

St Vincent's Health Network Sydney

Capital Investment Proposal

Integrated Translational Research and Education Centre



1. PROPOSAL OVERVIEW

1.1 Organisation Details

Organisation: St Vincent's Health Network Sydney

Contact Officer: Abbie Clark

Position: Director Strategy, Planning & Partnerships

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1.2 Proposal Details

Proposal name: Integrated Translational Research and Education Centre – West Street

1.3 Relevant Documents and Current Planning Status

Document	Status
Strategic business case	Completed 2019. New business case under development – 40% complete.
Campus masterplan	2017 – currently being reviewed. Updated Masterplan expected to be complete July 2021.
St Vincent's Health Precinct Sydney Plan	Stage 1 complete 2021.

1.5 Consultation

- Precinct MRIs Victor Chang Cardiac Research Institute; The Garvan Institute of Medical Research.
- Precinct university partners and associated research institutes University of NSW (UNSW) and the Kirby Institute; University of Notre Dame (UNDA); Australian Catholic University (ACU) and the St Vincent's / ACU Nursing Research Institute.
- Industry current and potential partners various.
- St Vincent's Private Hospital Sydney.

1.6 Board Endorsement

Has the Organisation's governing board endorsed this proposal? Yes [X-strategic business case] No $[\]$

1.7	Chief Execu	tive Approval ITREC - CIP July 2021
	Name:	Assoc. Professor Anthony Schembri AM
	Position:	Chief Executive
	Signature:	AyM. Scl.

2. PROPOSAL DESCRIPTION

2.1 **Proposal Description**

West Street Integrated Clinical Research and **Education Centre**

The West Street Centre is a Precinct priority to support rapidly growing demand for cutting-edge clinical trials and to boost our collective innovation and research impact.

The West Street facility will drive transformation in our pre-eminent clinical services through the development of new technologies and therapies and health services improvement.

The proposed development will invigorate effective collaborations and partnerships across the Precinct and with industry

The Centre will be the clinical trials hub for the Precinct and also include an Advanced Trianslational Facility, an Early Phase Clinical Trials Centre, a healthcare entrepreneurship and start up accelerator and an education centre.

The Precinct's philanthropic partners are actively engaged to help support the capital build costs.



The West Street Integrated Clinical Research and Education Hub, as an integral part of the 20-year St Vincent's Health Precinct Masterplan, will enhance the existing translational research, health and clinical innovation and learning capability and collaboration across the Precinct, bringing into play a multiplier effect, broadening the reach and maximising the impact to clinical patient care. As shown in Figure 1 below the proposed Hub will be located on West Street on the last remaining undeveloped site in the Precinct's Research Campus.

The St Vincent's Health Precinct Sydney partners are below.









SACRED HEART HEALTH SERVICE



St Vincent's Clinic





























The proposed Centre leverages the existing clinical service, translational research and basic science strengths of the Precinct partners to drive innovative treatment and care in the Precinct Centres of Excellence and core clinical strengths:

- · Heart & Lung Disease
- Cancer & Cellular Therapies
- Infectious diseases and immunology
- · Addiction and Mental Health
- Endocrinology

West Street Integrated Translational Research and Education Centre will be a new 11 storey 6,000m² building providing infrastructure and capability across five key areas and will include:

- Establishing a Clinical Trials and Clinical Research Hub for the Precinct to consolidate and grow clinical trials and healthcare research, promoting the development of new devices and technologies and new innovative models of care.
- Developing an Advanced Translation Facility (ATF) to position the Precinct at the forefront of health innovation and
 - transformation, by expanding on-site pre-clinical research and state of the art imaging capability. To establish a complete cardiovascular investigational pipeline as one footprint that spans fundamental basic science discovery, translational studies through to clinical trials, led by internationally recognised specialists will position the Precinct as a global leader. VCCRI is leading this aspect of the ATF development.
- Enhancing bio-specimen and biobanking and processing allowing for expansion and consolidation of biospecimen processing support and enabling critical biomedical research and research collaboration particularly arising from clinical trials.
- Establishing a start up health care accelerator to enable precinct researchers, clinicians and students to engage and work collaboratively and seamlessly with industry partners and innovators.
- Developing an education and learning hub to support an integrated clinical education, collaborative learning, professional development of staff, and exchange of knowledge.

