



Genetic testing



Sequencing

DNA

Test

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.

- Single point of access for all regulatory advice for Australia
- Speed start-up time for Australian clinical trials (PH I-IV)
- Ethics outcomes within 30 days of committee meeting
- Start-up to full study management options
- Ethics approval from single HREC for all Australian states (except NT)
- St Vincent's Hospital not required to be a participating site

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	✓

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.

With over 10 years in biomedical research and project management, the Clinical Trials Business Development Manager, Dr Wade Kruger, leads the team and combines analytical skills with a strategic outlook and a mature capacity to engage and collaborate effectively with stakeholders at all levels. He has a Bachelor of Biomedical Sciences, Bachelor of Science with Honours (Pharmacology) and a PhD in Physiology. Wade possesses an overall passion for facilitating and streamlining quality clinical research.

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



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