REVERSING THE 'QUASI-TRIBUNAL' ROLE OF HUMAN RESEARCH ETHICS COMMITTEES: A WAIVER OF CONSENT CASE STUDY

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This article traces the history of Human Research Ethics Committees ('HRECs') in Australia, noting their development from peer review bodies to a model more akin to quasi-tribunals. We illustrate this shift through the role of HRECs in authorising waivers of consent for health and medical research: a responsibility that is codified under federal and state privacy laws and national research ethics guidelines. Despite the increasingly rule-based nature of HREC decisions, the manner in which HRECs operate has barely changed from their peer review roots. In particular, very limited substantive oversight or appeals mechanisms apply to HREC decisions. Given the stakes involved in authorising – or refusing to authorise – waivers of consent, this may lead to a loss of trust in, and trustworthiness of, the Australian research enterprise. We suggest looking to the model in the United Kingdom and the Republic of Ireland, which delineates the ethical acceptability of a waiver of consent from its legal compliance.

I INTRODUCTION

Since the 1960s, Human Research Ethics Committees ('HRECs') and their international equivalents have become a ubiquitous part of the regulatory landscape for research involving humans. These committees were established to independently review the acceptability of research proposed to be conducted at a research institution. Since this time, their scope of responsibilities has expanded,

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moving from an institutionally-based peer review system to a model progressively akin to a 'quasi-tribunal', that is, acting as a gatekeeper with authority to decide whether, and on what terms, research may be conducted.[1] This shift is especially evident in the context of waivers of informed consent for the use of personal information in health and medical research, approvals for which depend on an HREC determination that the public interest in the research substantially outweighs the public interest in maintaining privacy protections.

Standard paradigms of research regulation focus on the consent of participants – and oversight of this consent and other aspects of the research by independent HRECs – as a key protection for ensuring the trustworthiness of the system.[2] Privacy laws also have been enacted to protect against the disclosure of identifiable information about individuals other than with the individual's consent or in limited other circumstances. Yet research involving waivers of consent or modifications to the consent process is becoming increasingly prevalent, particularly when it comes to large-scale data sharing activities. A culture of data sharing is especially evident in genomics, where it underpins the development of very large datasets required for efficient and clinically relevant research.[3]

A typical scenario in which a waiver of consent might be sought is the reuse of an existing collection of samples and data for research not covered by the original consent. Sometimes the proposed secondary use is reasonably similar to the purpose for which the samples or data were originally collected, such as when a research group has collected samples for a study on genetic risk factors for prostate cancer and is later asked to contribute genomic data to a consortium undertaking a meta-analysis to identify genetic variants associated with response to treatment. If this secondary use is not covered adequately under the original consent, the research team must either go back to the participants and reconsent them or apply for a waiver from the administering HREC. In other cases, the proposed secondary use is distinctly different from the original purpose; for example, a hospital pathology service which has been storing historical tumour samples collected for clinical purposes decides to reduce its collection, and a local research team requests to use the samples for research into cancer aetiology and treatment rather than having the samples destroyed. In such cases, no consent for research has ever been obtained, and the proposed use represents a significant departure from the samples' clinical origins.

Waivers of consent may be sought in such cases because returning to the original participants is challenging in some way: the samples or data may have been collected a long time ago and contact details for participants are no longer current, or a large proportion of participants are expected to be deceased and contacting family members could be expected to be distressing, or the process of

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1 David Townend and Edward S Dove, 'Approaching Ethics Review Equivalency through Natural Justice and a "Sounding Board" Model for Research Ethics Committees' (2017) 36(1) *Medicine and Law* 61, 73–4.

2 Fida K Dankar, Marton Gergely and Samar K Dankar, 'Informed Consent in Biomedical Research' (2019) 17 *Computational and Structural Biotechnology Journal* 463, 468 <https://doi.org/10.1016/j.csbj.2019.03.010>.

3 James Brian Byrd et al, 'Responsible, Practical Genomic Data Sharing That Accelerates Research' (2020) 21(10) *Nature Reviews Genetics* 615, 615 <https://doi.org/10.1038/s41576-020-0257-5>.

tracking down participants is expected to be unduly expensive or time-consuming. Waivers of consent offer a mechanism for researchers to argue that the potential value of the proposed research is greater than the risks to participants and the wider community of not obtaining consent, and this core justification is reflected in the criteria for waivers of consent, against which HRECs make their determinations.[4] Yet members of the public are often unaware of the extent to which data about them is shared for research purposes, and public expectations in relation to such sharing practices vary widely,[5] indicating the difficulty of the HREC's task.

Part II of this article tracks the rise of HRECs as mechanisms for protecting participant welfare in research involving humans. These started as localised peer review bodies that assessed research in accordance with general and highly discretionary principles of research ethics. A range of decisions about the acceptability of research has subsequently been delegated to HRECs, based on progressively more detailed and rule-based codes. These codes authorise HRECs to modify longstanding ethical and legal interests, provided the HREC is satisfied that specific criteria have been established. An exemplar here is the circumstances in which personal information can be disclosed for research purposes with modified versions of consent (discussed in Part III of this article) and – in some circumstances – in the absence of any consent whatsoever (discussed in Part IV of this article).

Part V explains that, despite the responsibilities with which HRECs have been tasked, the manner in which committees are supported, constituted, and overseen remains closely tied to the localised, peer review model upon which such committees were founded. Few, if any, mechanisms are available for transparency of HREC decisions or reasoning or appeals by researchers or members of the public against such decisions. While HRECs frequently engage in detailed communication with the research applicants, this process and the reasons revealed within it never become part of a public record, limiting opportunities for external scrutiny. Nor are there opportunities to build precedent among HRECs to reach an agreed understanding of the complex criteria upon which waiver of consent decisions must be based.