2.2 Investment Drivers

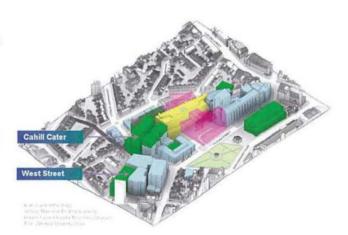
Driver 1: improving health outcomes through translational research partnerships

Across the medical and scientific community, there is increasing emphasis on precision healthcare and research-informed medicine and service delivery. There is also a pressing need to provide individualised care which provides minimally invasive, targeted interventions, leveraging genomics, advanced imaging, microbiome and metabolic analysis. Research and clinical trials are critical to advancing these efforts by providing the means to develop new drugs and devices, new models of care and improved clinical practice.

In Australia, the Commonwealth Government has placed increased emphasis on embedding research within existing health care settings. This can deliver improved outcomes for people with an existing disease as well as those at risk of contracting a disease. At the patient and clinician level, there is also an expectation that patient care will be supported through research and participation in clinical trials, with such trials increasingly becoming a part of the standard of care. The opportunity to participate in this way provides patients with a pathway enabling access to new therapies and medical devices long before mainstream availability.

Cross-disciplinary interactions are critical to medical research innovations and associated improvements in patient care and service delivery. St Vincent's Health Precinct partners have recognised this through our Research Strategic Plan 2019-2023 'Transforming Health Care', the

Figure 1 St Vincent's Health Precinct Sydney



Darlinghurst Clinical Services Strategy, and through the creation of the St Vincent's Health Precinct Sydney. The Precinct partners' ambition to leverage our demonstrated ability to deliver significant scientific and medical breakthroughs is constrained by the limited and fragmented space currently available.

In many instances, acute and sub-acute health services facilities have become highly constrained and unable to deliver high impact and efficient clinical trials. The Cancer Institute has developed translational research centres to help accelerate the translation and access of new therapies to patients. These Centres actually function collectively as networks, built on common foundations of leadership, good governance, research strategic direction, collaboration and sustainability.

Driver 2: Supporting growth in access to clinical trials for NSW patients

The West Street Integrated Clinical Research and Education Hub's vision is to deliver a similar model with our partners to accelerate clinical research through well run clinical trials across multiple therapeutic lines. The partnerships and connections provided by the Centre will bridge administrative and institutional boundaries, fostering collaboration across NSW working together to deliver 'trials as treatment'. This proposal will deliver on the NSW aspiration to become a national leader and the place to go for high quality clinical trials, both for national and international medical industry participants.

St Vincent's has an expectation that clinical trials will become part of standard of care. Clinical trials pathways provide an opportunity to access new therapies and devices long before mainstream availability. A key part of our research strategy is to align our clinical trials more closely with our therapeutic service lines. Improving our governance of and clinical trials operational efficiencies around the conduct of trials will be a key driver to deploy our clinical service plan and deliver on our aspirations around precision medicine.

This points to the growing need for additional integrated infrastructure to support the increased number of studies that will be required to support these ambitions. While the spatial requirements for each study vary, the growth in the number of trials is illustrative of the increasing demand for designated clinical trial space to conduct these Translational Research activities.

Driver 3: Establishing the pre-eminent national centre for heart disease and NSW's 'Heart Hospital'

The ATF is critical prerequisite infrastructure to deliver the pre-clinical translational research as part of the St Vincent's Precinct Heart and Lung Centre of Excellence vision which would establish a 'Heart Hospital' to rival Monash Heart Hospital in Melbourne.

The proposed VCCRI / SVHS Advanced Translational Facility (ATF) will enable surgical and device research in large animals to accelerate the translation to humans as well as promulgate linkages with biotechnology and meditech industry.

VCCRI / SVHS are uniquely positioned to expand our existing capabilities to accelerate the translation of cardiac research discoveries into effective prevention and treatment strategies that extend and improve quality of life for cardiac patients globally:

- VCCRI is physically located alongside St Vincent's Hospital (SVH), one of Australia's leading teaching hospitals with globally renowned clinicians in heart disease
- Longstanding affiliation both medically and operationally between SVH and VCCRI shared services, collaborative research, strong executive relationships
- Existing VCCRI faculty members (currently 5) hold key appointments in the Cardiology Depart at SVH
- Proven track record of delivering world first life saving clinical application from discovery research
- On site availability of state-of-the-art technologies at the Victor Chang Innovation Centre
- · Affiliation with UNSW with channels for collaborations, training and learning growth
- Existing relationship to global centres eg Icahn School of Medicine at Mount Sinai

