

Clinical Research Aboriginal Health Impact Statement

Summary/ Purpose

The St Vincent's Health Network Sydney (SVHNS) is nationally and internationally recognised for high quality research-driven healthcare, and for providing care to historically under-served by the healthcare system. SVHNS is committed to an embedded, organisation-wide approach to providing high quality, culturally safe care to First Nations people.

St Vincent's acknowledges the role of research and innovation in the continuous improvement of health care and in enhancing positive impacts for our community¹. Research and the translation of new evidence is critical to continuous improvement of the health systems, outcomes, services and products. Reflecting the commitment, St Vincent's places 'research and innovation' and 'health equity' at the forefront of its strategic vision¹.

COMPONENT 1: The health context for First Nations people

Who are the First Nations people that will likely be affected by SVHNS Clinical Research?

SVHNS sits within the South Eastern Sydney Local Health District (SESLHD). The SESLHD geographical area encompasses the traditional land of five Aboriginal language groups, including the Dharawal, Gadigal, Wangal, Gweagal and Bidjigal peoples². First Nations people comprise 4.2% of the total population in NSW, and 1.6% of the Sydney-Wollongong population³. More First Nations people live in NSW than in any other Australian state or territory, comprising over 34% of the total First Nations population in Australia in 2021. Our catchment area extends far beyond our local area, caring for communities from all over Australia.

In 2024, First Nations people accounted for 3.6% of admissions to SVHS. These admissions were highest across the Nephrology, Alcohol and Drug, Surgical, and Heart and Lung services. Of the over 50,000 emergency presentations in 2024, 5.9% identified as Aboriginal and/or Torres Strait Islander. It is important to note that First Nations people are known to be under-reported on population-based health and health-related data collections in NSW, therefore this number may not accurately represent the population⁴.

What is the burden of ill health and/or health priorities for First Nations people? What issues may potentially affect access to services for First Nations people?

First Nations people experience significant disparities in health outcomes compared to non-First Nations people. This includes, but is not limited to, life expectancy, and access to and use of health services. The burden of disease among First Nations people is more than two times that of non-First Nations people⁴. The leading contributors to this burden are mental and substance use disorders (23%), injuries (12%) and chronic diseases such as cardiovascular disease (10%), cancer (9.9%) and musculoskeletal conditions (8%)⁵. Nearly half of all deaths among First Nations people are due to cancers or circulatory diseases⁵. SVHNS is a centre of excellence in Heart Lung Vascular care, advancing the outcomes for community through world-class treatment, research and training.

¹ [St Vincent's Strategy 2030](#)

² [AboriginalHealthPlan2024-2026.pdf](#)

³ [Aboriginal Health - HealthStats NSW](#)

⁴ [Aboriginal Health - HealthStats NSW](#)

⁵ [AIHW NIAA Aboriginal and Torres Strait Islander Health Performance framework 1.23 Leading causes of mortality](#)

It is estimated that 35% of the total health gap between First Nations people and non-First Nations people is explained by social determinants including employment, income, education, housing⁶. A further 30% is estimated to be due to selected health risk factors such as smoking⁶. Around 35% of the gap was unexplained, reflecting factors that are likely to include access to affordable and culturally appropriate health care services, connection to Country and Language, as well as actual and perceived racism⁶.

Clinical research and trials frequently lack representation from diverse populations, with ethnic and racial minorities among the key groups that are commonly under-represented⁷. The lack of diversity in clinical trials may restrict the applicability of research findings to the wider population, and results in fewer at-risk people benefiting from novel and effective treatments, thereby widening health inequities. Implementing strategies that improve access to and enhance participation in clinical research is crucial to addressing these health inequities.

How does the initiative link to existing First Nations health policies, programs or strategies?

Clinical Research conducted across the SVHNS campus supports St Vincent's vision to continuously improve our care through research and innovation, and to work with partners to shape a better healthcare system that enhances positive impacts for our patients. In alignment with the strategic direction of the NSW Aboriginal Health Plan 2025-2035, SVHNS is committed to closing the gap, and the continued role and responsibility to provide high quality, culturally safe care for First Nations people.

