St Vincent's Hospital Melbourne (SVHM) Standard Operating Procedure (SOP) for Satellite Sites in Clinical Trials

1. Purpose

The purpose of this SOP is to provide comprehensive guidelines for conducting clinical trials at satellite sites under the auspices of St Vincent's Hospital Melbourne (SVHM). It ensures that all trials comply with National Standards, Ethical Guidelines, and regulatory requirements, safeguarding participant safety, data integrity, and the achievement of high-quality research outcomes.

2. Scope

This SOP applies to all clinical trials conducted by SVHM, including:

- **Primary Site**: The central location where the Principal Investigator (PI) and most trial activities are based.
- **Satellite Sites**: Additional sites, either teletrial or non-teletrial, geographically separate from the Primary Site but contributing to the clinical trial under the oversight of the PI at the Primary Site.

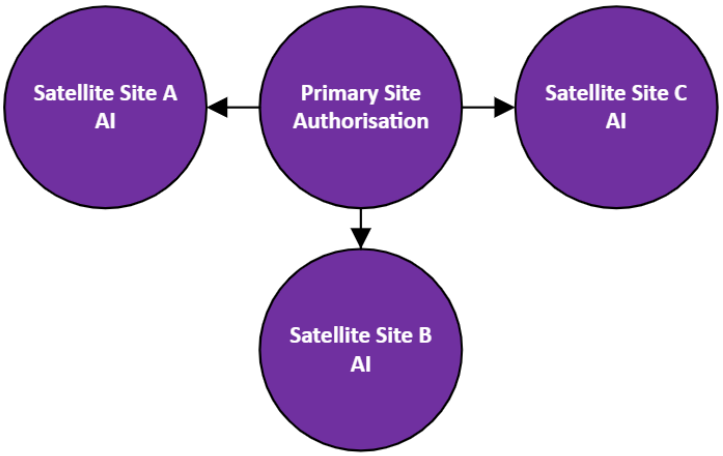
The purpose of a Satellite Site is to facilitate the conduct of clinical trial-related activities at the site and improve trial accessibility for remote participants.

3. Definitions

- **Primary Site**: The main site responsible for coordinating the clinical trial.
- **Satellite Site**: A secondary location conducting specific trial-related activities as defined in the trial protocol.
- **Teletrial Model**: A model utilizing telehealth technologies to connect the Primary and Satellite Sites for conducting trial activities. The Principal Investigator remains responsible for the trial across the cluster.
- **Non-Teletrial Model**: A traditional model where all trial activities are conducted physically at the respective sites without telehealth support.
- **Delegation Log**: A log maintained by the PI listing all qualified and trained personnel delegated with study-related duties and functions.
- **Supervision Plan**: A plan outlining the processes for the PI to supervise individuals or parties delegated with study-related duties. A supervision plan provides the framework for allocation and delegation. This template can be adapted to reflect the level of oversight and capability required for most clinical trial activities conducted at a Satellite site. Individual, site-specific supervision plans are developed and submitted to the relevant Research Governance Office as part of each Satellite site's governance application.
- **Sponsor's Agreement Letter**: An agreement to conduct the trial as a teletrial from the outset or to convert an already established trial into a teletrial.Sponsor's agreement to add Satellite Site(s).

4. Responsibilities

- **Principal Investigator (PI)**:
  - Ensure compliance with the protocol and all regulatory, ethical, and governance requirements at both Primary and Satellite Sites
  - Oversee trial conduct at both Primary and Satellite Sites.
  - Maintain a Delegation Log and supervise all trial-related activities.
- **Associate Investigators (AIs) and Site Staff**:
  - Conduct trial activities as delegated by the PI.