Driver 4: Tackling emerging infectious diseases

Emerging infectious diseases such as COVID-19 have highlighted the need to be prepared to undertake robust clinical trials while managing the biolohazard containment issues that are problematic in routine publicly facing and frontline health services. We plan to incorporate clinical consultation spaces and ancillary support areas that will cater to biological containment through specifically engineered rooms to isolate potentially infectious patients and procedures from the mainstream health service. The building will offer community facing facilities that are separate from

mainstream hospital workflows. This will offer a quarantined health pathway which will enable and support future clinical research in the era of emerging infectious diseases. Very few facilities in Australia were able to undertake timely and effective clinical research in COVID infected patients because segregated facilities were unavailable.

Projected Benefits

The immediate and long-term benefits the Centre will deliver to the Precinct and the community are outlined below.

Precinct Clinical Trials Hub

Description	Benefits to Campus	Benefits to system/community	Stakeholders
Creation of a highly functioning Campus Clinical Trials Headquarters to expand and promote excellence in clinical trials. The space will include	Innovation & improvement Early access to new devices, therapies, interventions and technologies. New and innovative models of care. Campus engagement Attracting and retaining world class employees.	Accessibility Increased access to clinical trials for patients in our Campus CoEs. Patient care & access Improved patient care and outcomes.	Campus AMR SYCF & prospective donors Multidisciplinary campus clinical trailists
clinical consultation, infusion capability, satellite pharmacy, support for the business aspects of well run trials.	Increase in industry, university, MRI, State & community engagement in research. Generating efficiencies Generating efficiencies through integrated support of Clinical Trials across the Campus.	Rapid access to newly developed interventions, therapies, devices and technologies.	TKCC, VCCRI & Garvan NRI SVPHS & Mater External, Industry &
	Campus recognition Increase in higher impact publications and number & value of high impact Grants.	Potential for improved health outcomes for the disadvantaged in the community.	 Pharmaceutical industry sponsors UNSW/Kirby
	Increase in number of international clinicians and researchers on Campus.	Access Addressing local drug	Universities & MR CESPHN
	Reputation in leading high quality and impactful clinical trials.	compounding issues and constraints.	Sponsors and pharma industry
		"Making it easy" to undertake Clinical Trials/Research.	

Advanced Translational Facility

Description	Benefits to Campus	Benefits to system/community	Stakeholders
A large animal facility for pre- clinical research. Interventional theatre teaching environment (robotics & advanced surgery). Large and small imaging, including PET/MRI. Works in concert with Clinical Trials Hub.	Strengthening campus capability Support SVHS and the VCCRI to maintain and enhance their leading role at the forefront of cardiovascular research and patient care. Enable the Campus to strengthen capabilities and leadership in Neuroscience, Orthopedics and advanced surgical training. Staff & partner engagement Attract and retain world class people. Increase in industry and University engagement. Access to amenity Access to Translational Research Infrastructure, services and systems on Campus.	Partnerships An intersection point and catalyst for student-physician-scientist-industry-government interactions. Patient care & access Improved patient care and outcomes. Improved access to newly developed interventions, therapies, devices and technologies.	Campus SVCF & prospective donors VCCRI SVHS Cardiology SVPHS Potentially also: Orthopaedics Neuroscience / Stroke External Industry Universities & NGO's NSW Health
	Campus recognition		

Bio-Specimen Lab

Description	Benefits to Campus	Benefits to system/community	Stakeholders
Part of the AMR suite of research infrastructure. Builds on and leverages	Generating efficiencies Expansion and consolidation of biospecimen processing support.	Community health Future health improvement driven by research.	Campus - AMR - SVCF & prospective
	Efficient management of core cryogenics infrastructure.		donors • Clinical trial staff &
Managing materials transfer for research	Streamlining connection to internal and external pathology providers.		clinical staffCampus Research Staff
 Biospecimen material collection and 	Increased revenue from biospecimen storage.		(i.e. Garvan, VCCRI, KCCC)
preparation Short term archival storage;	Continuous improvement Improved governance of biospecimens.		external, Industry & partners Academic, industry and campus researchers an
Material distribution	Staff & partner engagement Attract and retain world class people.		collaborators External research collaborators
	Increase in industry and University engagement and collaboration.		