SVHNS demonstrates this commitment through the alignment of our services with key First Nations health policies, programs and strategies. Improving access to, and the provision of culturally safe care and services to First Nations people are key focus areas for the NSW health system. In response to the recently published NSW Aboriginal Health Plan 2025-2035, SVHNS has developed and published the SVHNS Aboriginal Health Plan 2026-2028. This plan works in parallel with the SVHA Reconciliation Action Plan to drive cultural change that advances reconciliation and promotes equity and access to health care. The goal is to create culturally safe, person-centred environments, build capacity within our facilities and in the community, and strengthen partnerships to achieve these outcomes. Clinical Research at SVHNS is designed and delivered with patients and communities, aligning with this goal and the Australian Commission of Safety and Quality in Health Care's strategic priority of empowering patients, carers and communities to shape their care⁸.

COMPONENT 2: The potential impact of the policy, program or strategy on First Nations people

How will clinical research impact on First Nations people, and will the impact be different for First Nations people compared to non-First Nations people?

Clinical research may be undertaken specifically within First Nations communities to better understand health priorities and determinants that influence health outcomes and the delivery of care. Research of this nature has the potential to impact the health and well-being of First Nations people and communities. All research that affects First Nations people and communities requires approval through the Aboriginal Health and Medical Research Council Human Research Ethics Committee to ensure that First Nations peoples' needs and perspectives have been meaningfully considered and research is conducted in a culturally appropriate manner⁹. Clinical research may also be conducted in a specific therapeutic area, across the diverse populations SVHNS serves including First Nations communities. The emphasis is on

⁶ [Aboriginal and Torres Strait Islander Health Performance Framework - Summary report August 2024](#)

⁷ Pardhan, S., Sehmbi, T., Wijewickrama, R. et al. Barriers and facilitators for engaging underrepresented ethnic minority populations in healthcare research: an umbrella review. *Int J Equity Health* 24, 70 (2025). <https://doi.org/10.1186/s12939-025-02431-4>

⁸ [Australian Commission of Safety and Quality in Health Care Strategic Plan 2025–30](#)

⁹ [AHMRC Health-Ethics-guidelines-2023_01.pdf](#)

involving consumers at every stage of the research project including the design, collection and analysis of data and the dissemination of knowledge to the broader community. Meaningful engagement of First Nations people throughout the entire research lifecycle is essential to ensure studies are responsive to community priorities, foster culturally safe practices, and contribute to better health outcomes.

How can clinical research projects and services be designed to reach First Nations people?

SVHNS recognises the importance of partnering with consumers the planning, design, delivery, measurement and evaluation of care including clinical research services¹⁰. Taking a person-centred care approach, recognising that trust, mutual respect and knowledge sharing are needed for the best outcomes, ensures that research is relevant, respectful and aligned with the needs of the First Nation communities. The SVHNS workforce undertakes cultural safety training which incorporates the perspectives and lived experience of First Nations people.

The central tenant of clinical research is the protection of the rights, safety and wellbeing of participants¹¹. The informed consent process is of paramount importance, ensuring that participation in research is fully informed, culturally appropriate and ongoing. Research information is provided to participants in a way that meets the needs of the individual, with enough time and supports, including the utilisation of First Nations Health Workers, for the participant to fully understand the research project and determine if they would like to participate or not.

SVHNS Research Governance Office has developed and published Aboriginal and Torres Strait Islander Research Guidelines to assist researchers who are undertaking research that specifically targets Aboriginal and Torres Strait islander populations. This checklist helps support the planning, development and conduct of clinical research that adheres to the NSW Aboriginal Health Ethics Guidelines and facilitates collaboration and co-design of research with respect to cultural values and needs.

What might be the unintended impacts (including potential negative impacts) for First Nations people and what are the actions that will be taken to mitigate or prevent them?