5. Procedures

5.1 Satellite Site Setup and Management

- **Site Selection**: Evaluate personnel and facilities at potential Satellite Sites. Develop a Delegation Log and Supervision Plan tailored to the capabilities and resources of each site.
- **Delegation Log**: Each Satellite Site maintains its own Delegation Log, separate from the Primary Site, which must be kept up-to-date and sent to the Primary Site when requested.
- **Satellite Site Study File**: Maintain a Satellite Site Study File containing all relevant study documents. The content of this file will be agreed upon with the study team and Sponsor.
- **Rare Disease & Metropolitan Hospitals:** It is possible that metropolitan sites partner with other metropolitan sites where a Sponsor requires only one site to achieve the required recruitment target, such as in rare disease indications. In all cases, there is only one PI.

5.2 Teletrial Model Operations

- **Communication and Coordination**: Utilize telehealth technologies for remote consultations, monitoring, and data collection. Ensure that telehealth infrastructure and training are adequate to support this model.
- **Supervision**: The PI at the Primary Site retains overall responsibility for the trial across all sites, including supervision of Associate Investigators at Satellite Sites.
- **Access to EMR**: Facilitate access to the Electronic Medical Records (EMR) of the Satellite Site from the Primary Site for oversight and study monitoring.

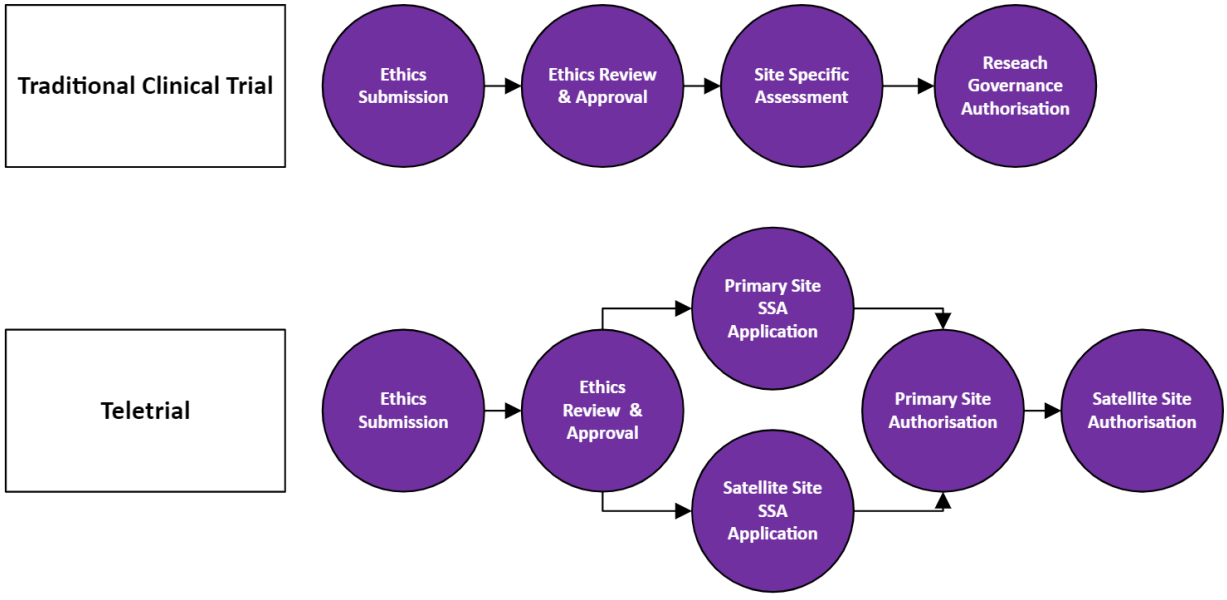
- **Teletrials PICF:**
  - A stand alone teletrial PICF will be needed when ***one or more exisiting sites are converting*** to a teletrial site.
  - Optional Teletrial Wording will need to be included in the Master PICF when a study is initiated as a teletrial from the outset. Optional Teletrial Wording.

5.3 Non-Teletrial Model Operations

- **On-Site Conduct**: All trial activities are conducted physically at the respective sites. Ensure that staff at Satellite Sites are adequately trained and that all site facilities meet the trial requirements.
- **Single PI Responsibility**: The same PI is responsible for both the Primary and Satellite Sites.

