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

1. Purpose

This SOP outlines the process and requirements for the use of recruitment sites in clinical trials, ensuring compliance with ethical guidelines, regulatory requirements, and the approved trial protocol.

2. Recruitment Site

A recruitment site may only be used to recruit participants into a clinical trial through methods such as distributing flyers, posters, or referrals by the Principal Investigator (PI) or Associate Investigator (AI). Obtaining consent from participants at a recruitment site is generally not permissible. If a situation arises within the SVHM precinct where obtaining consent at the recruitment site is advantageous, please inquire on a case-by-case basis. The PI or AI, as listed on the approval letter, must obtain consent in accordance with the approved protocol and clinical trial regulations. Participants who consent at a recruitment site are considered participants of the primary site and must attend the primary site for all trial-related activities.

Recruitment sites still require governance review at St. Vincent's Hospital Melbourne (SVHM). Recruitment sites must not conduct research activities, such as interviews or accessing medical records, on-site. The PI is responsible for overseeing recruitment activities, which may include distributing approved recruitment materials such as flyers, brochures, or email links. Recruitment site approval is valid for six months from the approval date, and the expiry date must be noted in the approval letter. Extensions beyond this period require re-approval.

3. Documentation

Document Title	Description
Letter of Support from the Head of **Department**	Relevant Department where the advertisement is intended to be distributed.
CVs & GCPs	All AIs and PIs at the Site – The institutional employee responsible at site.
HREC Ethics Approval Letter	The recruitment site must be listed on the HREC approval letter.
Patient Facing Documents	Documents that will be disseminated at site must be submitted as part of the governance process.

Protocol	A protocol submission is required to assess the type of project being advertised.
Fee Form	As per the SVHM Fee form.

4. Submission

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