

Submission to the review of PD2010_055

Ethical and scientific review of human research

To: Research Ethics and Governance Unit, Office for Health and Medical Research

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Re: PD2010_055 Discussion Paper, June 2026

Confidentiality: None of this submission is confidential.

About this submission

I make this submission in my independent capacity as a health law researcher. My perspective draws on experience in medical practitioner regulation and research with biomedical scientists on legal pathways for innovative treatments. I do not have direct experience administering hospital research governance.

This submission responds to the review of PD2010_055 on ethical and scientific review. References to the separate review of PD2010_056 identify responsibilities that remain with the organisation hosting the research.

I refer to existing legal obligations to clarify the scope of these recommendations and identify any changes to policy or legal authority needed to implement them. References to the *National Statement* are to the current 2025 edition.¹

Executive summary

The revised directive should make appropriate ethical review easier to obtain, with access to expertise determined by the research and its risks. I support combining shared specialist advice with a limited number of additional specialist HRECs where needed, preserving local knowledge while making external review more readily available. Acceptance should turn on demonstrated expertise and quality, rather than university or hospital affiliation. Recognising additional early phase reviewers and Bellberry for later phase trials would widen choice, provided the reviewers demonstrate the necessary capability and can maintain oversight.

AI and other emerging technologies should be assessed through ordinary review pathways, with specialist assistance matched to the questions they raise. Broader consent should enable patients to contribute information to ethically approved future research, including after death, within an explained scope and with meaningful choices. Such participation can support a learning health care system, provided institutions make responsible reuse possible through workable consent and access arrangements.

The immediate priority is to reconcile the directive and lower risk guidance with the current *National Statement*. I support incorporating essential guidance into PD2010_055 and maintaining accessible practical explanations alongside it. Unless NSW Health can resource regular updating, an express precedence provision should prevent more restrictive guidance from obscuring pathways available under the *National Statement*, subject to legislation. Implementation should be staged, with continuing stakeholder involvement and evaluation of delay, duplicated review and administrative effort.

¹ PD2010_055, policy statement and procedures; PD2010_056, procedures cls 2, 3.1 and 5.1. The PD2010_055 Discussion Paper (June 2026), sections 1–2, distinguishes the two reviews. References below are to the 2025 *National Statement*, which came into effect on 23 June 2026; the 2023 edition applied until 22 June 2026. See NHMRC, [National Statement on Ethical Conduct in Human Research](#) (accessed 11 September 2026).

4.1 Specialist HRECs

Question 1. To what extent do the existing specialist HREC arrangements meet current and emerging research needs? How should access to specialist ethics expertise within the NSW Health HREC system be structured to better support high-quality, timely and risk-proportionate review?

The Discussion Paper identifies specialist arrangements for Aboriginal health research, research involving people in custody, population health and data linkage research, and early phase clinical trials. Their functions extend beyond access to technical advice. Reform should preserve the applicable specialist pathways and the expertise concerning participants, communities and research settings that those arrangements provide.² The paper also reports demand for access to expertise in emerging research methods. A supported pool of advisers could help reviewing HRECs obtain that expertise without requiring every committee to maintain the same specialist membership.

Question 2. What areas or characteristics of research should require specialist ethics review, and what objective criteria should be used to determine when specialist review is necessary?

Referral criteria should distinguish mandatory specialist pathways from cases in which a reviewing HREC needs additional advice. For the latter, relevant considerations include:

- uncertainty about an intervention's effects;
- the novelty of the method;
- the consequences of an error;
- the sensitivity of the information;
- issues affecting consent or particular participant groups.

The presence of a GMO or an AI method should prompt assessment of the expertise required, rather than determine the ethical review route by label alone. The *National Statement* already provides for access to expertise outside a review body's membership.³

Question 3. What opportunities and considerations should NSW Health take into account when strengthening specialist ethics review arrangements, and how can these support effective implementation and long-term system sustainability?

I support Model C: a limited number of additional specialist committees where concentrated expertise is needed, combined with shared advice for local HRECs. An adviser pool alone may not ensure that suitable expertise is available when required. Additional standing committees should therefore be available for defined domains in which sustained specialist capability is necessary, without routing every novel project to a new committee.

Practical training should help HREC members interpret the *National Statement* and resolve questions about its relationship with law. This would build on its existing provisions for legal membership, induction and continuing education, making that expertise more accessible across the committee.⁴

² PD2010_055 Discussion Paper, section 4.1, pp 4–6; PD2010_055, procedures section 5, on research with specific review requirements. The proposal does not change the scope of any existing specialist pathway.

