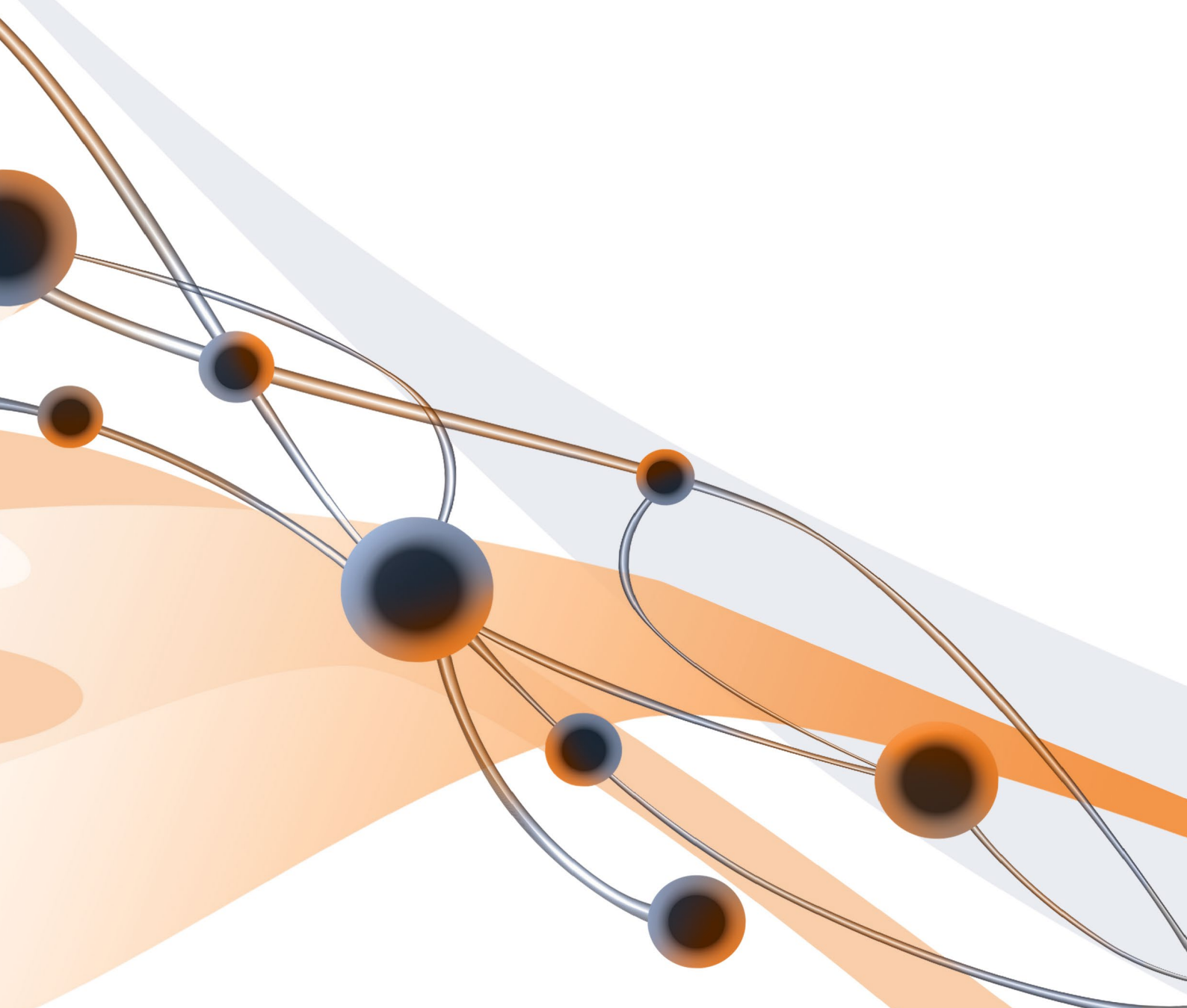


Response to Initial Draft of the NSQHS Standards (Third Edition) Consultation

Research Australia Submission

September 2026



**RESEARCH
AUSTRALIA**

*Championing
Australian health
& medical research
& innovation*

About Research Australia

Research Australia is the national peak body for health and medical research and innovation (HMR&I), representing organisations across the full research and innovation ecosystem. We provide national leadership to shape the policy agenda, mobilise the sector around shared priorities, drive evidence-based solutions to system-wide challenges, and build public and political recognition of the value and impact of HMR&I. Our work is focused through four advocacy platforms: Smarter Investment and Value Realisation, Health Innovation, A Supported and Diverse Research-Active Workforce and Equity.