In Part VI, we suggest two options for moving past this disconnect. Our preferred model would be to reinstate HRECs as a peer review mechanism to assess the broad ethical acceptability of research, with a separate public body responsible for making public interest determinations under privacy laws. This would emulate in many respects the model that operates in England and Wales through the committee known as the Confidentiality Advisory Group ('CAG') and equivalent processes in the Republic of Ireland. In the alternative, HRECs could remain the body responsible for assessing waiver of consent requests but

4 National Health and Medical Research Council, Australian Research Council and Universities Australia, 'National Statement on Ethical Conduct in Human Research: 2007' (Statement, 2007, updated 2018) 21 [2.3.10] <http://www.nhmrc.gov.au/guidelines/publications/e72> ('Updated 2018 National Statement'). See also Table 2 below.

5 See, eg, Christine Critchley, Dianne Nicol and Rebekah McWhirter, 'Identifying Public Expectations of Genetic Biobanks' (2017) 26(6) *Public Understanding of Science* 671 <https://doi.org/10.1177/0963662515623925>.

be provided with greater regulatory scaffolding, including decision-making transparency and rights of review. What cannot stand is the current arrangement: an institutionally-based diaspora of committees empowered to make decisions with weighty legal implications without corresponding mechanisms for support and oversight. This shaky middle ground serves no one adequately, least of all the members of the public whose personal information is being shared without their knowledge or consent.

II A SHIFT FROM PEER REVIEW TO QUASI-TRIBUNAL FUNCTIONS FOR HRECS

A The Rise of Independent Review of Research Involving Humans

The formalisation of codes for the ethical acceptability of research involving humans is often dated to the *Nuremberg Code*[6] and the subsequent World Medical Association's Declaration of Helsinki.[7] In Australia, the first Statement on Human Experimentation was issued by the National Health and Medical Research Council ('NHMRC') in 1966 ('1966 Statement on Human Experimentation'),[8] drawing on the principles set out in the Declaration of Helsinki.[9] These codes are an important milestone for the principles by which research is assessed. At least initially, however, they did not address the required systems for review. Instead, the codes relied on the responsible conduct of individual researchers and oversight by research institutions and colleagues.[10]

By the 1960s, requirements began to emerge for principles of ethical acceptability to be assessed by independent committees, starting with 1963 guidelines issued by the United States ('US') National Institutes of Health.[11] Although some Australian research institutions operated ethics committees from the 1960s, it only became mandatory in 1976, through an amendment to the 1966 Statement on Human Experimentation. The amendment specified the need for review by a medical ethics research committee of all applications to the NHMRC for research grants, as well as the need for all institutions conducting medical research to establish such committees.[12] Further impetus for the growth of research ethics committees came in 1985 when the NHMRC adopted a recommendation that preconditioned

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6 Nuremberg Military Tribunals, *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No 10, October 1946 – April 1949* (1949) vol 2, 181–2 ('*Nuremburg Code*').

7 World Medical Association, 'Declaration of Helsinki: Recommendations Guiding Doctors in Clinical Research' (Declaration, June 1964) <https://www.wma.net/wp-content/uploads/2018/07/DoH-Jun1964.pdf> ('Declaration of Helsinki'). See 'National Statement 2007 on Ethical Conduct' (n 4) 3.

8 National Health and Medical Research Council, 'Statement on Human Experimentation' (Statement, 1966).

9 'Updated 2018 National Statement' (n 4) 3.

10 Robert M Veatch, 'Human Experimentation Committees: Professional or Representative?' (1975) 5(5) *Hastings Center Report* 31, 33 <https://doi.org/10.2307/3561227>.

11 Ibid 32.

12 Donald Chalmers, 'Research Ethics in Australia' in *Ethical and Policy Issues in Research Involving Human Participants: Commissioned Papers and Staff Analysis* (National Bioethics Advisory Commission, August 2001) vol 2, A-1, A-8.

an institution's eligibility for funds from the Council on the institution arranging for an HREC review of *all* research involving humans.[13]

The regulatory landscape for overseeing the ethical acceptability of research shifted once more in 1992 with the passage of the *National Health and Medical Research Council Act 1992* (Cth). Section 8 of the Act authorised the NHMRC to issue ethics guidelines for the conduct of medical research involving humans. This constituted the 'first formal grant of authority for any national agency to issue human research ethics guidelines'.[14]

Coincident with this formalisation of guidelines was an increase in the regulatory standing of HREC review. The Clinical Trial Notification scheme, introduced in 1991, tasked HRECs with assessing the safety of the vast majority of unapproved therapeutic goods being used in clinical trials (as distinct from the Therapeutic Goods Administration, which previously performed such assessments for all clinical trials).[15] Introduction of Australian privacy laws and subsequent guidelines – in particular, the 1991 NHMRC Guidelines for the Protection of Privacy in Medical Research – relied on HRECs to determine the permissibility of disclosures of personal information for medical research.[16] Some state and territory laws also require HREC review for research involving adults and young people without decision-making capacity.[17] Through these changes, HRECs became formal gatekeepers of the acceptability of research activities, rather than a body akin to a peer review mechanism guided by informal collegial norms.[18]

Although it is unlikely to be a complete answer, at least one way of understanding the rise of HRECs is as a means of promoting public trust in, and trustworthiness of, human research. Human research as an enterprise relies on public trust.[19] Trust is generally defined in the literature as 'a willingness by the trustor to be vulnerable

13 Colin Thomson, 'Protecting Health Information Privacy in Research: What's an Ethics Committee like Yours Doing in a Job like This' (2006) 13(3) *Journal of Law and Medicine* 304, 306 ('Protecting Health Information Privacy in Research').

14 Colin Thomson, Kerry J Breen and Donald Chalmers, 'Human Research Ethics Guidelines in Australia' in Susan Dodds and Rachel A Ankeny (eds), *Big Picture Bioethics: Developing Democratic Policy in Contested Domains* (Springer International, 2016) 165, 173 <https://doi.org/10.1007/978-3-319-32240-7_9>.