First Nations people have historically been researched inappropriately, with little to no cultural acknowledgement and without respect for First Nation peoples' values and needs¹². As a result, the research has yielded limited improvements in health and well-being outcomes for First Nations communities, and a resultant lack of trust in institutions and systems¹³. Collaborative clinical research that adopts a codesign approach is essential to mitigating these negative impacts, establishing trust through sustained engagement and promoting research that is culturally safe and addresses the health needs of First Nations communities. This aligns with the ethical principles that ensure research conduct is safe, respectful, high quality, and of positive impact to First Nations people^{14,15}.

SVHNS has embedded a whole of organisation approach to improving health outcomes for First Nations people and communities. This patient - centred model of care is essential to the deliver holistic, culturally appropriate health care. Acknowledging the lived experiences of First Nations people, their deep connection to Country, and the resilience of their enduring culture is vital in delivering high quality care that is safe and respectful.

¹⁰ [The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials](#)

¹¹ [ICH Guideline for Good Clinical Practice | Therapeutic Goods Administration \(TGA\)](#)

¹² Brinckley M, Bourke S, Watkin Lui F, et al. Knowledge translation in Aboriginal and Torres Strait Islander research contexts in Australia: scoping review protocol. *BMJ Open* 2022;12:e060311. doi: 10.1136/bmjopen-2021-060311

¹³ Bainbridge, R., Tsey, K., McCalman, J. et al. No one's discussing the elephant in the room: contemplating questions of research impact and benefit in Aboriginal and Torres Strait Islander Australian health research. *BMC Public Health* 15, 696 (2015). <https://doi.org/10.1186/s12889-015-2052-3>.

¹⁴ [AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research \(2020\)](#)

¹⁵ NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018).

How will the impact of clinical research on First Nations people be actively monitored and evaluated?

SVHNS monitors the participation of First Nations people in clinical trials as part of the key metrics of the clinical trial service under the National Clinical Trial Governance Framework. SVHNS engages with the Aboriginal Health Services to ensure clinical research is meeting the needs of individual participants as well as broader First Nation communities. Consumer feedback on the SVHNS clinical trial service is actively monitored through a bi-annual campus wide survey. Feedback plays a vital role in highlighting areas for improvement, and helping us deliver holistic, integrated, and person-centred care.

COMPONENT 3: Engagement with First Nations people

Based on the anticipated impact of clinical research on First Nations people, what level and nature of engagement with First Nations stakeholders is appropriate?

The SVHNS approach of engaging First Nations stakeholders supports research that aligns with the priorities of our communities, and strives to improve health outcomes. The level and nature of engagement with First Nations stakeholders will differ based on the individual aims of the projects. Consumer codesign is the gold standard approach for clinical research conducted within the broad, diverse population SVHNS serves. First Nations people are best positioned to determine their care needs and how to improve health outcomes. For research projects intended to be conducted specifically with First Nation communities, codesign with First Nation stakeholders from the inception of the project and throughout the lifecycle of the project is essential to ensuring research is culturally safe and addresses the priorities of First Nation communities. In addition to consumer codesign, engagement and approval is also sought from the Aboriginal Health and Medical Research Council Human Research Ethics Committee to ensure research is meaningfully designed, ethical and culturally appropriate. Engaging with a wide range of support services is also essential to enabling participation and ongoing involvement in clinical trials.

SVHNS is committed to delivering compassionate, evidence-based care that respects cultural diversity throughout its services. Clinical research care is integrated within the broader SVHNS health service. The network works collaboratively with First Nations stakeholders to co-design and implements culturally safe models of care across varied contexts. To support this, SVHNS actively seeks guidance and validation from First Nations communities to inform the direction of engagement strategies, enabling an agile and responsive approach to meeting the needs of First Nations consumers and staff.

Are there potential barriers that might impact the ability of First Nations people to be meaningfully engaged?