This submission is grounded in our members' perspective including universities, Medical Research Institutes, public and private health systems and services, industry (including medtech, biotech and pharma) and consumer advocacy organisations. It builds on existing work of Research Australia including the imminent release of a policy discussion paper – *'Making Research Routine: Embedding Research into Australia's Health System'*. The paper was developed with extensive member-wide input. Research Australia is a member of the Stakeholder Advisory Group, of the Inter-Governmental Policy Reform Group for national reforms and regularly collates member perspectives to contribute to the clinical trials reform agenda, which is relevant to the Standards. In September 2026, Research Australia delivered a member workshop to harness input that has been incorporated in this submission. We acknowledge all our members who contributed their expertise and experiences to this submission.

Executive Summary

Research Australia supports the direction of the initial draft National Safety and Quality Health Service (NSQHS) Standards (third edition), including the consolidation of the eight second-edition Standards into three integrated Standards – Clinical Governance, Person-Centred Practice and Safe Clinical Systems – and the more explicit recognition of clinical research within clinical governance. The three proposed Standards provide a clearer organising framework and should strengthen the connection between governance, workforce capability and patient outcomes. Consolidation is beneficial where it removes duplication and makes accountability easier to understand; however, it must not dilute research-specific expectations or transfer additional evidentiary and administrative burden to services. Research is integral to high-quality care: it enables health services to identify unmet needs, generate and apply evidence, improve outcomes and operate as learning organisations. Retaining research in the national accreditation framework will strengthen board and executive attention and help establish research-enabled care as a core function rather than an adjunct activity.

On balance, the proposed structure can enable research if implementation guidance makes research responsibilities explicit, accepts evidence produced under recognised research and clinical-trial frameworks, and applies proportionate requirements across different service settings and research types. It could create new barriers if consolidation obscures responsibility, duplicates ethics or governance processes, or imposes uniform capability expectations on services with different resources and remits. Governance compliance alone will not embed research. The third edition will require visible leadership, organisational capability uplift, a skilled and supported workforce, meaningful consumer partnership, proportionate governance, cross-institutional collaboration, data capability and systematic translation of evidence into care. The Standards

should therefore be one component of a coordinated national approach linking accreditation with health-system funding, workforce, research, data, clinical trials, implementation and procurement.

The recommendations set out below build on Research Australia policy discussion paper – ‘*Making Research Routine: Embedding Research into Australia’s Health System*’ (which is set to release in October). The paper was initially developed to guide discussions at Research Australia’s University Roundtable, held at the University of New South Wales (UNSW) Sydney, in March 2026, comprised of a sub-committee and subsequently received input from across all of Research Australia’s membership representing the health and medical research and innovation ecosystem. The six priority areas identified include:

Priority Area 1 - Developing a research culture across the health system

Priority Area 2 - System-wide visibility and coordination of embedded research and funding

Priority Area 3 - Workforce capacity and career pathways

Priority Area 4 - Enable research activity through data access and data infrastructure

Priority Area 5 - Consumer and community involvement in research, including a focus on equity

Priority Area 6 - Effective and safe adoption of artificial intelligence

Addressing the systems reforms needed within these priority areas will all contribute to making research routine, and not an adjunct. As part of this systems reform, Standards play a significant role.

Our specific recommendations to strengthen the current draft National Safety and Quality Health Service (NSQHS) Standards (third edition) are:

- Ensure the definition of clinical research not be defined by a single ‘setting’.
- Retain and strengthen explicit recognition of research across clinical governance and high-quality care.
- Make boards and executives accountable for research capability, culture, participation, quality, translation and outcomes. This has to extend to adequately resourcing to meet the regulatory requirements.
- Apply mutual recognition and risk-proportionate governance to reduce duplication and unnecessary administrative burden.
- Recognise workforce capacity, including protected research time, career pathways, mentoring, research literacy and multidisciplinary participation.
- Connect research to service and population needs and require evidence to be translated into routine care and evaluated.
- Recognise research networks and partnerships beyond individual health services, particularly for rare diseases, First Nations, marginalised cultural groups (for example those where English is not first language), and regional, rural, remote and very remote communities.
- Strengthen data capability, including identification of material data gaps, interoperability, secure and ethical linkage, consistent data standards and governance, and the capacity to use routinely collected data to assess safety, equity, experience and outcomes. Services should be expected to make under-counted populations visible and participate in shared

data infrastructure and cross-jurisdictional data initiatives where local datasets are insufficient.¹

- Embed equity by design and strengthen consumer requirements, including targeted approaches for groups experiencing systemic barriers and meaningful, respectful, accessible and appropriately resourced consumer and community involvement throughout the research cycle – from priority setting and design to governance, translation and evaluation.
- Test the research provisions during the 2027 pilot for burden, duplication, accountability, capability, participation and impact on care.

Research as a Core Component of High-Quality Care

Research Australia strongly supports the draft's more explicit incorporation of clinical research and the integration of the National Clinical Trials Governance Framework. The final Standards should make clear that research-enabled care includes clinical research, clinical trials, health services research, implementation research and research-informed quality improvement. It should encompass the full cycle of identifying need, generating and evaluating evidence, translating and implementing findings, measuring outcomes and continuously improving care.

The proposed framing of clinical research as “all research conducted in clinical settings” may be unnecessarily restrictive and create ambiguity about the research activities captured by the Standards. Contemporary health and medical research associated with health services extends beyond research physically conducted in clinical settings and includes health services, implementation and translation, population health, data and digital research, and research undertaken through partnerships with universities, medical research institutes and other organisations. We recommend adopting a broader, setting-neutral definition of health and medical research, accompanied by proportionate governance requirements appropriate to different forms and levels of research risk.

The Standards should provide greater clarity on the boundary between quality improvement (QI), clinical benchmarking and clinical research, particularly in relation to clinical quality registries. Clinical quality registries are established primarily to monitor and benchmark the quality and outcomes of care and support continuous improvement; this purpose should remain distinct from clinical registries or research databases established specifically to generate research evidence. While data collected through a clinical quality registry may subsequently support valuable research, this does not mean the registry itself should automatically be characterised or governed as a research repository. Clear definitions will support proportionate governance and enable health services to embed both QI and research without conflating their different purposes and regulatory requirements.

Despite our strong support for the inclusion of research in the Standards, we acknowledge they are not sufficient for ensuring research-enabled care. Accreditation cannot by itself resolve fragmented funding, weak career pathways, lack of protected time, limited data access or institutional barriers between health services, universities, medical research institutes, industry and community

¹ Research Australia (2026) *Response to the Joint Select Committee on Artificial Intelligence*. Sydney: Research Australia

organisations. The final Standards and implementation guidance should therefore describe their role within the broader national reform agenda and align with the implementation of the National Health and Medical Research Strategy, the National Health Reform Agreement, NHMRC and MRFF research governance and funding arrangements, and the national clinical trials reforms, including the National One Stop Shop.^{2 3}

Leadership, Accountability and Organisational Capability

The Clinical Governance Standard should distinguish between having policies and controls for research and possessing the capability, culture and partnerships to conduct ethical, high-quality and impactful research. Boards and executives should be expected to oversee research as part of clinical governance; set and integrate research priorities with service priorities; develop organisational capability and culture; monitor participation, quality, safety, translation and outcomes; and maintain effective partnerships with consumers, universities, medical research institutes, industry and other research organisations.

Implementation guidance should provide an organisation-wide research assurance model that connects research risks and incidents, quality indicators, monitoring and audit, research governance, clinical governance and board assurance. It should encourage a balanced set of measures covering capability, participation, consumer involvement, timeliness, translation, equity and outcomes - not simply counts of approvals or studies. Research priorities should be demonstrably related to population health needs, burden of disease, unmet clinical need, service performance and patient outcomes.

In addition, the Standards should explicitly recognise the role of contract research organisations (CROs) and clarify institutional accountability where research delivery involves third parties, including requirements for appropriate research agreements, indemnity and oversight. This is particularly important where responsibility for research participants and standards of care may differ.