Healthcare Accelerator

Description	Benefits to Campus	Benefits to system/community	Stakeholders
Collaboration and project spaces. Enabling precinct researchers, clinicians and students working with industry & partners to solve health care challenges. Enabling a priority-driven approach to research and innovation.	Innovation & improvement Development / evaluation of new treatments and models of care. Campus engagement Supports engagement with Industry and entrepreneurs in the development of new health related products and services. Staff & partner engagement Attracting and retaining world class employees. Access to amenity Enhanced access to flexible spaces to build research capability and partnerships across clinical streams. Campus recognition Embed the Campus as an Innovation precinct Governance Improved governance and management of commercialization	Patient care & access Improved access to newly developed interventions, therapies, devices and technologies. Improved patient care and outcomes.	Campus AMR SVCF & prospective donors SVHNS, SVPHS, AMR Students Campus clinical academic partners External, Industry & partners Industry collaborators Universities & NGO's Commercialisation partners

Education Hub

Description	Benefits to Campus	Benefits to system/community	Stakeholders
The Education Hub would support: Conferences and seminars; Learning commons and small group collaborative learning spaces; "Case" study and formal clinical education spaces. SIM centre including lab space and control rooms	Access to amenity Additional fit-for-purpose learning spaces on campus. On-site conference and seminar facilities. Increased education revenue from conferences, seminars, workshops and courses. Staff & partner engagement Improved engagement & experience of clinicians, students and researchers research. Increase in skill base and capacity of researchers. Campus recognition Campus reputation and attractiveness as a leading teaching hospital Training hospital of choice for students and universities Future security of our clinical school partnerships	Community engagement Increase in community engagement in research. Patient care & access Opportunity to participate in learning and development conferences, seminars & talks.	Campus SVCF & prospective donors SVHNS, SVPHS, AMR Medical, Allied Health & Nursing students HDR students Clinical Schools External, Industry & partners Industry partners iMRI researchers and students Visitors and collaborators from universities & the community

The implications of the status quo

Failure to proceed with the Centre and maintaining status quo would:

- Limit growth in patient access to clinical trials in St Vincent's particular areas of clinical and research strength.
- Lost opportunities to develop new treatments, therapies and service delivery models, for the benefit of St Vincent's patients, and the NSW Health system.

- Limit the Precinct's competitiveness in continuing to attract and retain world class clinical researchers and health care professionals and researchers.
- Lost opportunities to engage with industry on priority driven Health and Medical Research and its subsequent translation to impact.
- Lost opportunity to develop St Vincent's Precinct through deep and longstanding collaboration between VCCRI and SVHS – as the NSW 'Heart Hospital' to rival the new Monash Heart in Victoria.

Current infrastructure

Currently, existing Translational Research infrastructure (clinical trials) on the Precinct are dislocated from each other and easy access from the clinical environment. Infrastructure that supports translational research and clinical trials is spread across some 5-6 different facilities with specialised resources (trial managers, clinical governance etc.) remote to and often completely disconnected from this activity. Current clinical trials infrastructure is at capacity and is unable to accommodate the projected growth in both number and type of clinical trials the Precinct will be undertaking.

In addition, as the current COVID Pandemic has highlighted, while Precinct members have played integral roles in supporting the State and National responses, there is an urgent need to develop the types of specialised clinical research environment required to support further research into the impact of infectious diseases.

Further, some essential pre-clinical research infrastructure such as large animal holding and procedure rooms and research imaging is either too small or currently non-existent. The VCCRI has conducted large animal (pig) research at the VCCRI in Darlinghurst for many years. This has led to game-changing breakthroughs and the "heart-in-the-box" that has already saved many lives of patients awaiting heart transplant. However, this research is critically hampered by the total lack of capacity to house large animals on site.

St Vincent's Precinct is in a highly constrained inner city location and there are considerable pressures on space for all functions right across the Campus.

The current proposed development site is significantly underutilised with only a residential terrace and a 4 bed temporary accommodation facility (previously nursing accommodation). The existing facilities are not suitable for clinical care or research and cannot be refurbished to meet clinical and research needs due to their age and spatial limitations.

2.3 Options Considered

The St Vincent's Health Precinct, being in the inner Sydney area of Darlinghurst, is space constrained. The current Masterplan identified only one viable option for expansion of translational research and education functions: the proposed location on a currently underutilised block of land located with the research campus of the precinct. There is also an existing volumetric DA for the development of this site.