The historical mistreatment of First Nations peoples and communities by Australian Governments and Institutions, and the ongoing impacts of colonisation, including systemic racism and intergenerational trauma have led profound and lasting impacts on the health and wellbeing of First Nations people. It is essential to recognise this mistreatment and understand the potential impact it may have in undermining trust in institutions and systems. It is equally important to acknowledge that First Nations people are best positioned to determine their care needs and how to improve health outcomes. This extends beyond looking at the inequities and focussing on elevating the cultural determinants that act as protective factors to strengthen and support the health and wellbeing of First Nations people^{16,17}.

¹⁶ [NSW Aboriginal Health Plan 2024–2034](#).

¹⁷ [The Australian National University and the Lowitja Institute \(2019\). The extent of evidence about Aboriginal and Torres Strait Islander culture and wellbeing.](#)

To ensure coordination and avoidance of duplication, what existing governance mechanisms such as committees, networks or partnerships exist that could be used to support engagement with First Nations people?

SVHNS has several existing governance mechanisms to support engagement with First Nations people. The network has fostered strong partnerships with several key organisations that play vital roles in First Nation communities. These include the Sydney Metropolitan Local Aboriginal Health Partnership, a formal alliance between the Redfern Aboriginal Medical Service, Sydney Local Health District, Northern Sydney Local Health District, South Eastern Sydney Local Health District, St Vincent's Hospital and the Sydney Children's Hospital; Aboriginal Community Controlled Health Organisations (ACCHO) and the Health Medical Research Council (AH & MRC). Service level business decision making is also supported by the inclusion of First Nations representation key committees, including the Clinical Trials Governance Committee. The SVHA National Reconciliation Action Plan (RAP) Steering Committee and the Dalarinji Aboriginal Advisory Health Committee are integral mechanisms for the improvement of service delivery and outcomes for First Nations consumers. The SVHS Aboriginal Health Unit and the Executive Director of First Nations Health, play central roles and are instrumental in enhancing service delivery and outcomes for First Nations consumers at the local SVHNS level.

Health equity and research innovation are key elements of the St Vincent's Strategy 2030, and are echoed in both the NSW and SVHNS Aboriginal Health plans. SVHNS and the Murrumbidgee Local Health District have shared a long-standing relationship with outreach clinics in the region supported by St Vincent's clinicians across a range of specialities. SVHNS has established a clinical trial satellite site at Griffith Base Hospital, supporting equitable access to clinical trial care, and reducing the burden associated with long-distance travel to access healthcare services for regional communities including First Nation communities.

What information will be provided back to First Nation stakeholders and how will continued engagement through the implementation and evaluation of the initiative be facilitated?

The Clinical Trial Governance Committee supports and evaluates the engagement of First Nations stakeholders in clinical research, and reports to the Patient Outcome and Experience Senior Leadership Team (SLT) Committee and applicable NSQHS Standards Committees. Membership of this Committee includes a wide range of clinicians, consumers, and the Executive Director of First Nations Health.

Ongoing utilisation of SVHNS platforms such as the St Vincent's website and established community partnerships, link researchers with community organisations, enabling staff to promote research and reach First Nations communities across the state. This is critical to addressing access barriers to care and enabling clinical research to include the diverse population that extends beyond the local catchment area.

Knowledge translation is a key component of research codesign and evidence-based practice improvement, facilitating the dissemination of research insights to people, communities or organisations to improve health systems, services and outcomes¹⁸. Within a codesign approach, research findings are communicated back to the participants and the broader community including First Nations communities, academics and policy makers. SVHNS recognises the importance of Indigenous Data Sovereignty in addressing the health challenges of First Nation communities and ensuring First Nation peoples' rights are respected and enabled throughout the entire data lifecycle¹⁹.

¹⁸ Brinckley M, Bourke S, Watkin Lui F, et al. Knowledge translation in Aboriginal and Torres Strait Islander research contexts in Australia: scoping review protocol. *BMJ Open* 2022;12:e060311. doi: 10.1136/bmjopen-2021-060311

¹⁹ [MAIAM NAYRI WINGARA Principles: Indigenous Data Sovereignty](#)