Reduce Duplication Through Mutual Recognition and Proportionality

Health services already operate under ethics, research governance, clinical trials, commercial and regulatory requirements. The third edition should not create a parallel accreditation layer. Where an organisation has demonstrated compliance through an appropriate national or recognised framework, the same evidence should satisfy corresponding NSQHS requirements. Evidence generated under the National Clinical Trials Governance Framework should, for example, be accepted rather than recreated through separate committees, documentation or audits.

The Standards and guidance should also explicitly support risk-proportionate governance. Oversight should reflect the nature, scale and risk of the activity: a first-in-human trial should not attract the same processes as low-risk health services research, implementation activity or a digital health

² Research Australia (2025) Strategic Examination of Research and Development SERD Submission

³ Research Australia (2026) *Workforce – Looking Ahead: Shaping the Research Workforce for Tomorrow*. Research Australia, Sydney

pilot. Proportionality will protect participants while reducing delays and making the Standards an enabler rather than a barrier to responsible research and innovation.

Workforce Capacity and Research-Active Workplaces

Research-enabled care depends on people having the time, skills, support and authority to undertake and apply research. Clinician researchers cannot be expected to maintain full clinical workloads while conducting research outside paid hours. Research Australia's clinician-researcher work and policy discussion paper on Workforce⁴ identifies protected time, integrated clinical–research career pathways, training, mentoring, research leadership and active health-service support as essential to sustaining this capability.⁵ The final Standards should identify these features, together with research and data literacy, multidisciplinary participation, implementation capability and partnerships with research organisations, as characteristics of a high-performing service. This should extend beyond medical practitioners to nursing, midwifery, allied health, public health, health services researchers, health economists, implementation scientists, data professionals and lived-experience researchers.

A strong research culture can benefit the whole organisation rather than only people enrolled in individual studies. A systematic review found positive associations between research activity and organisational performance, including improvements in healthcare performance, staff development and retention, and patient outcomes, although the strength and measures of evidence varied across studies.⁶ Research participation should therefore be recognised as a workforce retention and development strategy and as an enabler of learning, evidence adoption and service improvement – not only as a source of research outputs. Expectations must remain adaptable to different service contexts. Regional, rural, remote and very remote services face distinctive workforce, backfill, infrastructure and mentoring constraints, while primary care and private practice operate under different incentives from public hospitals. Accreditation should recognise participation in shared capability, networks and partnerships where every service cannot maintain all expertise internally.

Data, Translation, Networks and Evidence Gaps

The Standards should promote nationally consistent data standards, interoperable systems, secure and ethical linkage, clear stewardship and participation in shared data infrastructure so that information can be used across organisational and jurisdictional boundaries without requiring patients and families to repeatedly reconstruct it.⁷ Requirements to collect and analyse data should be complemented by an expectation that health services identify material data gaps and limitations. Some conditions and populations, including people with rare diseases, can be effectively invisible in routinely collected data. Services should consider how missing, unrepresentative or poorly structured information affects their ability to measure safety, equity, experience and outcomes.

⁴ Research Australia (2026) *Workforce – Looking Ahead: Shaping the Research Workforce for Tomorrow*. Research Australia, Sydney

⁵ Research Australia (2024) *Clinician Researchers: Research Activating the Australian Health System*. Sydney: Research Australia

⁶ Harding K, Lynch L, Porter J, Taylor N.F. (2017) *Organisational benefits of a strong research culture in a health service: a systematic review*. Aust Health Rev. 2017;41(1):45-53. doi:10.1071/AH15180.

⁷ Research Australia (2026) *Response to the Joint Select Committee on Artificial Intelligence*. Sydney: Research Australia

Health services should demonstrate not only that research occurs, but that relevant evidence generated internally and externally is systematically considered, implemented and evaluated. Translation requires planning, workforce training, integration into workflows and standard operating procedures, and assessment of effectiveness, cost and system impact. The Standards should reinforce an evidence-building approach in which routine data and practice generate learning while established evidence is applied.⁸

Accreditation centred on individual organisations can overlook conditions and communities for which expertise is necessarily distributed. For rare diseases and other areas of scarce expertise, high-quality care may depend on national and international research, clinical and knowledge networks. The Standards should recognise participation in such networks and require mechanisms for accessing expertise beyond organisational and jurisdictional boundaries. Where clinical guidance or evidence does not exist, services should identify the gap, connect with relevant expertise, collect appropriate data and participate in research that contributes to new evidence and guidance.