Two options for the West Street building, which present similar benefits but different overall floorspace and associated costs and revenue estimations are being considered.

Option 1 has a lower floorspace. The key advantages of this option are lower capital cost and closer to the existing volumetric DA for the site.

Option 2 has higher floorspace allowing more space for growth in clinical research, more education space and a dedicated floor of conference facilities. This option will allow more capacity for growth and support flexibility into the future to support new services, partnerships and innovation.

Non-capital solutions are not feasible to meet the identified needs as clinical trials and translational research require physical infrastructure. However, as part of functional briefing, we are undertaking a review of functional space needs for services such as the Hospital library which could be delivered virtually and/or consolidated on Campus with our MRI partners. Flexible dry research spaces are also being developed to reduce overall space requirements.

3. STRATEGIC ALIGNMENT OF PREFERRED OPTION

3.1 Strategic need and benefit

Premiers Priorities

The Initiative supports delivery of two of the Premier's priorities:

- Improving outpatient and community care
- Improving Service Levels in Hospitals

Translational research underpins the development of new treatments, technologies and therapies to support services within Hospital and in the community setting.

The West Street Integrated Translational Research and Education Centre aims to drive transformation of care for people living with chronic or complex health conditions including heart disease.

NSW Government Response to the NSW Health & Medical Research Strategic Review

The proposal fully aligns with the 2012 NSW Government Response to the Health & Medical Research Strategic Review which charted a ten year plan.

Of particular note, the St Vincent's research precinct is recognised by NSW Ministry of Health Office of Health and Medical Research (OHMR) as one of the eight designated Research Hubs in NSW. These hubs play an important role in promoting collaboration and coordinating medical research institutes, local health districts, universities and community-oriented research taking place in the local area. They operate as "engines of innovation" to drive improvements in patient and population health outcomes.

The government invests annual funding to support research hubs, with one of the key aims being "strengthen links between centres of research excellence and centres of teaching and health care practice". The West Street project will both enhance and benefit from this investment in hub operations.

Alignment to NSW Health and Education Precinct Strategy

The West Street development aligns with NSW Health's developing precinct work and will be a critical facility to drive our Centre of Excellence strategy for Heart & Lung and realise the shared vision of the St Vincent's Health Precinct Sydney partners: namely to pioneer compassionate, research-driven healthcare through research-clinical collaborations

When fully functioning, the West Street Centre will be a hub for transformative partnerships in applied learning and translational research and a destination for industry and other non-government investment. The St Vincent's Precinct team is currently working with the Partnership and Engagement team from Health Infrastructure to ensure our precinct-specific strategy aligns with whole-of-government objectives and maximises opportunities for health and economic benefits.

True to our Precinct vision, the West Street Centre will also respond to the needs of our diverse Darlinghurst community, with particular focus on the needs of the vulnerable and disadvantaged.

Alignment to NSW Treasury's outcomes budgeting framework

This proposal directly aligns with Health Cluster Outcome 5:

Our people and systems are continuously improving to deliver the best health outcomes and experiences.

A skilled workforce with access to world-leading education and training, and a system that harnesses research and digital innovation is essential to continuously improve outcomes and experiences of care across the system.

Translational research capacity also underpins the delivery of all outcomes in the Health Cluster.

Service need

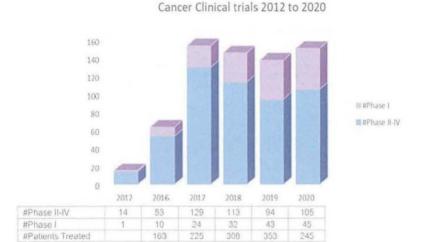
There is significant growth in demand for space for research and education, and issues with fragmentation across the campus

Clinical trials capacity

Across the Precinct there has been increase in demand for infrastructure and services to support clinical trials. Between 2013 and 2017 there was a doubling of clinical trials conducted across the campus, and in 2021 there are close to 400 active clinical trials operating on the Darlinghurst campus.

In cancer alone, clinical trials grew 10 fold from 15 in 2012 to 150 in 2020, with the oncology trials unit recognised as the leading cancer trials unit in NSW in 2019 offering early phase including phase one clinical trials.

Cancer Clinical Trials trend data by Phase I and II-IV 2012 to 2020



This increase reflects the success of current initiatives to support research on campus. It also points to the growing need for additional infrastructure to support the increased number of studies taking place.