15 Therapeutic Goods Administration, Department of Health, *Australian Clinical Trial Handbook: Guidance on Conducting Clinical Trials in Australia Using 'Unapproved' Therapeutic Goods* (Handbook, version 2.4, August 2021) 26–7 <https://www.tga.gov.au/sites/default/files/australian-clinical-trial-handbook.pdf?fbclid=IwAR16WHSIqu-SG3NOvN65Knx34lW76xeXoBAdG6NvQ2pMtrDMhGNoywc2QNo>.

16 Privacy Commissioner, 'NHMRC Guidelines for the Protection of Privacy in the Conduct of Medical Research: Privacy Commissioner's Reasons for the Approval of the Guidelines' (Publication, November 1991) app A para 3.7(iv). See also *Privacy Act 1988* (Cth) s 95.

17 See, eg, *Medical Treatment, Planning and Decision Act 2016* (Vic) s 81.

18 For a discussion of the rise of regulatory responsibilities of Institutional Review Boards (HREC equivalents) in the United States ('US'), see generally Sarah Babb, *Regulating Human Research: IRBs from Peer Review to Compliance Bureaucracy* (Stanford University Press, 2020) 20–4 <https://doi.org/10.1515/9781503611238>.

19 Don Chalmers and Dianne Nicol, 'Commercialisation of Biotechnology: Public Trust and Research' (2004) 6(2–3) *International Journal of Biotechnology* 116, 117 <https://doi.org/10.1504/IJBT.2004.004806>.

or to risk being dependent in some way on the trustee'.[20] In the context of human research, trust is expressed in two main ways. At the individual level, individuals providing informed consent to participate in research demonstrate trust in the research team and the broader research ethics system that the research will be conducted as described in the information sheet, and that their data and samples will be used in the way described. At a collective level, the public exhibits trust in the systems that regulate access to and use of personal information when the requirement for consent is waived.

In order for public trust in research to be warranted, regulatory systems need to be trustworthy. The characteristics that constitute trustworthy systems are ability, integrity and benevolence.[21] In the context of waivers of consent, the system is trustworthy if decisions to grant waivers are made by HRECs with the technical capacity to make decisions that are ethically, legally and socially appropriate; decisions are made in accordance with principles that the public finds acceptable; and decisions are made in the interests of potential participants and the public more broadly. Real and/or perceived enhancements to the trustworthiness of the human research enterprise underpin the increasingly detailed criteria that HRECs are required to apply in deciding whether to approve a project – this forms the subject of the following section of this article.

B From Principle-based Frameworks to Rule-based Frameworks

As outlined above, early codes of research ethics were extremely brief and based on high-level principles. However, successive frameworks for HREC decision-making have become increasingly detailed; in particular, following the issuing of the 1999 National Statement on Ethical Conduct in Research Involving Humans ('1999 National Statement'). Professor Susan Dodds has detailed the shift from the 1992 version of the Statement – made up of a list of 13 principles plus 20 pages of supplementary notes – to the 1999 National Statement comprising

> a 66 page document identifying its purpose, 21 relevant ethical principles, the role and functions of HRECs, ethical aspects associated with the review of a range of different kinds of research, a range of privacy issues related to research and a glossary of definitions.[22]

The result, as Dodds notes, is a 'regulatory code of ethical practice or policy' to provide national standards for ethical research conduct, against which HRECs and research proposals can be externally evaluated.[23] In this way, HRECs progressively

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20 Christine Critchley and Dianne Nicol, 'Commercialisation of Genomic Research: The Issue of Public Trust' in Ian Freckelton and Kerry Petersen (eds), *Tensions & Traumas in Health Law* (Federation Press, 2017) 350, 355.

21 Roger C Mayer, James H Davis and F David Schoorman, 'An Integrative Model of Organisational Trust' (1995) 20(3) *Academy of Management Review* 709, 717 <https://doi.org/10.2307/258792>; Bernadette J Richards, Mark Taylor and Susannah Sage Jacobson, *Technology, Innovation and Healthcare: An Evolving Relationship* (Edward Elgar, 2022) <https://doi.org/10.4337/9781788973144>.

22 Susan Dodds, 'Human Research Ethics in Australia: Ethical Regulation and Public Policy' (2000) 19(2) *Monash Bioethics Review* 4, 8 <https://doi.org/10.1007/BF03351236>.

23 Ibid 10.

become a regulatory actor responsible for administering the increasingly detailed National Statement requirements.[24]

A further review of the 1999 National Statement commenced in 2003, with the revised version issued in 2007.[25] The format and content of the revised National Statement remained broadly similar to its predecessor, although the length of the document again increased (from 68 to 107 pages).[26] Since this time, the National Statement has been subject to rolling review with the most recent update being in 2018. The present iteration of the National Statement includes provisions ranging from high-level principles to detailed codes (see Table 1). Despite the prescriptiveness with which many of the provisions are drafted, the authors of the National Statement stress the ongoing role for HREC discretion and judgement. Most notably, section 1 advises that:

> These ethical guidelines are not simply a set of rules. Their application should not be mechanical. It always requires, from each individual, deliberation on the values and principles, exercise of judgement, and an appreciation of context.[27]

In sum, over time, the principles for ethical conduct of human research have become progressively more codified. The upshot is bodies appointed, run, and overseen by individual institutions tasked with interpreting – and subsequently permitting or proscribing – research activities based on lengthy and complex criteria. This involves a fundamentally different landscape from the 'peer group assessment' model initially envisaged for HRECs,[28] guided by high-level professional norms.[29]

The following Part tracks the increasingly regulatory nature of the HREC's role in assessing and authorising modifications to a specific ethical and legal protection when it comes to human research: the requirement for participant consent. As will be shown, deviations from specific, individual-level consent allow researchers to answer potentially important questions, including through the widespread sharing of genomic and other data. However, modifications to consent requirements also have potential implications for trust in, and the trustworthiness of, the human research enterprise. HRECs are presently entrusted with balancing these competing interests based on detailed yet ambiguous regulatory criteria.

