St Vincent's Hospital (Melbourne)

Satellite/Recruitment/Service Site Guidelines

Commercially Sponsored Studies

Satellite and Recruitment sites must be included on the HREC Review Only Indemnity for all commercially sponsored trials.

Satellite Site

A satellite site is a site that is a geographically separate health facility to the primary sites that have received ethical approval. The satellite site must be listed under the same legal entity of the primary site, the only exception to this rule is the addition of a rural satellite site; where the participants' geographical location is inconvenient to regularly attend the primary site for trial related requirements. The purpose of a satellite site is to aid the conduct of the trial.

The overall responsibility of satellite sites are delegated by the primary site and the associated Principal Investigator (PI) at this site. The PI must also be affiliated or have an appointment at the satellite site.

In the event that the PI is unable to attend to the responsibilities of the satellite site, the PI may designate an Associate Investigator (AI) to oversee the activities and conduct of the trial.

The designated individual (PI or AI) in charge of a satellite site must understand and accept full and total responsibility for providing the service in accordance with the approved study protocol and act according to the principles as outlined in the National Statement on Ethical Conduct in Research Involving Humans (2007 including all updates) published by the National Health & Medical Research Council (NHMRC). As well as the principles of Good Clinical Practice (GCP) guidelines and the Australian Code for the Responsible Conduct of Research (2018).

A satellite site may be used for one or more of the following purposes:

- Recruitment
- Consenting
- Access to medical records
- Administration and maintenance of the Investigational Product (IP)
- Administration of study related assessments
- All trial related invasive and non-invasive medical procedures

Recruitment Site

A recruitment site may only be used to assist recruitment of participants into a trial. This may be in the form of flyers, posters, referrals or by the PI or AI directly.

A recruitment site may also be used to consent participants into a trial, however the participant will be consenting to the primary site and the primary site participant information sheet and consent form. An appropriately trained PI or AI (AI must be approved to consent as listed on the delegation log) must consent the patient in line with the approved protocol and clinical trial regulations. The participant who is consented at a recruitment site is consenting to participate at the primary site and will be required to attend the primary site in order to participate in the trial.

Service Site

A service site may only be used for service provision. Service provision may include the following:

- Radiology (x-rays, MRI's, CT scans etc.)
- Pathology (Blood tests etc.)
- Pharmacy

If SVHM (primary site) is utilising an external service site to conduct study activities – a Service agreement will need to be implemented and submitted with the application.

Please Note:

- All Satellite, Recruitment and Service Site applications will be reviewed on a case-by-case basis, upon review it may be deemed appropriate to request a standard addition of site.
- All satellite, recruitment and service sites approved by SVHM HREC **must be listed as sites** on Annual Progress Reports.

Authorized by:

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