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Strategic Ethics Reform Project

What we heard

OFFICIAL

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Overview

Safer Care Victoria (SCV) ran a listening program as part of the Strategic Ethics Reform Project from March to June 2026. The listening program included feedback from surveys, focus groups, roundtables, interviews and written submissions. This report summarises what SCV heard.

SCV undertook the listening program to understand Victoria’s readiness for emerging national Human Research Ethics Committee (HREC) quality standards and accreditation. This national work aims to strengthen the quality and consistency of ethical review and provide greater assurance that review processes are working well.

Through the statewide listening program, we heard from people involved in research, research ethics and research governance across Victorian public health services and the research sector.

This report outlines the key themes raised by contributors. It also discusses the implications of these themes for the broader system that supports ethical review in Victoria. It does not announce government decisions, policy changes or accreditation requirements.

Understanding ethical review

Ethical review in research

Research helps improve healthcare by finding better ways to prevent, diagnose and treat illness. Before a research project involving people can begin, ethical review makes sure the research is safe and appropriate.

In Australia, ethical review is guided by the *National Statement on Ethical Conduct in Human Research*. Developed by the National Health and Medical Research Council (NHMRC), the national statement sets out the principles and standards for research involving people. It outlines different ways ethical review can happen.

The principles and standards help ensure risks are properly considered. They also confirm that research is worthwhile, conducted safely and in the interests of participants and the community.

Ethical review is one part of a broader system that supports safe, people-centred, high-quality research. Research offices, governance teams, institutions, researchers, consumers and community representatives all play a role in helping protect participants while supporting research that can improve healthcare.

Why ethical review matters

Ethical review matters because it helps ensure research involving people is conducted responsibly. It affirms that participants' rights, safety, wellbeing and privacy are protected. It also provides independent scrutiny of research proposals and helps ensure potential risks are identified, minimised and justified by the expected benefits.

Ethical review also matters because it supports public trust in research. It provides assurance that research is conducted according to recognised ethical standards. It also helps institutions meet their responsibilities.

Victoria has a strong and healthy medical research and clinical trials sector. As research becomes more complex, systems that support ethical review need to keep pace. This includes research involving new technologies, advanced therapies, large datasets and multi-site studies.

Understanding how the broader system that supports ethical review is working can help identify pressures and opportunities for improvement. This is important for maintaining a research environment that is safe, trusted, efficient and able to support high-quality research and innovation.

Choosing an ethical review process

Research projects are reviewed in different ways depending on their level of risk, complexity and local requirements. This helps decide which review process is needed. HRECs review higher-risk research. Lower-risk research may be reviewed through other ethics or research governance processes.

Ethical review involves more than HREC meetings. Research support teams also play an important role. They may:

- advise researchers
- assess lower-risk projects
- manage research governance requirements
- monitor approvals
- help institutions meet their responsibilities.

Human Research Ethics Committees

HRECs are independent committees that review research proposals that involve people. They assess whether research proposals meet the standards set out in the national statement and whether research can proceed.

They consider issues such as participant rights, safety, wellbeing, privacy, risk, consent and the value of the research to the community.

HREC members bring a range of expertise and perspectives. They may include:

- researchers
- health professionals
- legal or ethical experts
- pastoral care representatives
- community members, to represent the public.

This mix helps ensure research is considered from scientific, ethical and community perspectives.

Research participants

Research participants are people who volunteer to take part in research. They may be asked to:

- complete a survey
- take part in an interview
- share their health information
- provide a biological sample
- participate in a clinical trial testing a new treatment or model of care.

Research ethics and research governance

Research ethics and research governance are related but not the same (Table 1). Ethical review considers whether a research project is ethically acceptable. Research governance considers whether the institution can safely support, approve and conduct the research. Both are important to making sure research is safe, ethical and responsibly managed.

Table 1: Research ethics and research governance focus areas

	Research ethics	Research governance
	Assesses whether a research project is ethically acceptable and appropriate to undertake.	Assesses whether an institution can safely support and conduct a research project.
Focus	- Protecting the rights, safety and wellbeing of participants - Ensuring informed consent processes are appropriate - Minimising potential risks and harms - Ensuring the research has merit and is conducted ethically	- Ensuring the institution can safely conduct the research - Confirming the necessary resources, approvals and agreements are in place - Managing institutional risks and responsibilities - Providing local oversight of research activities - Monitoring compliance with relevant policies, standards and requirements

Together, ethical review and research governance help ensure research is conducted safely, responsibly and in keeping with relevant standards and requirements.