³ *National Statement* (2025) para 5.1.38, on access to scientific, technical, participant-related and research-context expertise outside the review body's membership where necessary; para 5.1.39 addresses relevant knowledge for review of research involving Aboriginal and Torres Strait Islander people or communities.

⁴ *National Statement* (2025) paras 5.1.30(e) and 5.1.26(c). The lawyer need not be practising and, where possible, should not be engaged to advise the institution on legal matters. Paragraphs 5.1.25 and 5.1.26(d)–(g) address resources, unnecessary delay, transparent and consistent decisions, conflicts and communication.

Question 4. What importance, if any, do stakeholders place on HRECs being embedded within NSW Local Health Districts versus a centralised or networked model? What are the perceived benefits, risks or implications of these approaches?

HRECs embedded in LHDs may bring valuable knowledge of local clinical services and research capability, although the extent of that advantage would need to be assessed with those involved. I would not favour replacing established committees with dynamically constituted panels under Model D (panels assembled from a wider pool for particular applications). A wider membership pool may support independence, but continuity, consistency and reliable access to advice would need attention. Where ethical review occurs outside the district, relevant local circumstances should inform that review without requiring a second local ethics assessment.

Product classification and clinical practice:

Where product classification affects the proposed research, the HREC should be able to obtain specialist advice and rely on relevant existing assessments. OHMR could facilitate referral to the appropriate regulator where a question remains unresolved. Guidance should distinguish product regulation, ethical review and institutional clinical governance, so that product terminology or absence of ARTG inclusion does not itself determine the ethical review route.

A qualifying hospital-based autologous human cell or tissue product may be excluded from Commonwealth therapeutic goods regulation.⁵ Guidance should direct non-research clinical innovation to existing clinical governance processes, without adding research review or reporting requirements solely because a product is novel or excluded.

The design of specialist arrangements should address:

- funded coordination;
- appointment criteria;
- declarations of interests;
- confidentiality arrangements;
- clear expectations for response times.

Access to specialist advice should be timely and accountable, with arrangements for continuity when an adviser is unavailable (for example, access to another adviser with the required expertise). Institutions and reviewing committees are best placed to determine how referrals are managed. Evaluation should examine whether the advice assists review and whether the arrangements introduce avoidable delay.

4.2 Acceptance of university and private HREC approvals

Question 1. Should NSW Health Organisations accept ethics approvals from university or private HRECs for research conducted at NSW Health Organisation sites? Why or why not?

I support Model C, with acceptance determined by the risks and complexity of the project and assurance of the quality of the review. Acceptance should depend on the reviewing committee's demonstrated expertise and the risks of the particular project, rather than whether the committee belongs to a university or a hospital. Requiring a second review of the same protocol can duplicate work where the first review meets the relevant standards and covers the proposed sites and participants. The *National Statement* directs institutions

⁵ *Therapeutic Goods (Excluded Goods) Determination 2018* (Cth) s 6, sch 2 item 4A. The exclusion requires the same patient, the relevant practitioner's professional supervision, manufacture in the relevant hospital subject to the contracted storage or testing exception, and no direct-to-consumer advertising. See [Explanatory Statement, Therapeutic Goods \(Human Cells, Tissues and Organs\) Determination 2018](#), 2–3: the original exclusion relied on practitioner control, practitioner–patient consultation and management of risks within the hospital setting, regardless of the level of manipulation or processing. See also TGA, [Manufacturing excluded autologous human cell and tissue products](#), especially “Clinical care of a registered medical or dental practitioner” and “All steps in manufacture must occur in the hospital, except storage and testing”.

to minimise unnecessary duplication and to establish criteria for accepting external review.⁶ NSW policy should give practical effect to that direction through a proportionate acceptance process.

Question 2. If acceptance were expanded, what minimum standards or assurance requirements should apply to external HRECs (for example, NHMRC registration or certification, minimum review standards, or demonstrated public health expertise)?

OHMR should assess external HRECs centrally against published quality criteria and specify the scope and conditions of their recognition under the proposed risk-based pathway. NHMRC registration, relevant expertise and compliance with the *National Statement* should be assessed alongside existing certification. Where the applicable acceptance scheme does not require certification, documented evidence against published criteria should be sufficient to establish assurance. National Mutual Acceptance requirements would continue to govern acceptance under that scheme.⁷

Recognition should provide a basis for relying on an external committee's assessed capability, subject to review when circumstances change (for example, loss of expertise on which recognition depended). Local acceptance would still need to establish that the approval is current and covers the proposed research and oversight arrangements. The objective is to avoid repeating the assessment of the committee itself whenever an institution accepts one of its approvals.

