

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

## 1. Purpose

This SOP outlines the process for the use of service sites in clinical studies conducted by St Vincent's Hospital Melbourne (SVHM) and the requirements for submitting applications related to service sites.

## 2. Service Sites

This procedure applies to studies where SVHM (primary site) utilizes external service sites for service provision, which may include radiology (e.g., x-rays, MRIs, CT scans), pathology (e.g., blood tests), pharmacy services, and standard of care day surgery.

Service Sites are Governance-related provisions and only require **Governance Approval**.

## 3. General Principles

### Service Site Use

A service site may only be used for the provision of specific services such as radiology, pathology, pharmacy, or standard care day surgery. These sites should not be used for any investigational activities unless otherwise stated.

### Service Agreement

When SVHM engages an external service site to conduct study-related activities, a formal service agreement must be implemented. This agreement must be submitted alongside the application for ethical approval to SVHM Human Research Ethics Committee (HREC). This agreement protects the study team from potential authorship and IP disputes with a service provider.

## Application Review

Applications for service sites will be assessed on a case-by-case basis by the SVHM Research Governance Unit. It is necessary to include these sites as part of a standard site addition process. All approved satellite, recruitment, and service sites must be listed as active sites in the Annual Progress Reports for the study.

## Additional Requirements

If the study involves procedures like radiography or radiology requiring radiation notification, the necessary documentation, including radiation notification letters, must be included in the submission.

## Responsibilities

It is the responsibility of the Principal Investigator and study team to ensure that all service agreements and related documentation are submitted and that approved sites are appropriately tracked and reported during the study's progress.

## 4. Documentation

Document Title	Description
<b>Amendment Request Form</b>	General description of the amendment request.
<b>SVHM Addition of Satellite/Recruitment/Service Site Form</b>	Declaration and description of the service provision.
<b>Service Agreement</b>	Legal framework to govern the Data, IP and financial arrangement with the service provider.
<b>Fee Form</b>	As per the SVHM Fee form.

## 5. Submission

Service site submissions should be made through SAGE. For further assistance, please refer to the general submission guidelines for new applications available on our website.