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24 Regulatory actors can be defined as 'the organised attempt to manage risks or behaviour in order to achieve a publicly-stated objective or set of objectives; a regulatory system consists of the (sometimes shifting) set of interrelated actors who are engaged in such attempts and their interactions with one another and the dynamic institutional and organisational environment in which they sit': Julia Black, 'Learning from Regulatory Disasters' (2014) 10(3) *Policy Quarterly* 3, 4 <https://doi.org/10.26686/pq.v10i3.4504>.

25 National Health and Medical Research Council, Australian Research Council and Australian Vice-Chancellors' Committee, 'National Statement on Ethical Conduct in Research Involving Humans' (Statement, 2007) ('2007 National Statement').

26 Eliza Goddard and Susan Dodds, 'Consultation, Deliberation and the Review of the National Statement' in Susan Dodds and Rachel A Ankeny (eds), *Big Picture Bioethics: Developing Democratic Policy in Contested Domains* (Springer, 2016) 191, 201 n 12 <https://doi.org/10.1007/978-3-319-32240-7_10>.

27 'Updated 2018 National Statement' (n 4) 11.

28 See Chalmers (n 12) A-8.

29 Babb (n 18) 20.

III CHANGES IN REQUIREMENTS FOR PARTICIPANT CONSENT

Seeking a participant's informed consent has long been a foundational requirement for research ethics.[30] The *Nuremberg Code* was absolute in its approach to informed consent, with the definitive statement in rule 1 that '[t]he voluntary consent of the human subject is absolutely essential'.[31] This approach was softened to some extent in the first iteration of the Declaration of Helsinki, published in 1964, which provided:

> If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.[32]

The traditional model of consent from a research participant was for a particular study with a specific purpose and clearly defined timeframe.[33] Advances in medical technologies and expansion in the types of data being collected have borne witness to a corresponding shift in the approach to consent. There has been a particular focus on human tissue and related data resulting in the establishment of tissue and data repositories/biobanks. Recognition of the valuable nature of such resources has been accompanied by a desire to optimise the research endeavour and extract maximum value from these biospecimens and related data. The capacity for long-term storage of samples and data, and its utility as a resource across potentially multiple projects has further focused attention on the type of data being collected, and the future uses to which it will be put, including data storage, data sharing and potential linkage with other data.

In this data-intensive research environment, with additional advancements in the capacity to link and analyse data, the ground has shifted considerably in terms of how research samples and data from an individual research participant might be deployed. This has moved away from traditional conceptions of consent, which had focused on a single study. Inevitably, this has significantly changed what research participants are being asked to consent to, including consent to store samples and data, to share and link with other data, and to use for future undefined research projects.

New frameworks for consent have emerged to cater for these changing research needs in relation to future use of tissue and data in research. The traditional 'specific consent' has been augmented with acceptance of other forms of consent, including broad consent covering future unspecified use. These new

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30 See generally Jochen Vollmann and Rolf Winau, 'Informed Consent in Human Experimentation before the *Nuremberg Code*' (1996) 313(7070) *British Medical Journal* 1445 <https://doi.org/10.1136/bmj.313.7070.1445>; Austin Connor Kassels and Jon F Merz, 'The History and Policy Evolution of Waivers of Informed Consent in Research' (2021) 41(1–2) *Journal of Legal Medicine* 1 <https://doi.org/10.1080/01947648.2021.1917464>.

31 *Nuremburg Code* (n 6) 181.

32 'Declaration of Helsinki' (n 7).

33 Dankar, Gergely and Dankar (n 2) 468.

understandings of consent were incorporated into the 2007 National Statement. In particular, paragraph 2.2.14 provides that consent may be:

(a) 'specific': limited to the specific project under consideration;
(b) 'extended': given for the use of data or tissue in future research projects that are:
    (i) an extension of, or closely related to, the original project; or
    (ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research);
(c) 'unspecified': given for the use of data or tissue in any future research.[34]

Importantly, the National Statement goes on to clarify that '[t]he necessarily limited information and understanding about research for which extended or unspecified consent is given can still be sufficient and adequate for the purpose of consent',[35] referring back to paragraph 2.2.2, which spells out that voluntary participation 'requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research'.[36] Recognising the far-reaching nature of this form of consent to unspecified future research, the National Statement further stipulates:

> When unspecified consent is sought, its terms and wide-ranging implications should be clearly explained to potential participants. When such consent is given, its terms should be clearly recorded.[37]

By endorsing the ethical permissibility of this approach, this provision answered calls by an influential 2003 Australian Law Reform Commission and Australian Health Ethics Committee Inquiry for clarification of the matter and provision of guidance to researchers.[38] It also addressed concerns voiced by researchers that an overly strict approach to consent could seriously impede genomic research.[39] This expansion of the categories of consent did, however, cast new responsibilities on HRECs in managing this spectrum of consent modalities and increasing the complexity of their workload. One example of this heightened complexity relates to the right of a research participant to withdraw, which remains a fundamental right of those participating in research. In the context of genetic research, this right may in practice be curtailed if tissue samples have been used and data has been shared – all of which must be carefully explained to research participants in advance so that they are aware of any limitations on withdrawal at the time they consent.