Question 3. What responsibilities should remain with NSW Health Organisations when relying on an external ethics approval?

The receiving organisation should retain responsibility for site authorisation and the practical capacity to undertake the research, including:

- staffing;
- facilities;
- equipment and materials;
- clinical support;
- service feasibility.

Privacy compliance, data custodianship, security, indemnity and insurance arrangements, and acceptance of local organisational risk also remain with the responsible organisation. It should also agree with the reviewing body and researchers who will monitor the project and communicate changes, safety concerns, suspension or withdrawal of approval. The *National Statement* addresses these arrangements and limits supplementary scientific or technical review without agreement from the reviewing body.⁸ Site governance should identify local conditions relevant to the ethical review and refer them to that body, rather than conduct a second ethical assessment through SSA.

Question 4. Are there specific categories of research where acceptance of external HREC approvals would be appropriate, or not appropriate, and why?

Acceptance should generally be straightforward for lower risk projects where the reviewing committee has appropriate expertise and the approval covers the proposed work. As risk and complexity increase, the receiving organisation should examine the

6 *National Statement* (2025) paras 5.5.1–5.5.4. Institutional acceptance should follow established criteria and be decided case by case. PD2010_055 Discussion Paper, section 4.2, pp 7–8, proposes conditional and risk-tiered acceptance models.

7 NHMRC, [HREC Registration Guide](#); [National Certification Scheme for the ethics review of multi-centre research](#). Certification concerns institutional ethics-review processes; NMA acceptance is governed by participating jurisdictions' arrangements.

8 *National Statement* (2025) para 5.5.5, particularly (b)–(c); PD2010_056, procedures cls 3.1, 3.3 and 5.1.

adequacy and relevance of that expertise more closely; higher-risk research should remain eligible for acceptance on a case-by-case basis. A university committee may be better placed to assess some emerging laboratory methods, while a hospital committee may have stronger expertise in particular clinical settings. Neither affiliation establishes competence for every project. A data-only study should not qualify solely because it involves no intervention: identifiability, linkage, sensitivity and consequences for participants require assessment.

Question 5. What implementation considerations or system impacts should NSW Health take into account when considering changes to the acceptance of external HREC approvals, and how can these be managed to support efficiency, quality and system sustainability?

Implementation should establish clear responsibility for administering external approvals, communicating conditions and resolving questions about reliance. Institutions should determine the allocation of those functions within their own arrangements. A decision not to rely on an approval should carry reasons. Training and transition arrangements (including how applications already under review would be handled) should be developed with experienced reviewers and research staff, with evaluation of duplicated review, elapsed time and the costs of assurance.

4.3 Early phase clinical trial approval pathways

Question 1. To what extent does the current EPCT Framework support high-quality, timely and risk-proportionate ethics review of EPCTs conducted within NSW Health Organisations?

The designated-HREC framework provides a basis for concentrating early phase expertise. Under the current scheme, adult EPCTs at NSW PHO sites are routed to Bellberry. The paediatric position includes SCHN review for trials with a NSW PHO lead site and acceptance of specified interstate specialist-paediatric HREC approvals; the scheme also contains mixed-age criteria.⁹ These distinctions should appear in referral guidance.

The Discussion Paper raises questions about capacity and the operation of the framework. It does not supply comparative performance data sufficient to attribute delay to a particular committee or establish that review quality is unaffected. To guide the staged recognition of additional committees and identify where resources are needed, OHMR should assess:

- demand;
- time to an initial response;
- time awaiting applicant information;
- total review time;
- the nature of recurring issues.

Question 2. What is the preferred approach to EPCT ethics review in NSW Health: maintaining the current model of designated HRECs, expanding to include additional HRECs, embedding local capacity within existing NSW Health HRECs or an alternative model? Please outline the reasons for your view.

I support Model B, allowing a limited number of additional HRECs to undertake early phase review once they demonstrate the necessary expertise, resources and capacity for continuing oversight. Each committee should operate within the scope of its recognised

⁹ Office for Health and Medical Research, *Early Phase Clinical Trials HREC Scheme: Frequently Asked Questions*, 1–2 (reference copy captured 3 September 2026). The FAQ distinguishes adult and paediatric routing, interstate specialist-paediatric approvals and mixed-age criteria. See also the linked OHMR quick reference guide.

expertise. OHMR should not require evidence that an existing designated reviewer has failed to meet demand before recognising another HREC. It should nevertheless consider demand and likely case volume when assessing whether the new HREC can maintain specialist capability. Recognition should precede allocation of trials, with clear referral arrangements and monitoring of the quality and timeliness of review.