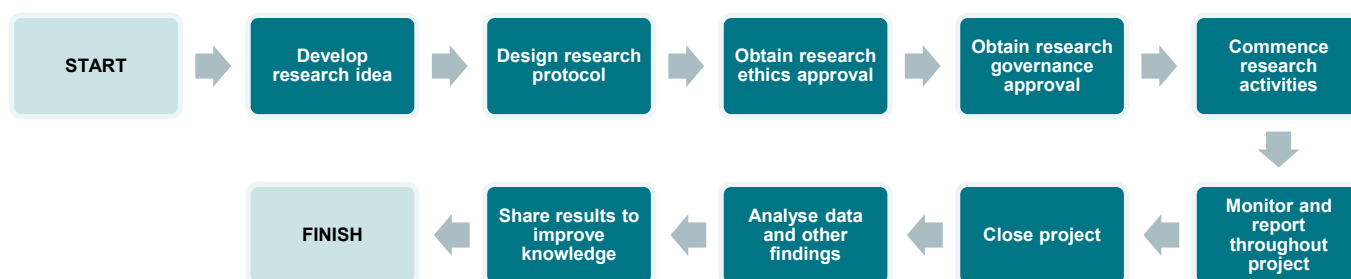
Where ethical review fits in a research project

Ethical review and research governance processes must occur before research begins.

Research projects require planning, oversight, ongoing monitoring and reporting. After a research project closes, findings are analysed and shared to inform knowledge and practice.

Research projects typically move through several stages before participants can be enrolled and research activities can begin (Figure 1).

Figure 1: Typical research project stages



Research ethics and accreditation

Across Australia, work is underway to strengthen the quality, consistency and efficiency of ethical review. While the national statement sets out ethical principles for research involving people, new national quality standards will focus on how HRECs operate. An accreditation scheme will assess whether HRECs meet those standards and recognise those that do.

Accreditation provides assurance that institutions have the people, processes, governance arrangements, records and systems needed to support high-quality ethical review. It looks not only at the work of HRECs but also at the broader institutional environments that support ethical decision making.

About the project

Why we did this project

The project was established to assess Victoria's readiness for emerging national HREC quality standards and accreditation requirements. The listening program let us hear directly from contributors.

National reforms are being developed to strengthen the quality, consistency and assurance of ethical review. Understanding the potential implications of these reforms for Victorian public health services and the research sector is an important part of preparing for future change.

The listening program was designed to gather perspectives from across the research sector on:

- strengths of the current system
- challenges it faces
- opportunities for improvement
- factors that may influence readiness for future reforms.

This report does not announce government decisions, policy changes or accreditation requirements. Instead, it:

- presents what contributors told us
- identifies the themes that emerged repeatedly across the listening program
- considers why those themes matter for the broader system that supports ethical review in Victoria now and into the future.

What we heard about the broader system

While accreditation was recognised as important, contributors highlighted wider issues relating to:

- workforce capacity
- research governance
- technology
- quality systems
- access to specialist expertise
- institutional support
- consumer involvement.

These perspectives reinforced the importance of understanding the broader system that supports ethical review in Victoria.

This report considers both the implications of emerging reforms and the wider factors that contribute to the effectiveness and sustainability of ethical review across Victoria's public health and research sector.

Key findings

The listening program identified 7 connected themes:

1. **Public trust and confidence** – trust cannot be assumed and must be built through transparency, meaningful consumer involvement and clear communication about research.
2. **Access to expertise and support** – access to ethical review capability is uneven across Victoria, particularly for smaller and regional services.
3. **Workforce sustainability** – a small and highly specialised workforce is carrying growing responsibilities.
4. **Increasing research complexity** – current systems, guidance and support arrangements are not always keeping pace with changing research practices.
5. **Accreditation and assurance** – institutional readiness will be critical to supporting future accreditation requirements.
6. **Research system and infrastructure** – systems and technology are not always fit for current needs and often rely on workarounds and individual expertise.
7. **Visibility of the research assurance function** – the specialist work supporting ethical review and research governance is not always visible or well understood.

How we listened

We used several listening methods so we could hear from different parts of the system and test themes across different settings.

Analysis was ongoing throughout the listening program. Early themes from the survey informed later focus groups and roundtables. Findings were then tested and refined through interviews, written submissions and the targeted resourcing survey (Table 2).

This means the report reflects repeated patterns heard across methods, rather than relying on one data source of feedback alone.

Table 2: Listening methods and contributors

Method	Contribution
Online survey	259 responses
Focus groups and roundtables	17 sessions across metropolitan, regional and rural Victoria
Individual interviews	5 senior research system leaders
Written submissions	7 submissions
Targeted resourcing survey	24 respondents with direct responsibility for ethics and research governance functions

Note: The 259 figure excludes 9 duplicate or incomplete responses.