Equity and Consumer Partnership

Person-centred systems should ensure that relevant accessibility, inclusion, and complex-care requirements follow people across services, so they and their families are not repeatedly required to reconstruct essential information. Continuity and coordination expectations should extend between organisations and jurisdictions, including transitions between paediatric and adult care and access to specialised expertise.

Research governance should require meaningful consumer and community involvement in setting priorities, design, conduct, translation and evaluation. Engagement should be representative, inclusive, appropriately resourced and supported by consistent recognition and remuneration. These principles are also essential for the safe adoption of artificial intelligence. Standards should align terminology and expectations with national consumer and community involvement frameworks, including the NHMRC Statement on Consumer and Community Involvement in Health and Medical Research and recognise the partnership role of consumer organisations.

Fundamental to strengthening a culture of research across our health systems is ensuring a dedicated focus on diversity, equity and inclusion and addressing intersectional and systemic discrimination. It is acknowledged that the draft NSQHS's has a focus on equity, however, like other aspects of the Standards, it needs to be seen within broader related frameworks and reforms to address equity in research as well as equitable health outcomes and not in isolation. As the NHMRC outlines, 'inclusive research is research that is safe, sensitive and effective; will provide critical data to improve understanding of health gaps and solutions; uses funding to support broad application of research across all population and community groups; and will lead to more inclusive, safe and appropriate health care and health outcomes'⁹. Achieving equity in health outcomes requires addressing intersectional and systemic discrimination embedded within health systems and supported by dedicated health research and funding systems to address this.

⁸ Research Australia, *Making Research Routine: Embedding Research into Australia's Health System*, Policy Discussion Paper, unpublished

⁹ National Health and Medical Research Council. (2024), *Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research*. Australian Government. Pg.9.

Overcoming existing systemic barriers to research access for traditionally underrepresented groups within health systems should be an immediate priority for developing research cultures across the health system. Under-represented groups including First Nations peoples; people in regional, rural, remote and very remote communities; culturally and linguistically diverse communities; women and gender-diverse people; children and young people; older people; people experiencing socioeconomic disadvantage; people living with rare diseases and people with disability.

From a First Nations perspective, it is important to knowledge the unintended cultural burden the Standards may cause on First Nations staff (particularly not in governance and executive roles) to uplift organisational capability. This may also apply to local area community-controlled health services or Aboriginal Medical Services that public, private hospitals, day procedure services and public dental practices may collaborate with as part of their approach to complying with First Nations health related actions.

With regards to regional, rural, remote and very remote, for example, studies across New South Wales, Victoria and Queensland all found that perceptions of research capacity and culture (RCC) were higher in metropolitan areas than non-metropolitan areas, suggesting a potentially widespread issue across the Australian public healthcare context ¹⁰. Overcoming these barriers relies on scoping existing models and examples of best practice. Within the regional, rural, remote and very remote (RRRvR) context, as an example, Deakin Rural Health (DRH) has led targeted investment in place-based embedded researchers and rural research–practice partnerships to effectively support and drive impactful research in rural western Victoria ¹¹. Research Australia’s policy discussion paper on RRRvR provides further recommendations and examples of addressing dedicated approach to RRRvR leveraging the existing strengths whilst addressing the systems deficits.

A rare-disease lens demonstrates why the Standards must recognise research and care networks beyond a single accredited service. More than 7,000 rare diseases are recognised; many involve small patient cohorts, limited treatment options, sparse evidence and incomplete routinely collected data, so Australian studies often depend on national registries, shared data assets, targeted investment and international collaboration. ¹² For many people living with a rare disease, access to research and clinical trials is integral to best-practice care. The Standards should require services to identify rare-disease data and evidence gaps; participate in relevant national and international clinical, research and knowledge networks; provide pathways to specialised expertise across organisational and jurisdictional boundaries; and support continuity of care, including transitions from paediatric to adult services. These requirements would reduce the burden on individuals and families to locate expertise and coordinate care, while helping services generate guidance where established clinical pathways do not yet exist.