Question 3. What values should underpin the future design of the EPCT Framework?

Participant safety and the quality of ethical and scientific review should govern the design. Timeliness, equitable access to review, transparent reasons and continuity of oversight also matter. Assessment of alternative models should consider how each would maintain those functions, including public accountability where review is provided outside NSW Health.

Question 4. If EPCT review were expanded beyond the current designated HRECs, what minimum standards, capabilities or assurance requirements should apply to ensure consistent, high-quality and trusted ethics oversight?

Recognition should require demonstrated expertise relevant to the trials reviewed, including early phase design, statistics, safety monitoring and applicable good clinical practice requirements. OHMR should examine how expertise will be maintained, how conflicts will be managed and whether the committee has the resources to monitor approved trials. Case volume is relevant to maintaining competence but should not be the sole measure.

Question 5. What are the key risks or system impacts associated with expanding EPCT review beyond the current designed HRECs, and how could these be mitigated?

Expansion could create inconsistent referral decisions, fragmented oversight or insufficient work to sustain specialist capability. Clear recognition criteria, review of performance, shared training and arrangements for transferring oversight (for example, from a committee whose recognition is suspended to another recognised committee) would help address those risks. A trial should have an identified reviewing body throughout its conduct, including during a change of committee or a suspension of recognition.

4.4 Bellberry review of later phase clinical trials

Question 1. What is the preferred approach to the role of Bellberry HREC in later phase clinical trials conducted at NSW Health sites: maintaining the current scope, expanding it, or adopting an alternative model? Please outline the reasons for your view.

I support Model B, expanding recognition of Bellberry HREC approvals to later phase clinical trials as an additional option, subject to appropriate assurance of expertise, review quality and continuing oversight. Researchers and sponsors should retain a choice between eligible Bellberry, NSW Health and NMA-recognised reviewers, as contemplated by the Discussion Paper.¹⁰

Question 2. What are the potential benefits, risks or system impacts of expanding Bellberry HREC approval to later phase clinical trials?

An additional recognised reviewer could increase available capacity and provide continuity for some sponsors moving between trial phases. The risks include:

¹⁰ PD2010_055 Discussion Paper, section 4.4, pp 10–11, Models A–B. The current scope is also described in the OHMR EPCT FAQ, pp 1–2.

- differences in fees and conditions of review;
- movement of work away from public sector committees;
- inconsistent handling of local ethical concerns;
- attempts to obtain a different decision after an adverse review.

These are matters for assessment rather than assumed consequences of private review. Applicants should disclose prior ethics decisions.¹¹

Question 3. What implementation considerations should NSW Health take into account if changes to Bellberry HREC scope were introduced, and how could these be managed to support system sustainability?

The terms recognising Bellberry for later phase trials should specify eligible research, assurance requirements, monitoring responsibilities and arrangements for communicating amendments and safety concerns. NSW Health should assess the effects on public sector capability, sponsor costs and review times, including the resources required to oversee the arrangement. Existing trials should have a clear transition process, with no gap in monitoring responsibility.

4.5 AI and emerging technologies

Question 1. What key challenges do researchers and HRECs face when preparing and reviewing applications involving AI or emerging technologies?

A central challenge is whether reviewers have the information and technical expertise needed to assess the particular system. An application described simply as “using AI” may leave them unable to judge either its safeguards or its risks. This is a reason to provide access to specialist advice, while retaining ordinary ethics review pathways. Complexity and unpredictability are not unique to AI; other interventions, including gene editing or gene therapy (for example), may present comparable difficulties of assessment.

Assessment should address the whole arrangement through which the model operates. A command line interface (CLI) is a way of interacting with software; the surrounding “harness” controls how the model uses tools, retrieves information and performs tasks. These arrangements can support checks against source records. Retrieval augmented generation (RAG), including systems using vector search to find relevant material, can help ground an answer in identified sources (for example, retrieving the passage on which a generated summary relies). Retrieval alone does not authenticate a record or establish that an answer is correct; reviewers need to understand what is checked and how errors are detected.¹²

The movement of information raises a separate question. Reviewers need a sufficiently clear account of:

- which tasks use AI and what information they require;
- where that information is processed and retained (including any external model, search or storage service);
- who can access it, including providers and subcontractors in Australia or overseas;
- whether prompts, retrieved passages or outputs are retained in logs or used for further training;
- how outputs are checked and who is responsible for resolving errors.