Who we heard from

Contributors to the project included:

- HREC chairs and members
- research ethics and research governance professionals
- researchers and clinician scientists
- research leaders
- consumers and community representatives
- sponsors
- contract research organisations
- universities
- medical research institutes
- government stakeholders.

Table 3 lists online survey roles and numbers of responses.

Table 3: Online survey roles and numbers of responses

Online survey – identified roles	Responses
Clinical trials unit or research delivery team member	51
Clinician researcher	40
Research governance or research governance office	33
Industry, sponsor or contract research organisation	30
HREC member (researcher or scientific)	25
Director of research or research leader	23
HREC ethics advisor, coordinator or secretariat	11
University or medical research institute partner	8
HREC member (non-scientific, community or professional)	7
HREC member (consumer or community)	7
HREC chair	6
Consumer or community representative	4
Executive or organisation leadership	1
Other	13
Total survey responses	259

Table 4 details online focus groups and attendee numbers.

Table 4: Online focus groups and attendee numbers

Role-based online focus groups (two of each)	Attendees
Research governance officers, research office managers and staff	37
HREC managers, ethics officers and coordinators	21
HREC members	17
Clinician researchers, trial coordinators and research teams	15
HREC chairs	11
Sponsors, contract research organisations, medical research institutes, universities	11
Consumer, patient advocates and community	7
Total online focus group attendees	119

What we heard

Across all listening methods, the same themes emerged consistently.

Contributors consistently described ethical review as one part of a broader system that is highly valued and continues to operate effectively but is increasingly under strain.

While accreditation readiness was recognised as important, many contributors said ethical review is affected by wider system issues. These pressures include:

- workforce capability
- technology
- access to specialist expertise
- consumer involvement and institutional support.

Contributors did not describe ethical review as a stand-alone HREC process. Instead, they described a broader system dependent on skilled people, clear governance, suitable technology, quality systems, institutional support and public trust.

Many contributors said the system relies heavily on the commitment, experience and judgement of those who keep it functioning despite these pressures. Ethical review often revealed issues that researchers saw as signs of wider system challenges, not problems with the review process alone.

Consumers and community representatives spoke about wanting clearer information, meaningful involvement and better feedback about research. Their perspectives reinforced a broader message heard throughout the listening program: trust in research depends not only on sound decisions but also on systems that are responsive, accessible and transparent.

‘Patients don’t know where to [look] for clinical trials. You certainly wouldn’t be presumptuous enough to say to your oncologist or GP, “Well, isn’t there a trial I can go on?” We would never have said that in a million years. We just did what we were told.’ **Carer and consumer representative**

What we heard in detail

1. Public trust and confidence

Trust cannot be assumed. Contributors said people are more likely to support and take part in research when they understand how research is reviewed, how risks are managed and how decisions are made.

Contributors said public trust increasingly depends on partnership, with consumers wanting to understand how research decisions are made and how they can contribute in meaningful ways.

‘Please, please, please – if you decide to drop a particular project, let us know. Because consumers often are not told. We are forgotten.’ **Patient and consumer representative with more than a decade of HREC experience**

Only 4 of 259 survey respondents identified as a consumer or community representatives. This may indicate the challenges of engaging consumers and community members through consultation approaches that primarily reach professional research networks.

2. Access to expertise and support

Contributors described major differences in ethical review capability across health services and the research sector. They said practical access to ethical review support should not depend on the size, location or maturity of an institution.

Regional and smaller services described challenges in accessing specialist expertise, research governance support and sustainable operating models for their ethical review processes. Contributors said these challenges can affect whether research can be reviewed, approved and conducted locally.

Contributors described a gap between formal access to review pathways and practical access to the workforce, systems and expertise needed to use those pathways well.

‘Research is designed in metro[politan] but does not translate to regional, rural and remote settings due to completely different structures.’ **Regional roundtable contributor**

3. Workforce sustainability

Contributors described a small and highly specialised workforce supporting ethical review and research governance. However, they said there are no recognised professional pathways, formal training programs and structured career frameworks for this workforce. As a result, people often develop expertise through experience and informal learning. This contributes to differences in capability, role expectations and how ethics and research governance functions are carried out across institutions.

The lack of formal workforce development pathways also makes it harder to recruit, retain and replace staff. In the resourcing survey, 13 of 24 institutions reported losing staff to better-resourced settings, while 18 of 24 had no plan for replacing critical roles.

‘We train them up really good and they tend to leave and get paid \$50,000 a year more in the next job.’ **Research director**

4. Increasing research complexity

Contributors said research is becoming more specialised, data-rich and multidisciplinary. They said current systems, guidance and operating models have not kept pace with this complexity. Examples included genomics, artificial intelligence, advanced therapeutics, adaptive designs and complex data environments.

