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, Research Valet 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 a 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 First in Human/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: 0412 051 215
E: valet@svha.org.au

Dr Trixie Shinkel
Research Valet Manager
T: (03) 9231 6977
E: valet@svha.org.au

Level 1; 93-101
Victoria Parade Fitzroy 3065

researchvalet.com.au

ST VINCENT'S HOSPITAL MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

Your lead site solution

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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.

*Additional fees apply for more complex submissions e.g. more than 8 PICFs or more than 50 documents. Please contact us for more information.

Valet® Fee (AUD)	5,500 + GST*
Service Provision	**Full**
Complete preparation & review 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	✓
Submission acknowledgement from HREC Secretary	✓
Committee review acknowledgement/decision within two business days of meeting	✓
Ethics outcome within 30 days+ (Excludes First in Human and Phase 1 trials)	✓

+Dependent on fast response timelines from sponsors to valet comments/recommendations

Research Valet® Lead Site Management

St Vincent's Hospital Melbourne Research Directorate also offers Research Valet post approval management services that facilitates all post approval project submissions and ongoing ethics management.

Post Approval Management*	Cost
Major amendment fee (IB, Protocol submission with additions to ICF, Addition of sites exceeding 4 sites, Total number of documents exceeding 20)	$1,000
Intermediate amendment fee (IB, Protocol submission without updates to ICF, Addition of sites (2-4) only, Administrative and patient facing documents exceeding 20)	$750
Minor amendment fee $500 (Administrative and patient facing documents, Addn of single site)	$500
Submission of documents for HREC email acknowledgement	$100

*All costs AUD (excluding GST)

Amendments will receive acknowledgement and be submitted once the review is finalised in consultation with the study sponsor.

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.