Another watering down of the explicit consent requirement has been the inclusion in chapter 2.3 of the 2018 version of the National Statement of an 'opt-out' approach for certain types of projects. The 'opt-out' approach is a method used in the recruitment of participants into research where information is provided

34 'Updated 2018 National Statement' (n 4) 18 [2.2.14].
35 Ibid.
36 Ibid 16 [2.2.2].
37 Ibid 18 [2.2.16].
38 Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia* (Report No 96, May 2003) 91 Recommendation 15–4.
39 Margaret FA Otlowski, 'Tackling Legal Challenges Posed by Population Biobanks: Reconceptualising Consent Requirements' (2012) 20(2) *Medical Law Review* 191, 207–8 <https://doi.org/10.1093/medlaw/fwr035>.

to the potential participant regarding the research and where their participation is presumed unless they take action to decline to participate.[40]

What is clear from this reflection on the evolution of consent in the research context is that there have been significant changes to what is acceptable for consent in response to the changing research environment. Broad or 'unspecified' consent has been codified, adding considerable responsibility for HRECs, and an 'opt-out' approach is possible in very specific circumstances.[41] The following Part of this article discusses the move towards waivers of consent: what may be considered the extreme end of the spectrum when it comes to this shift away from specific consent in the research environment.

IV WAIVERS OF CONSENT FOR HEALTH AND MEDICAL RESEARCH

A Waivers of Consent under Research Ethics Guidelines

Australian research ethics guidelines initially expected that consent would be granted from all participants. Clause 7 of the 1966 Statement on Human Experimentation provided that '[t]he subject or his legal guardian should have given free consent, after comprehending the nature of the study, before research is undertaken'.[42] This was broadly emulated in the 1976 Statement on Human Experimentation.[43]

It was in the 1982 revisions to this Statement that waivers of consent were first mentioned.[44] The newly introduced 'Supplementary Note 2 on Research on Children, the Mentally Ill and Those in Dependent Relationships or Comparable Situations', advised that a waiver was permissible for interventions 'intended or expected to benefit a patient' provided the intervention could reasonably be adopted 'in the interests of the patient'.[45] Interventions that were neither intended

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40 'Updated 2018 National Statement' (n 4) 19. Under paragraph 2.3.6 of the National Statement, before approving an opt-out approach for research, an HREC must be satisfied that involvement in the research carries no more than low risk; that the public interest in the research outweighs the public interest in the protection of privacy; and that the research activity is likely to be compromised if the participation rate is not near complete and the requirement for explicit consent would compromise the necessary level of participation, amongst other requirements: at 21. Paragraph 3.3.15 advises that an opt-out approach should not be used in genomic research: at 49.

41 Ibid 18 [2.2.14(c)].

42 National Health and Medical Research Council, *Report for 1970* (Report, 30 June 1971) 359 <https://trove.nla.gov.au/work/239546353>.

43 National Health and Medical Research Council, 'Statement on Human Experimentation' (Statement, October 1976) cl 7:

> Before research is undertaken, the subject, his legal guardian or next friend shall have given free consent. To this end the investigator is responsible for providing the subject, his legal guardian or next friend, at his level of comprehension, with sufficient information about the purposes, methods, demands, risks, inconvenience and discomforts of the study. If at all possible, consent shall be obtained in writing.

44 National Health and Medical Research Council, 'Statement on Human Experimentation and Supplementary Notes' (Statement, 1982) Addition to Supplementary Note 2 ('1982 Statement on Human Experimentation').

45 Ibid 79.

nor expected to benefit a patient needed to satisfy a longer list of requirements including the absence of material risks and preservation of the confidentiality of information identifying the patient.[46] This approach recognised the potential societal benefits from research of this kind, even if there were no immediate benefits to the patient. It worked from the assumption that patient trust could be maintained – even in the absence of consent from individuals themselves – under conditions where the risks were minimal and the benefit to society sufficiently great.

The list of permissible situations for the granting of a waiver of consent was broadened further in the 1999 National Statement, which expressly recognised the ethical acceptability of conducting certain types of research without obtaining participant consent. This included 'the use of de-identified data in epidemiological research, observational research in public places, or the use of anonymous surveys'.[47] More specific criteria for HREC consideration of waivers of consent were set out with respect to epidemiological research, human tissue research, and genetic research, as detailed in Table 2.

Paragraph 2.3.10 of the 2007 National Statement specified similar but not identical conditions for permitting waivers of consent (see Table 2). The most substantive change was a move from asking whether consent would be 'impossible or difficult or intrusive to obtain' to whether obtaining consent would be 'impracticable'. Consistent with a broader shift towards a more regulatory model of decision-making, HRECs no longer had to just *consider* the criteria for granting a waiver, but had to be *satisfied* that the criteria had been met.

In 2018, the National Statement was further revised, including through the addition of a new chapter 3.3, which specifically addressed genomic research. The chapter envisages that consent may be waived for genomic research in specified circumstances. This includes where the data or information to be accessed or used was previously collected and either aggregated or had identifiers removed;[48] where prior consent for the use of the data or information was provided under the scope of a research program that encompasses the proposed research project[49] or where prior consent for the use of the data or information was provided in the clinical context for research that encompasses the proposed research project.[50]

Evident from this history is a rise in the availability of waivers of consent for an increasingly broad array of research activities. This has been accompanied by a trend in the National Statement towards more specific, rule-based criteria for such waivers, which HRECs are required to apply as a part of their decision-making process.

B Waivers of Consent under Privacy Legislation

Additional principles and procedures governing waivers of consent for the use of personal information in research were enacted through the *Privacy Act*

46 Ibid.
47 National Health and Medical Research Council, 'National Statement on Ethical Conduct in Research Involving Humans' (Statement, 1999) 13 [1.11].
48 'Updated 2018 National Statement' (n 4) 49 [3.3.14(a)].
49 Ibid [3.3.14(b)].
50 Ibid [3.3.14(c)].