Despite this, the supply of research space on the Darlinghurst Campus is inconsistent in terms of quality, with further investment needed to provide sufficient high-quality space to accommodate continued growth in clinical trials. Current clinical trials infrastructure, including the Kinghorn Cancer Centre, is at full capacity and there is inadequate space to accommodate the rapid growth in oncology and haematology trials – now and into the future. In addition, there is a lack of available space which would be suitable or attractive to industry partners who might sponsor or participate in research activities on the campus.

Current limited capacity for large animal research

Led by the work of Peter Macdonald, the VCCRI has conducted large animal (pig) research, at the VCCRI in Darlinghurst, for many years. This has led to game-changing breakthroughs and the "heart-in-the-box" that has already saved many lives of patients awaiting heart transplant.

However, this research is critically hampered by the total lack of capacity to house large animals on site. To do 1 porcine heart transplant, an unsustainably difficult series of manoeuvres needs to be undertaken, with the delivery of a first pig to the VCCRI early in the morning for heart explant, followed by the delivery of a second pig hours later that is to be the recipient, given there is no ability to house a single pig in a pen even for short periods. This is unsustainable for the delivery of world-class cardiovascular research.

Fragmentation of research across the campus

Leading health institutions are now establishing centres of innovation which bring together clinicians, researchers, industry and students with facilities that are flexible to accommodate project-based research needs.¹

Existing research facilities on the Darlinghurst Campus are dislocated from each other and there is no single 'hub' for translational research on the campus. The dispersed nature of activities limits the

¹ Examples include the Harvard Wyss Institute, Mayo Clinic Centre for Innovation, MaRS Innovation and Discovery District

frequent informal interactions which have been demonstrated to lead to collaboration and innovation. There is also limited opportunity to share facilities or resources such as clinical spaces or technologies which leads to duplication of investment and operational inefficiencies.

3.2 System and Service Transformation

The system-wide benefits of developing the complete footprint from basic science through to translational research in a single facility on the St Vincent's Precinct are:

- Shorter time to market of medical innovations to practical treatments and therapeutics (led by Industry, SVH, VCCRI, other) and dramatically increasing partnership opportunities with industry
- · Long-term development for the Australian medical and innovation industries
- Local investment and commercialisation of Australian medical breakthroughs
- Synergistic collaboration through disease-focused global research networks of clinicians, researchers and industry
- · Better health for the global community, courtesy of new medical treatments and therapeutics
- Attracting world-class clinicians and students to NSW and providing enhanced training opportunities.

The ATF and the Centre more broadly would be a facility for collaboration across the NSW research network and industry, and there has already been strong interest from Precinct university partners including UNSW and UNDA, as well MRIs not currently on Campus, but seeking to collaborate with VCCRI, Garvan and SVHS.

3.3 Sustainability and Efficiency

Recurrent costs of operation would be supported by contributions from partners and tenants relative to the space they occupy, and funded through research revenues and industry contributions. A detailed lifecycle cost analysis has not yet been undertaken. It is expected that this will be undertaken at a later date, once there is greater definition in relation to material selection, plant and services strategy and major maintenance responsibilities and requirements. Basic building maintenance costs, e.g. cleaning and minor repairs, have been included in the recurrent cost estimates below.

4. ESTIMATED CAPITAL COST

4.1 Capital Cost Estimate

Capital cost estimate

A high level cost estimate was sought from a Quantity Surveyor in 2020 to inform the project development. This estimate includes total construction cost, preliminaries, builders margin, fit out, FF&Es, contingency, consultant fees.

Of note, this estimate does not include the specialist costs of fit out and FFE for the ATF, which will be significant given the infrastructure required.

We are currently in the process of agreeing high level concept design between SVHS and VCCRI and then will have a QS review and update the capital cost estimates.

Table - Capital costs and floorspace by option

Item	Option 1	Option 2
Gross floor area	11,563 m ²	14,479m²
Net lettable area	6,8795m ²	8,903m ²
Total ETC (excl GST)	\$83.8m	\$105.7m

We are proposing significant co-investment, supported by partner contributions and philanthropy, towards the capital costs of the building providing a unique value for money proposition. Proposed contributions from partners are not confirmed at this stage and are subject to internal governance consideration.

- 5. PRELIMINARY COST BENEFIT ANALYSIS
- 5.1 Preliminary Cost Benefit Analysis (PCBA) Excel Template

Attached.