A tool running on an institutional computer may still send information to an external service. The proposed use should therefore be assessed by reference to its configuration and data flows, rather than its interface or product name. OAIC guidance identifies the

¹¹ *National Statement* (2025) para 5.5.6(d), on disclosure of prior decisions to approve, reconsider or deny approval.

¹² Microsoft, [Build advanced retrieval-augmented generation systems](#) (accessed 13 September 2026), explaining retrieval, vector search and evaluation of generated answers.

need to understand providers' handling of personal information and cautions against entering sensitive information into publicly available generative AI tools.¹³ Where the applicable requirements confine records to an approved environment, inability to demonstrate that the proposed system meets those requirements may preclude its use with those records. The affected use should not proceed until a compliant arrangement is established; this does not imply that all AI research requires records to remain on one server.

Question 2. How can PD2010_055 support, if at all, a risk-proportionate approach to AI-enabled or emerging technology research, and where are the key gaps in the current policy framework?

NSW guidance should build on NHMRC's existing guide for assessing research involving AI, issued in December 2025.¹⁴ OHMR could map that guide to the information required in applications and provide NSW-specific instructions where privacy law, local information systems or institutional responsibilities require clarification. Applicants should be able to refer to an existing protocol or assessment rather than complete a second account of the same matters.

Question 3. What key ethical or scientific considerations should be explicitly addressed when reviewing research involving AI or other emerging technologies?

The assessment should identify:

- the provenance and lawful basis of data (where the information came from and what permits its use);
- the suitability of the method;
- foreseeable bias;
- the population to which findings may apply;
- the consequences of error.

Where an output may influence care (for example, a recommendation about treatment), reviewers should examine validation, the role of human judgement and the arrangements for identifying and responding to unsafe performance. For methods that change during research, the protocol should identify what will be monitored and which changes require further review. Genomic and other emerging methods should be assessed against the relevant provisions of the *National Statement* rather than treated as interchangeable with AI.

For a method intended to influence care, the application should identify the required institutional permission. The protocol should distinguish changes within the assessed use from amendments affecting clinical purpose, patient population or reliance on the output.

Question 4. What practical guidance, tools or assurance mechanisms are needed to support consistent, proportionate and efficient ethics review of AI-enabled and emerging technology research?

Technical advice, worked examples and training should help reviewers distinguish what a system can demonstrate from what its description merely promises (for example, whether source checking is actually performed and whether external transfers are technically restricted). The specialist arrangements proposed in section 4.1 could provide access to

¹³ Office of the Australian Information Commissioner, [Guidance on privacy and the use of commercially available AI products](#) (accessed 13 September 2026). The guidance concerns entities subject to the Commonwealth Privacy Act; the applicable NSW obligations and institutional conditions require separate assessment.

¹⁴ NHMRC, [Guide for assessing research involving Artificial Intelligence, Machine Learning and Large Language Model Technology](#) (2 December 2025). The guide provides a question-based tool for researchers and ethics review bodies. The operational proposals here should be mapped to that existing guidance.

expertise in AI systems, information security and privacy. Reviewers should be able to rely on a relevant technical assessment without each committee having to reproduce it. Guidance should be developed with researchers and reviewers and tested for proportionality.

Question 5. What implementation considerations should NSW Health take into account to ensure that policy guidance on AI and emerging technologies supports innovation, maintains public trust, and remains adaptable as technologies evolve?

Technical guidance should be maintained separately from the directive, with a named owner and review schedule. NSW Health should test the guidance with researchers, reviewers and consumer representatives to check whether documentation requirements are proportionate and participant information is clear. Version histories should help reviewers reassess methods or intended uses when they change.

4.6 Consent for research use of patient data

Question 1. What role, if any, should universal or broader consent models play in supporting research use of patient data within NSW Health?

I support enabling patients to give informed and voluntary consent to ethically approved future health research, including research undertaken after their death, where the scope, safeguards and lawful conditions of use have been explained. The *National Statement* distinguishes specific, extended and unspecified consent. It permits consent for future research but requires the terms and implications of unspecified consent to be explained and recorded, and later proposals relying on that consent to describe its terms.¹⁵ ‘Universal consent’ should not imply permission obtained from every patient or unrestricted authority for every future use.

There is an ethical case for asking patients to contribute information that may improve the care of others. Faden and colleagues’ account of a learning health care system places obligations on patients and institutions to contribute to that common purpose, subject to patients’ rights and interests.¹⁶ Institutions should make such contributions possible through trustworthy arrangements for retaining, finding and using the information, while preserving meaningful choice under a consent-based scheme.