1988 (Cth) ('*Privacy Act*'). This Act proscribes the collection, use or disclosure of personal information by Commonwealth government agencies and other organisations defined by the Act, other than in specific circumstances. This Act also allows the Privacy Commissioner to approve guidelines issued by the NHMRC for the protection of privacy in agencies conducting medical research, provided the Commissioner is satisfied that 'the public interest in the promotion of research of the kind to which the guidelines relate outweighs to a substantial degree the public interest in maintaining adherence to the Australian Privacy Principles'.[51] An act done in accordance with these guidelines is deemed not to breach privacy laws.[52]

It fell to the Medical Research Ethics Committee of the NHMRC to draft section 95 of the NHMRC Guidelines – a group of people that reportedly were familiar with principles of medical ethics, but less so with the concept of privacy (then still a new concept in Australia more generally).[53] The NHMRC Guidelines for the Protection of Privacy in Medical Research were issued on 1 July 1991. These were drafted to apply to all medical research reviewed by an HREC (then termed an Institutional Ethics Committee ('IEC')), and specified the need for an HREC to decide on the permissibility of a potential privacy breach based on whether 'the public interest in the proposed research outweighs, or does not outweigh, to a substantial degree the public interest in the protection of privacy'.[54] The Guidelines have since been updated and reissued several times, with the most recent version being the Guidelines under Section 95 of the *Privacy Act 1988* ('2014 Guidelines').[55]

Paragraph 1.2 of the 2014 Guidelines requires an agency that seeks to disclose personal information for medical research without consent to satisfy itself that the research 'has been approved by a[n] … HREC, for the particular research purpose in accordance with these guidelines'. The 2014 Guidelines go on to give HRECs detailed directions on making decisions whether to approve such research:

1. *Capability to Assess*: Before making any decision, an HREC must 'assess whether it has sufficient information, expertise and understanding of privacy issues' in order 'to make a decision that takes proper account of privacy'.[56] No guidance is provided on what is necessary for an HREC to satisfy this criterion, nor what steps should follow should the HREC reach a negative answer.

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51 *Privacy Act 1988* (Cth) s 95.

52 Ibid s 95(4).

53 Thomson, 'Protecting Health Information Privacy in Research' (n 13) 306.

54 Privacy Commissioner (n 16) app A para 3.7(iv).

55 National Health and Medical Research Council, 'Guidelines under Section 95 of the *Privacy Act 1988*' (Guidelines, 2014) <https://www.nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988#block-views-block-file-attachments-content-block-1> ('2014 Guidelines').

56 Ibid 5 [3.1]. See also ibid 5 [3.2(b)], which requires HRECs to

> ensure that the committee has the competence to determine if the public interest in the proposed research outweighs, or does not outweigh, to a substantial degree, the public interest in the protection of privacy. If the public interest in the proposed research does not outweigh, to a substantial degree, the public interest in the protection of privacy, then the research should not be carried out.

2. *Assessment of the Scope of the Breach*: An HREC must then determine what privacy principles would be breached by the proposed research, including 'whether it is necessary for the research to use identified or potentially identifiable data and whether it is reasonable for the research to proceed without the consent of the individuals to whom the information relates'.[57] The HREC also must assess whether it has the competence to determine interests in the proposed research as compared with the public interests in the protection of privacy.[58] Again, no guidance is provided on how an HREC should make this assessment or the steps that should be taken should the answer be in the negative.
3. *Weighing the Public Interest*: The 2014 Guidelines go on to provide an extensive list of criteria for HRECs to consider in order to determine whether the public interest in the proposed research outweighs to a substantial degree the public interest in the protection of privacy (see Table 3).

Similar (but not identical) requirements are set out for medical research involving organisations under section 95A of the *Privacy Act* and the associated Guidelines Approved under Section 95A of the *Privacy Act 1988*.[59] Moreover, some state and territory privacy laws mirror the federal regime by designating HRECs as the bodies responsible for balancing the requisite public interests. For example, the New South Wales ('NSW') Statutory Guidelines on Research: *Health Records and Information Privacy Act 2002* (NSW) ('NSW Statutory Guidelines') applies to the collection and handling of health information by all public and private sector organisations in NSW. The NSW Statutory Guidelines generally replicate the approach adopted in the Federal sections 95 and 95A guidelines, including the requirement that HRECs weigh the public interests in the research activity against the public interest in protecting privacy.[60] This same framework is also adopted in the Victorian Statutory Guidelines on Research Issued for the Purposes of Health Privacy Principles 1.1(e)(iii) & 2.2(g)(iii).[61]

In sum, HRECs play a key, potentially even determinative, role in interpreting the conditions under which personal information can be disclosed for health and medical research in circumstances that otherwise would amount to breaches of privacy laws. In our view, an HREC's role – at least when it comes to authorisations of waivers of consent for the use or disclosure of personal information for medical research – can be described as 'quasi-tribunal'. By this, we mean a body that makes determinations about information-disclosure entitlements based on its

57 Ibid [3.2(a)].
58 Ibid [3.2(b)].
59 See generally National Health and Medical Research Council, 'Guidelines Approved under Section 95A of the *Privacy Act 1988*' (Guidelines, 2014).
60 Information and Privacy Commission (NSW), 'Statutory Guidelines on Research: *Health Records and Information Privacy Act 2002* (NSW)' 13 [1.1].
61 Office of the Health Service Commissioner (Vic), 'Statutory Guidelines on Research Issued for the Purposes of Health Privacy Principles 1.1(e)(iii) & 2.2(g)(iii)' (Guidelines, February 2002) 11 [1.1] <https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0019/171316/guidelines_research-PDF.pdf>.

interpretation of administrative guidelines.[62] Arguably, the quasi-tribunal role applies to HREC decision-making more generally.[63] However, any such broader categorisation goes beyond the scope of this article.

V A MISALIGNMENT BETWEEN GROWING HREC POWERS AND STAGNANT OVERSIGHT AND ACCOUNTABILITIES

Parts II, III and IV of this article have evidenced a progressive shift from the founding model of an HREC as a deliberative body responsible for making discretionary judgments based on broad ethical principles to one of a 'quasi-tribunal', based on increasingly detailed codes of regulatory conduct.