5.4 Regulatory and Governance Compliance

- **Site-Specific Assessment (SSA)**: Complete an SSA Form for both the Primary and Satellite Sites.
- **Ethics Approval**: Obtain ethics approval from the relevant Human Research Ethics Committee (HREC) and local governance approval from the RGO for all Satellite Sites.



6. Compliance and Reporting

- **Periodic Reporting**: Submit periodic progress reports to the HREC and RGO as required. Report all adverse events (AEs) and serious adverse events (SAEs) per the protocol and regulatory requirements.
- **Protocol Amendments**: Obtain authorization from the RGO for any protocol amendments at both the Primary and Satellite Sites

7. Required Governance Documents

NEW GOVERNANCE APPLICATION FOR SVHM-AFFILIATED SITE-SPECIFIC AUTHORISATION (SSA)		
Document Title	**Teletrial**	**Non-teletrial**
1. Site Specific Assessment	Mandatory	Mandatory
2. HREA	Mandatory	Mandatory
3. HREC Approval letter	Mandatory	Mandatory
4. Supervision Plan	Outlines processes for a Principal Investigator in the supervision.	Outlines processes for a Principal Investigator in the supervision.
5. Delegation Log	Proof of a Delegation Log	Proof of a Delegation Log
6. Investigator Brochure (IB)	For studies involving drugs and/or device	For studies involving drugs and/or device
7. Protocol	Mandatory	Mandatory
8. Victorian Specific Module (VSM)	Mandatory	Mandatory
9. Sponsor Agreement Letter	Sponsor Agreement Letter	Not Applicable
10. Master PICF	If participants are enrolled in the study, Teletrial Wording	If participants are enrolled in the study
11. Site-Specific PICF	If participants are enrolled in the study, Teletrial Specific	If participants are enrolled in the study

DocumentTitle	Teletrial	Non-teletrial
12. Patient-Facing Materials	If participants are enrolled in the study	If participants are enrolled in the study
13. Budget	As per sponsor or institution guidelines	As per sponsor or institution guidelines
14. Medical Physicist Letter	If ionising radiation is involved	If ionising radiation is involved
15. Radiation - Notification to the Reviewing HREC (Acknowledged)	For all studies involving ionising radiation.	For all studies involving ionising radiation.
16. Form of Indemnity - Standard	For all commercially sponsored trials where SVHM is providing premises for the conduct of the study	For all commercially sponsored trials where SVHM is providing premises for the conduct of the study
17. CTRA (Commercially Sponsored)	A separate agreement between the sponsor and the Satellite Site.	A separate agreement between the sponsor and the Satellite Site
18. RCA (Investigator Initiated)	A separate agreement between the sponsor and the Satellite Site	A separate agreement between the sponsor and the Satellite Site
19. Contract Submission Form	For all submissions that have forwarded a legal agreement via DocuSign/Adobe Sign	For all submissions that have forwarded a legal agreement via DocuSign/Adobe Sign
20. Clinical Trial Notification Form (CTN)	For use of unapproved therapeutic goods under the CTN scheme	For use of unapproved therapeutic goods under the CTN scheme
21. GCP & CVs	For Site PI & AIs	For Site PI & AIs
22. Certificate of Insurance	For all commercially sponsored trials	For all commercially sponsored trials
23. Fee Form	Mandatory	Mandatory

8. Review and Amendments

This SOP will be reviewed periodically to ensure compliance with current regulations and best practices. Amendments will be made as necessary based on feedback and changes in the regulatory landscape.

9. Additional Resources

1. The Department of Health: **Clinical Trials and Research.**
2. A Teletrial Supervision Plan template is available on the **Australian Teletrial Program** (ATP) webpage and can be downloaded as a WORD document.
3. Medicines Australia: **Australasian Teletrials Model**

10. References

- National Standard Operating Procedures for Clinical Trials Including Teletrials in Australia (2020)
- National Principles for Teletrials Australia (2020)
- Relevant SVHM policies and guidelines
- Applicable regulatory and ethical standards

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SVHM SOP for Sateliite Sites

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