The model should distinguish consent-based reuse from reliance on the research provisions in HPPs 10–11 and the Statutory Guidelines on Research; an opt-out arrangement is not itself a legal basis.¹⁷ This distinction matters to the design of the proposed consent process and the alternatives available when consent does not cover a later use.

The identity of the recipient also matters. NSW public universities are HRIP-bound for health information; a separately constituted organisation may have different or concurrent obligations. Guidance should identify the actual recipient and applicable regimes rather

¹⁵ *National Statement* (2025) paras 2.2.14–2.2.18, particularly the requirements to explain and record unspecified consent and identify its terms when later relied on.

¹⁶ Ruth R Faden, Nancy E Kass, Steven N Goodman, Peter Pronovost, Sean Tunis and Tom L Beauchamp, ‘An Ethics Framework for a Learning Health Care System: A Departure from Traditional Research Ethics and Clinical Ethics’ (2013) 43(S1) *Hastings Center Report* S16, S22–S24, especially S23, [doi:10.1002/hast.134](https://doi.org/10.1002/hast.134). Their obligations to learn and contribute are qualified by the framework’s protections for patients; the post-death consent proposal here is not attributed to that article.

¹⁷ *Health Records and Information Privacy Act 2002* (NSW), Sch 1 HPPs 10–11, particularly 10(1)(f) and 11(1)(f); s 64. *Statutory Guidelines on Research*, Part 2 cls 1.1–1.6 and 2.1, address the identifiable-information research pathway, HREC approval, the requirement that the public interest in the research substantially outweigh the public interest in the privacy protection otherwise afforded and the organisation’s ability to decline use or disclosure. Ethical approval does not replace the statutory conditions.

than assume that every university-related disclosure moves from NSW to Commonwealth privacy law.¹⁸

Question 2. What safeguards, mechanisms or transparency measures would be necessary to support public trust in a universal consent approach?

Patients should receive an accessible explanation of:

- the purposes and scope of future research (for example, research on a specified condition or a broader range of health questions);
- the information concerned and types of recipients;
- the duration of the permission;
- oversight and safeguards;
- withdrawal arrangements.

The IPC's guidance on informed, voluntary, specific and current consent provides a basis for designing the process.¹⁹ Refusal should not disadvantage care, and choices should be recorded so that later uses can be checked against their scope. Carter's survey of 511 Australian adults found support for medical research alongside a strong expectation of consultation about reuse of personal health information, cautioning against equating support for research with acceptance of consent-exempt reuse.²⁰

Legacy records that leave consent's scope unclear should be flagged for resolution before access, rather than treated as agreement to unspecified research.

The Five Safes framework can inform access and disclosure controls, with re-identification risk assessed against the available data and proposed access.²¹ Patients and consumer representatives should contribute to the design and review of the consent process.

Research after death

The consent process should expressly address future research after death and preserve the patient's wishes and restrictions. NSW Health's Privacy Manual recognises continuing privacy protection for 30 years and the relevance of wishes expressed before death.²² The proposed model should make those wishes usable when later research is considered.

Question 3. What practical considerations should NSW Health take into account when assessing the appropriateness of implementing a universal or broader consent model (e.g. communication with patients, withdrawal processes, system capability)?

Before rollout, NSW Health should test whether its systems can record consent versions, restrictions and changes, and communicate those changes to the people controlling access. Withdrawal information should explain the consequences for new uses and for work already undertaken, including limits on retrieving data that can no longer be linked to

18 HRIP Act ss 4, 11; *Privacy Act 1988* (Cth) ss 6C(1), 6C(3)(c). See also Information and Privacy Commission NSW, [NSW Privacy Laws](#). Recipient status and the activity concerned require assessment; Commonwealth coverage does not necessarily exclude NSW health-information obligations.

19 Information and Privacy Commission NSW, [Fact Sheet: Consent](#), especially 'What are the elements of consent?' and the discussion of specific consent and blanket consent.

20 David J Carter, 'Use of Personal Health Information under Consent – Exempt Circumstances for Research: Views of the Australian General Public' (2021) 28(3) *Journal of Law and Medicine* 780, 786–787, 790, 794, 796. The 2018 survey used a non-probability online panel with demographic quotas. At 794 Carter distinguishes empirical acceptability from the correctness of a normative obligation; at 796 he discusses limitations of generalisability.

21 Australian Bureau of Statistics, [Five Safes framework](#), describing controls concerning people, projects, settings, data and outputs. The framework informs risk management; the applicable legal basis remains a separate requirement.