This Part goes on to assess the challenges and controversies associated with this shifting role based on two somewhat competing features of modern HRECs. We start by tracking the growth of HREC powers. One facet of this is the sheer number of decisions for which HRECs are responsible and, more specifically, the number of authorisations for waivers of consent. Moreover, agreements for mutual recognition of HREC decisions mean that decisions that previously applied solely at an institutional level now are commonly accepted (and, indeed, required to be accepted) by other institutions, both within and across states and territories.

Despite this growth in powers, the manner in which HRECs are established and overseen remains almost identical to their 'peer review' roots. There is no structured process for HRECs to share understandings of how key terms should be defined or for settling disagreement among HRECs. The result is the potential for conflicting HREC decisions about the conditions required for a project to be acceptable under the National Statement. In the context of ethical deliberation, differing moral judgments should be expected – and arguably even encouraged based on legitimate differences in the manner in which different HRECs deliberate between competing interests.[64] However, Andrea Seykora et al explain that 'widespread inconsistency can lead to concerns about arbitrariness, unpredictability, inefficiency, and the inadequacy of participant protection'.[65] Potential concerns about inconsistency are especially pronounced once HRECs are recognised as regulators with the power and responsibility to act as gatekeepers with regards to the permissibility of medical research. Accordingly, as HRECs evolve from their peer-review roots, strategies to promote consistency, appeals and other mechanisms for procedural fairness take on increasing importance.

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62 For a broad discussion about defining tribunals in the Australian context, see Robin Handley, 'Research Note: Collecting Information about Tribunals' (1995) 6 *Australian Institute of Administrative Law Forum* 37.

63 Townend and Dove (n 1) 74.

64 Sarah JL Edwards, Richard Ashcroft and Simon Kirchin, 'Research Ethics Committees: Differences and Moral Judgement' (2004) 18(5) *Bioethics* 408 <https://doi.org/10.1111/j.1467-8519.2004.00407.x>.

65 Andrea Seykora et al, 'Steps toward a System of IRB Precedent: Piloting Approaches to Summarizing IRB Decisions for Future Use' (2021) 43(6) *Ethics and Human Research* 2, 2 <https://doi.org/10.1002/eahr.500106>.

A A Growth in HREC Operations and Powers

The HREC review model started as a means of addressing what appeared to be an ethically challenging model of human subject research – the use of healthy volunteers – but has since evolved into an oversight mechanism for all health and medical research.[66] As detailed in Part II, in Australia and internationally this subsequently morphed into a review mechanism encompassing all human subject research, whether or not it was medical. According to NHMRC data, over the course of 2020, the 195 registered HRECs reviewed a total of 15,575 research proposals.[67]

Authorisations for waivers of consent for health and medical research have followed a similar upwards trajectory. Notably, the Australian Privacy Commissioner's initial approval of the NHMRC Guidelines for the Protection of Privacy in Medical Research raised some concerns about the use of HRECs (then termed IECs) as the approving body for waivers of consent. However, in the Commissioner's view, a tempering factor was that 'most IECs will never be called upon to consider research proposals involving access in identifiable form to Commonwealth records of personal information'.[68] This is far from the current reality. Waiver of consent applications and approvals are now commonplace for access to Commonwealth agency and organisational data. In 2017,[69] the most recent year for which information is available, HRECs reviewed 57 applications under the section 95 guidelines (56 of which were approved) and 144 applications under the section 95A guidelines (144 of which were approved).[70] Although the numbers of waivers issued under state and territory privacy laws are not consistently reported, these are likely to be even greater. In NSW, for example, in 2019–20, HRECs reported 516 proposals to use or disclose personal or health information without consent, of which 460 were approved.[71]

The referral of review responsibilities to HRECs under privacy guidelines comes with significant legal implications. Release of personal information by a Commonwealth agency or organisation without an (adequate) HREC authorisation would constitute a breach of the *Privacy Act*.[72] This implicates HRECs in assessing

66 See Laura Stark, *Behind Closed Doors: IRBs and the Making of Ethical Research* (University of Chicago Press, 2012) 4 <https://doi.org/10.7208/chicago/9780226770888.001.0001>.

67 National Health and Medical Research Council, *Report on the Activity of Human Research Ethics Committees and Certified Institutions for the Period: 1 January 2020 to 31 December 2020* (Report, October 2021) 12.

68 Privacy Commissioner (n 16) 27.

69 This is the most recent year for which the NHMRC has published the number of applications reviewed and approved by HRECs under the section 95 and section 95A guidelines in its annual publication: National Health and Medical Research Council, *Report on the Activity of Human Research Ethics Committees and Certified Institutions* (Report, November 2018) <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/2017-activity-report.pdf>.

70 Ibid 37, 44.

71 Information and Privacy Commission (NSW), *Annual Report 2019/20* (Report, November 2020) 39 <https://www.ipc.nsw.gov.au/sites/default/files/2020-12/IPC_Annual_Report_2019_20__0.pdf>.

72 The data custodian will also have independent legal responsibilities to assess the merits of disclosure, as discussed in Felicity Flack, Carolyn Adams and Judy Allen, 'Authorising the Release of Data without Consent for Health Research: The Role of Data Custodians and HRECs in Australia' (2019) 26(3) *Journal of Law and Medicine* 655. The authors provide evidence from data custodians, however, that it would be highly unusual to refuse an application that has received HREC approval.

compliance with privacy laws: departing from standard understandings that ethics and law are distinct and separable activities.[73] Moreover, an HREC that purported to authorise the release of information without following the guidelines also could constitute grounds for a complaint, potentially subject to remedies.[74] As Professor Colin Thomson – an expert in health law and ethics who was closely involved in drafting the 2007 National Statement – explains:

> The legalisation of part of the HREC process changed the consequences for their members of the exercise of their responsibility. The fact that a mistaken approval of disclosure of personal information could result in a breach of the legislation (by an agency) and a determination of the payment of compensation was an unfamiliar legal vulnerability.[75]