HRECs and research governance office staff are increasingly asked to consider issues that require specialist expertise, contemporary guidance and stronger support systems.

This means complexity is not only a feature of research projects. It is also a test of workforce capability, infrastructure, training and access to specialist ethical review advice.

Some contributors said that even projects considered to be lower risk can now involve complex questions about data, privacy, technology or implementation.

'A "low-risk" application today is as complex as a full application was 10 years ago.' **Clinician researcher**

5. Accreditation and assurance

Contributors generally supported stronger quality, consistency and transparency in ethical review. At the same time, many said accreditation will test whether institutions have the systems, records, governance arrangements, quality processes and workforce needed to prove readiness.

They described accreditation as more than an HREC exercise. It depends on appropriate institutional support, including clear quality management systems, documentation, training, technology and ongoing oversight.

Several contributors warned that without resourcing, accreditation could add pressure to teams that are already running at capacity.

'If accreditation is mandated without resourcing, you will just get compliance theatre.' **HREC member**

6. Research system and infrastructure

Contributors said ethical review sits inside a larger set of systems and processes that are not always fit for current needs. These include:

- technology platforms
- business processes
- governance arrangements
- quality systems
- reporting requirements
- workforce capability.

Contributors said formal systems are often supplemented with local workarounds, parallel spreadsheets, manual tracking and informal processes to keep work moving. These workarounds can help teams manage day-to-day demands, but they also create risks. They can make processes harder to standardise, increase reliance on individual staff knowledge and limit an institution's ability to plan, report and improve.

The resourcing survey found that 17 of 23 applicable respondents described their mandated technology platform as only partly fit for purpose or worse.

‘Processes are poor and take too long, but we don’t have time or staff resourcing to rise above the day-to-day work to improve them.’ **Resourcing survey respondent**

7. Visibility of the research assurance function

Some roles are seen as administrative, even when they involve specialist regulatory knowledge, judgement, quality management, risk assessment and institutional assurance. Contributors repeatedly said the specialist work that supports ethical review and research governance is not well understood inside institutions.

Contributors said this matters because the function is not always clearly linked to institutional strategy, research priorities or service value. When the work is not visible to leaders, it may be left out of planning, budgets, recruitment, backfill and succession planning.

They also said the continued functioning of the system often depends on individuals whose knowledge is not captured elsewhere.

This theme is strongly connected with workforce sustainability, accreditation readiness and public trust.

‘I looked at our strategic plan – there’s one line about research.’ **HREC chair**

Thank you to contributors

We thank everyone who contributed to the listening program. Contributors generously shared their time, experience and insights to help us better understand how the system that supports ethical review is working in Victoria. Their feedback has shaped this report and will help inform future work to strengthen safe, ethical and high-quality research.

Accessibility and language

This document has been prepared as an accessible Word report with a clear heading structure, short paragraphs, simple tables and no decorative text boxes or multi-column layouts. It uses plain language and avoids images of text, in line with Victorian Government accessible communications requirements and Department of Health guidance.

Technical policy and governance language has been simplified where possible.

This document is intended to support public communication and may be read alongside web content, consistent with Victorian Government guidance that webpages are often the most accessible format for public information.

Glossary

Term	Plain language meaning
Accreditation	A process used to assess whether institutions meet defined quality standards.
Accreditation readiness	An institution's preparedness to meet accreditation requirements, including having appropriate people, processes, systems and governance arrangements in place.
Clinical trial	A type of research study that tests a medical treatment, device, procedure or mode of care to learn whether it is safe and effective.
Consumer and community representative	A person who brings the perspective of patients, carers or the community to research decision making.
Contributor	A person who contributed to this project through a survey, focus group, roundtable, interview or written submission.
Ethical review	The process used to assess whether a particular research project meets ethical principles and standards.
Human Research Ethics Committee (HREC)	An independent committee that reviews research proposals involving people before the research begins.
National Health and Medical Research Council (NHMRC)	Australia's leading expert body in health and medical research.
National Statement on Ethical Conduct in Human Research	The main Australian guidance document for ethical research involving human participants.
Public health service	A Victorian health service operated by, or on behalf of, the public health system.
Quality system	The policies, processes and records used to support consistent, safe and accountable practice.
Research assurance	The people, systems and processes that help ensure research is ethical, safe and that it meets required standards.
Research ethics	The principles and standards that guide how research involving people should be conducted.
Research governance	The process used to assess whether an institution has the capability and resources needed to safely conduct a research project.
Research participant	A person who volunteers to take part in a research study.
Safer Care Victoria (SCV)	An administrative office of the Department of Health responsible for safety, improvement, governance, research and strategy to help health services deliver better, safer healthcare.