Research Australia’s Women’s Health Research Roadmap also provides recommendations specific to addressing sex and gender inequities in health and medical research that are also applicable to

¹⁰ Nicole Raschke, Joanne Bradbury, Jacqui Yoxall (2022) *Perceptions of research capacity in public health organisations: comparison of NSW metropolitan and non-metropolitan Local Health Districts*. Australian Health Review 46(6).

¹¹ Anna Wong Shee, Kevin Mc Namara, Laura Alston, Marley Binder, Alison Buccheri, Karina Demasson, Michael Field, Bianca Kavanagh, Olivia King, Mary Malakellis, Samantha Russell, Alesha M. Sayner, Kate Schlicht, Drew Aras, Vincent L. Versace. (2026), *Building Rural Health Research Capacity Through Embedded Researchers and Ecosystem Development*, Australian Journal of Rural Health. Volume 34, Issue 2. April 2026.

¹² Rare Voices Australia (2026) Researchers. Rare Awareness Rare Education, Available from: [RARE Portal researchers page](#).

the Standards ensuring systems reforms are implemented to address inequities in women's health outcomes.¹³

AI and technology

Where AI is used in research, clinical decision support, service planning or administration, health services should demonstrate fit-for-purpose governance, data quality and representativeness, privacy and cybersecurity protections, transparency about material limitations, evaluation for safety, efficacy and bias, human oversight, and monitoring of real-world performance.¹⁴ The Standards should ensure that governance supports broader technical change, not just AI.

Further to the inclusion of technology, in particular the mention of devices, the Standards should recognise the importance of appropriate governance for both unapproved medical devices and unapproved medicines, rather than focusing on devices alone. Where an unapproved therapeutic good is used for research, the Standards should clearly reflect applicable TGA requirements, including the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) pathways as relevant, alongside ethics approval and institutional/hospital research governance, to ensure consistent oversight of medicines and devices.

Implementation, Incentives and the 2027 Pilot

Research Australia supports incremental implementation with adequate guidance, transition time and evaluation. The 2027 pilot should specifically test whether the research provisions:

- reduce rather than duplicate existing accreditation and research governance activity
- create clearer board and executive accountability
- increase research participation and organisational capability
- work proportionately across different research types and service settings
- support consumer and community involvement and equity
- strengthen translation of evidence into care
- produce observable improvements in patient experience, outcomes or service performance

Accreditation expectations will have limited effect if health-service leaders remain accountable only for immediate activity, budgets and waiting times, without corresponding incentives and resources for research. The Commonwealth and jurisdictions should examine how research participation and research-enabled care can be reflected in funding, performance and accountability arrangements, including future National Health Reform Agreement settings. National implementation should connect rather than multiply initiatives across research policy, health policy, workforce, data, clinical trials, translation and procurement.

Whilst we acknowledge these Standards do not apply to aged care and disability care services, lessons from implementing the Standards could be adopted into other sectors to increase a focus on research-enabled care into other sectors.

¹³ Research Australia (2025) *Shaping the future of women's health research: White paper*.

https://researchaustralia.org/wp-content/uploads/2025/11/Shaping-the-future-of-Womens-Health-Research-Whitepaper-v.2_20251114.pdf

¹⁴ Research Australia (2026) *Response to the Joint Select Committee on Artificial Intelligence*. Sydney: Research Australia

Conclusion

Research Australia supports the third edition's shift towards research-enabled care as an integral component of high-quality healthcare. The final Standards should move beyond assurance that research is governed safely to promote the capability, leadership, partnerships, workforce, data and implementation systems that allow health services to generate and use evidence. If aligned with existing frameworks and implemented proportionately, the Standards can help make research routine, strengthen learning across the health system and improve care for all Australians.

Thank you for the opportunity to provide a submission in response to the consultation on the initial draft National Safety and Quality Health Service Standards (third edition). Research Australia is committed to collaborating with governments, healthcare providers, researchers, industry partners, and communities to translate our recommendations into equitable outcomes that can be clearly measured and beneficial to all Australians.

For further information regarding this submission please contact Dr Talia Avrahamzon, Head of Policy, Projects and Advocacy at talía.avrahamzon@researchaustralia.org or policy@researchaustralia.org

Warm regards,



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