



Medical
Devices



Diagnostic

Regenerative
Medicine

Clinical
Trials

Health



Research Valet[®]



ST VINCENT'S
HOSPITAL
MELBOURNE

A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

Your lead site solution

Service Features

The Research Directorate aims to make St Vincent's a premier and preferred site to conduct sponsored clinical trials across a broad range of disciplines.

To improve support for sponsors, researchers and companies, the Research Directorate is proud to announce the Research Valet Service.

Valet includes full HREC submission preparation and liaison throughout the submission and approval process. St Vincent's Hospital Melbourne is not required to be a participating site to utilise this service.

Valet® Fee (AUD)	\$4,500 +GST
Service Provision	Full
Complete preparation & customisation of all ethics documentation:	
- PICF Master	✓
- HREA & distribution of site SSAs	✓
- Victorian Specific Module	✓
Single point of contact for ethics and HREC liaison	✓
Coordination of essential documentation	✓
Distribution of approved documents to CRO/Sponsor/Sites as required	✓
Concurrent Ethics & Governance review and approval (for SVHM only)	✓
Submission acknowledgment from HREC Secretary	✓
Committee review acknowledgment/decision within two business days of meeting	✓
Ethics outcome within 30 days (Excludes Phase 1 trials)	✓

Research Valet® Lead Site Management

St Vincent's Hospital Melbourne (SVHM) Research Directorate is pleased to offer Research Valet® post approval management services that facilitates all post approval project submission and ongoing ethics management where SVHM is the reviewing HREC.

Post Approval Management	Cost
Major amendment fee (IB, Protocol submission with significant additions to ICF, addition of sites exceeding four sites)	\$800
Intermediate amendment fee (IB, Protocol submission with/without minor updates to ICF)	\$600
Minor amendment fee (Administrative documents)	\$350
Submission of documents for HREC email acknowledgment	\$200

*All costs AUD (excluding GST)

*Hardcopies to be provided by sponsor

Amendments will receive acknowledgment of receipt on the day (within standard operating hours) and be submitted within a maximum of two business day to the RGU (pending arrival of printed copies if applicable).

This service provides researchers a smooth start up with a highly competitive timeline to gain ethics approval, providing St Vincent's a competitive edge on the global market for clinical trials.

Valet Contracted

Submission deadline

HREC meeting

Comments returned

Final outcome

Preparation ≤10 days

HREC Review ~14 days

Countdown begins

HREC Report

Day 0

Day 2

Ongoing liaison

By Day 30

Research Valet® St Vincent's

The key feature of this unique service is close communication between sponsors/researchers and the Research Valet team at each step of the process.

Senior members of the Research Valet Team include:

Dr Megan Robertson, Director of Research

As a current clinician (ICU) and over 10 years as Research Director in both the public and private sector, Megan has focused on facilitating research and embedding clinical research as a core component of clinical care. Her clinical knowledge and experience running clinical trials at the bedside provides a deep understanding of the trial process and the requirements for effective and efficient governance.

Dr Trixie Shinkel, Valet Business Manager

Trixie joined the Valet team in 2018, bringing over 20 years of HREC and research governance experience to her position. Trixie is the first point of contact for all Valet enquiries and manages our strict timelines and close communication processes. Trixie has BSc (Hons) and PhD in neuroendocrinology and broad experience in preclinical and clinical research.

Sponsors or researchers will receive study outcome within 30 days of HREC meeting (except Phase 1 studies), and governance approvals will be targeted at seven days after submission of all required documentation.



For more information contact:

Dr Megan Robertson

Director of Research

T: (03) 9231 3895

E: valet@svha.org.au

Dr Trixie Shinkel

Valet Business Manager

T: (03) 9231 3915

E: valet@svha.org.au

PO Box 2900 Fitzroy

VIC 3065 Australia

(03) 9231 2211

researchvalet.com.au



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