curriculum vitae 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 Investigational Product 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 of the Investigational Medicinal Product (IMP)/Investigational Medicinal Device (IMD).
- Any specialised equipment required will be available throughout the period of the trial, e.g. centrifuge, freezer, etc.
- The Case Report Form (CRF), completion guidelines and that they are accessible by all sites.
- Training in all aspects required by the Protocol is recorded on the 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.

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.

Appendix 7

Initiation Checklist Example

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Associate Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Study Coordinator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Sponsor or CRA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Pharmacist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Other relevant staff e.g. Laboratory Staff	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Review Investigational Product (overview and background as per Investigational Brochure)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Shipment records	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Review and confirm relevant staff (e.g. Associate Investigator) understanding of the:				
– ICH GCP / the National Statement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Informed Consent Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Roles and Responsibilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

ACTIVITY	YES	NO	N/A	ACTIONS/COMMENTS
– Record Keeping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Ethics and Governance Reporting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Study Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Randomisation Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Un-blinding Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Sampling Handling Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Recruitment Target	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Study Timelines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Archiving Procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Other (specify) _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Review and confirm that site resources are adequate to conduct the trial				
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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

ACTIVITY	YES	NO	N/A	ACTIONS/COMMENTS
– Training Log	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
– Other (Specify)_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Collect all documents as necessary e.g. CV				

Glossary

TERM	DESCRIPTION
ADE	Adverse Device Effect
ADR	Adverse Drug Reaction
AE	Adverse Event
AHPRA	Australian Health Practitioner Regulation Agency
AI	Associate Investigator
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARPANSA Code of Practice	ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research
CAPA	Corrective and Preventative Actions
CASA	Civil Aviation Safety Authority
CIOMS	Council for International Organizations of Medical Sciences
CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Approval scheme (previously Clinical Trials Exemption (CTX) scheme)
CTN	Clinical Trial Notification scheme
CTPRG	Clinical Trials Project Reference Group
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
DSMB	Data and Safety Monitoring Board
EMR	Electronic Medical Record
GCP	Good Clinical Practice
HHS	Hospital and Health Service
HREC	Human Research Ethics Committee
IATA	International Air Transport Association
ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IP	Investigational Product
IMD	Investigational Medicinal Device

IMP	Investigational Medicinal Product
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
National Statement	National Statement on Ethical Conduct in Human Research (NHMRC)
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
PICF	Participant Information and Consent Form
PMS	Post Registration or Marketing Surveillance Study
RGO	Research Governance Officer
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SMF	Study Master File
SSA Form	Site Specific Assessment Form
SSI	Significant Safety Issue
SSSF	Satellite Site Study File
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
UR	Unit Record
USADE	Unanticipated Serious Adverse Device Event
USM	Urgent Safety Measure

○ Revision Chronology

Document History			
Version	Effective Date	Summary of Changes	Author
1.0	<i>13/11/2025</i>	Initial Version	Katie Ozdowska