22 NSW Health, [Privacy Manual for Health Information](#) (2025 revision) section 15.10, 98; *Health Records and Information Privacy Act 2002* (NSW), Sch 1 HPPs 10–11. The manual also distinguishes compassionate disclosure from other grounds of use or disclosure.

the individual or reversing completed analyses. The *National Statement* requires participants to be informed of the consequences of withdrawal before consenting.²³

The NSW Health Consent Toolkit for biobanking offers useful materials on future unspecified research and data linkage, to be adapted for broader patient record use.²⁴ Implementation should accommodate non-digital participation, varied language and accessibility needs, and people unable to make the relevant decision. Systems should retain consent histories and later access decisions, with development coordinated nationally. Adams, Allen and Flack's interviews with data custodians support clear contacts, public guidance, training, coordinated applications, reasons and adequate resources: practical measures needed to make the consent reform usable.²⁵

4.7 Lower risk research

Question 1. To what extent is NSW Health specific interpretation of the National Statement required for lower risk research? Are there areas of the current framework that are unclear or difficult to apply in practice?

NSW guidance should resolve the interaction between the current *National Statement* and requirements still expressed in PD2010_055. Clauses 2.1, 2.3 and 3.1 respectively retain the earlier review structure, exemption formula and categories requiring full HREC review. Replacing GL2023_007 without reconciling those provisions would leave applicants and institutions facing inconsistent instructions. The revised directive should identify which HREC routes are required by legislation, which follow the current *National Statement*, and which NSW Health chooses to retain as policy. The *National Statement* assigns risk assessment to institutions and permits competent non-HREC review of lower risk research; it does not itself remove a separate statutory or NSW policy requirement.²⁶

The present guideline's exemption provisions are narrower than those now available under the *National Statement*. NSW guidance should assist institutions to apply the national framework, including its proportionate review and exemption pathways.²⁷ Maintaining separate guidance requires resources for regular review and prompt updating whenever the *National Statement* changes. Otherwise, guidance risks becoming fixed around superseded requirements and misleading users into treating nationally available pathways as unavailable.

Unless NSW Health can resource that maintenance, the guidance should include an express precedence provision: **where this guidance imposes a more restrictive requirement for ethics review than the current *National Statement*, the *National Statement* prevails, subject to any applicable legislative requirement.**

Use of personal information without consent cannot be exempted from ethics review under the 2025 framework, and waiver for research using personal health information requires an HREC. Those distinctions should be explicit in triage guidance.²⁸

²³ *National Statement* (2025) paras 2.2.19–2.2.20. Communication of the consequences of withdrawal should reflect the actual data arrangements and applicable obligations.

²⁴ NSW Health Statewide Biobank, [NSW Health Consent Toolkit](#), describing consent for future unspecified research and data linkage. Its application to broader patient-record use requires separate assessment.

²⁵ Carolyn Adams, Judy Allen and Felicity Flack, 'Data Custodians and the Decision-making Process: Releasing Data for Research' (2018) 26(2) *Journal of Law and Medicine* 433, 438–445, 450–453. The study involved 13 interviews in 2017, predominantly with government custodians; it supports these institutional recommendations without establishing that every arrangement described remains unchanged.

²⁶ PD2010_055, procedures cls 2.1, 2.3 and 3.1; *National Statement* (2025) paras 5.1.10–5.1.14 and ch 2.1. Institutional risk assessment and competent non-HREC review are distinct from HREC review of higher-risk research.

²⁷ [GL2023_007, Low and Negligible Risk Research](#), section 5; *National Statement* (2025) paras 5.1.15–5.1.18. See also PD2010_055 Discussion Paper, section 4.7, pp 14–15.

²⁸ *National Statement* (2025) paras 5.1.16 and 2.3.9–2.3.10, read with the applicable privacy legislation and statutory guidelines.

Examples should contrast identifiable record research requiring consent waiver with lower risk research eligible under paragraph 5.1.17(a), including its safeguards against re-identification. That distinction would help applicants understand why low participant risk or the description of data as coded does not, by itself, establish eligibility for exemption.

Question 2. What would be the impact of rescinding GL2023_007? Would its removal create gaps in guidance or lead to inconsistencies across NSW Health Organisations?

Rescission should coincide with the replacement instructions and training, so that applicants and Research Offices know which process applies to new and continuing projects. The transition should identify how existing decisions, pending applications and amendments are handled.

Question 3. Which of the following options do you prefer, and why?

- **Option 1. Rescind GL2023_007 without replacement**
- **Option 2. Rescind GL2023_007 and incorporate relevant content into the revised PD2010_055**
- **Option 3. Rescind GL2023_007 and replace it with a new, updated guideline aligned to the current National Statement.**

I prefer Option 2: incorporate essential responsibilities and decision criteria into PD2010_055, supported by examples and a web-based decision aid linked to the controlling provisions (for example, questions that help a researcher identify the applicable review pathway). The web guidance should have a named owner and revision date. HRECs need the expertise to interpret primary documents; researchers should be able to identify their pathway without equivalent expertise. The precedence provision proposed above should apply to supplementary guidance.

Question 4. If Option 2 or 3, which elements of GL2023_007 are most valuable and should be retained in any future approach? Please provide examples where possible.

(Prompt: determining the level of risk and appropriate level of ethical review; projects that must be reviewed by a HREC; projects that may be suitable for review by non-HREC levels of ethics review; projects that may be exempt from ethics review; and journal request for ethics review.)

Retain guidance on risk assessment, the appropriate review body, mandatory HREC routes, eligibility for exemption, and requests for evidence of ethical review from journals. Examples should distinguish a lower risk project requiring consent waiver from one that meets the exemption criteria. An exemption decision should be recorded by the responsible institution or granting body, and the researcher should retain the required auditable record.²⁹ A journal letter should describe the decision actually made; it should not imply that retrospective approval had been obtained before the research commenced.

The boundary of human ethics review

Guidance should distinguish:

- work outside the scope of human research;
- human research eligible for exemption;
- research suitable for non-HREC review;
- research requiring an HREC.

The *National Statement* expressly recognises that activities which are not human research do not require human ethics review.³⁰ In our article on desktop legal research, my co-authors and I argue that analysis of publicly available legal materials should fall outside

²⁹ *National Statement* (2025) paras 5.1.18, 5.3.9 and 5.1.6. GL2023_007, section 6, addresses journal requests; any letter should accurately describe the prior review or exemption process.

human research, rather than require an institutional grant of exemption.³¹ That argument is relevant to policy and legal research concerning health services, although it should not be taken to establish that every use of publicly accessible personal information is outside review. Clarifying the boundary would help prevent the extension of review processes to work for which their protective function has not been established.

Reasons and responses within the existing review process

NSW guidance should implement the *National Statement*'s existing provisions for reasons, constructive communication and clear decisions (including whether a requested change is a condition of approval or a suggestion).³² Researchers should be able to answer a request by making the change or explaining why it is unnecessary, with the HREC addressing any remaining disagreement. Supporting that exchange would avoid an additional routine review stage. Guidance should also offer a means of resolving whether review is required without first demanding a full application; unresolved complaints about the conduct of review should follow the published complaints process.³³

Implementation priorities

Implementation should be staged. NSW Health should first align the directive with the current *National Statement* and correct superseded guidance, without waiting for reforms that require new staff or systems. Changes to specialist capacity, external review and broader consent should follow as the necessary capability becomes available.

NSW Health should continue to involve researchers, reviewers, data custodians and consumer representatives throughout implementation, publishing how feedback has informed changes. Evaluation should test whether applicants can identify their pathway, reviewers can explain and apply it consistently, and the arrangements work in practice.

The reforms should avoid additional review stages or information demands beyond the national framework and applicable legislation. Assessment should consider:

- turnaround times;
- the clarity of instructions;
- consistency of decisions;
- repeated requests for information;
- the effort required of researchers and review staff.

Thank you for the opportunity to contribute. I would welcome the opportunity to discuss the legal and governance conditions for these proposals.

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30 *National Statement* (2025), 'Purpose, scope and limits', 9; paras 5.1.10–5.1.18. Paragraph 5.1.16 precludes exemption where personal information is used without consent; paragraph 5.1.17(d) addresses specified information made publicly available through legislative or regulatory mechanisms.

31 Cameron Stewart, Christopher Rudge, George F Tomossy and Ian Kerridge, 'Desktop Legal Research and Human Ethics Review: Problems of Juridification and "Ethics-Creep"' (2025) 32 *Journal of Law and Medicine* 36, 44–48, especially 46–47. The authors argue for exclusion from the scope of human research, not merely a grant of exemption from review.

32 *National Statement* (2025) paras 5.2.7 and 5.2.11–5.2.13. Paragraph 5.2.7 expressly addresses reasons and relevant provisions for requested modifications. Paragraph 5.2.13(b) permits written or, where appropriate, informal communication of modification requests, with a record of informal communication and clear directions for the researcher's response.

33 *National Statement* (2025) paras 5.7.3–5.7.4. These address complaints about the conduct of review bodies and permit referral of unresolved complaints to an independent assessor; they do not establish an automatic independent merits appeal.