B Powers for HREC Decisions to Apply across Institutions (and across Jurisdictions)

A foundational tenet of when HRECs and their international counterparts were established was individual institutional judgment, with the idea that the decisions required by these committees were highly discretionary and dependent upon local knowledge and conditions. For this reason, codes of research ethics were drafted intentionally broadly and their application by individual committees was not amenable to appeal. In her pivotal account of the genesis of Institutional Review Boards ('IRBs') in the US, Laura Stark cites the 1966 memorandum sent to the heads of research institutions who were required to establish IRBs as a condition of their National Institute of Health funding. The memorandum advised institutions that:

> The wisdom and sound professional judgment of you and your staff will determine what constitutes the rights and welfare of human subjects in research, what constitutes informed consent, and what constitutes the risks and potential medical benefits of a particular investigation.[76]

However, the landscape within which HRECs and IRBs operate has shifted substantially over this time. In particular, many HREC decisions no longer apply solely to their establishing institution. The 1990s saw a rapid growth in multicentre trials,[77] conducted across Australian jurisdictions and national borders. The result was huge duplication in the ethical reviews needing to be conducted and consequent pressures for establishing a system for single ethical review.[78]

Australian states, initially led by NSW in 2007, developed models for single ethical review of multicentre research, whereby any one research project would be reviewed by only one HREC within the state.[79] The NHMRC soon followed with

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73 Beth Gaze, 'Privacy and Research Involving Humans' (2003) 10(4) *Journal of Law and Medicine* 410, 415.

74 Thomson, 'Protecting Health Information Privacy in Research' (n 13) 307.

75 Ibid.

76 Stark (n 66) 154, quoting William H Stewart, 'Memorandum to the Heads of Institutions Receiving Public Health Service Grants from the Surgeon General' (Memorandum, 8 February 1966).

77 Kerry J Breen, 'Ethical Review of Multi-centre Research: Obstacles to Reform' (2005) 12(1) *Australasian Epidemiologist* 21, 21.

78 Helen E Fraser, Ainsley E Martlew and Deborah J Frew, 'Model for a Single Ethical and Scientific Review of Multicentre Research in New South Wales' (2007) 187(1) *Medical Journal of Australia* 7, 7 <https://doi.org/10.5694/j.1326-5377.2007.tb01106.x>.

79 Ibid.

a national model for harmonising single ethical review, which became operational in 2011: the Harmonisation of Multi-centre Ethical Review ('HoMER') initiative. A core component of HoMER was certification of institutions and institutional HRECs to ensure that the ethics review process was consistent with agreed national standards.[80] Alongside the implementation of HoMER were memoranda of understanding between Victoria, NSW and Queensland to agree to cross-jurisdictional acceptance of reviews conducted by HRECs within their public health organisations. This became known as the National Mutual Acceptance ('NMA') scheme, and now encompasses all Australian states and territories.[81]

Single ethical review systems mean that one HREC's decision to approve a waiver of consent for the use of personal information in research can then apply to other institutions, including across jurisdictional boundaries. This has clear efficiency dividends. However, it also increases the magnitude of risk created by one HREC's overly broad (or narrow) interpretation of the waiver of consent provisions.

C Interpreting and Applying the Criteria

The increasingly rule-based nature of research ethics guidelines, such as the National Statement, imposes challenging interpretive responsibilities on HRECs. Consider, for example, the requirement for an HREC to assess the 'impracticability' of obtaining consent prior to authorising a waiver. No definition of impracticability is included in the National Statement, other than the explanation that it might apply 'due to the quantity, age or accessibility of records'.[82] Clearly, this is intended to be more encompassing than the previous version of the National Statement: that is, that obtaining consent would be 'impossible in practice'. But just how far does 'impracticability' extend? The Office of the Australian Information Commissioner's 2019 Australian Privacy Principles Guidelines provides examples of impracticability as including:

- the integrity or validity of health research could be impaired, for example, because the organisation is conducting a participant observation study and obtaining the consent of participants may alter their behaviour and the research results. Consideration could be given to consulting a human research ethics committee as to whether obtaining consent would have this effect
- where obtaining the individual's consent would adversely impact an investigation or monitoring activity
- there are no current contact details for the individual and the organisation has insufficient information to obtain up-to-date contact details.[83]

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80 Tegan Cox, *Review and Evaluation of the National Certification Scheme for Institutional Ethical Review Processes* (Final Report, 21 November 2016) 6–7 <https://www.nhmrc.gov.au/sites/default/files/documents/reports/ncs-evaluation.pdf>.

81 'National Mutual Acceptance', *NSW Health & Medical Research* (Web Page) <https://www.medicalresearch.nsw.gov.au/national-mutual-acceptance/>.

82 'Updated 2018 National Statement' (n 4) 21 [2.3.10(c)].

83 Office of the Australian Information Commissioner, 'Australian Privacy Principles Guidelines' (Guidelines, July 2019) 5 [D.16] <https://www.oaic.gov.au/__data/assets/pdf_file/0012/1236/app-guidelines-chapter-d-v1.1.pdf>.

The final of these bullet points especially suggests the intention of a broad interpretation of 'impracticable', similar to the definition provided in the *Macquarie Dictionary* (something 'that cannot be put into practice with the available means').[84] On the other hand, 'impracticable' has been defined in the waiver of consent provisions in Canada's Tri-council Policy Statement as going beyond mere inconvenience to 'a degree of hardship or onerousness that jeopardizes the conduct of the research'.[85] We have no way of knowing how HRECs are interpreting this term, nor a clear standard for how the term *should* be interpreted.

Similarly, the National Statement requires a reviewing HREC to assess whether there is any known or likely reason for thinking that participants would not have consented if they had been asked ('presumed consent').[86] But the National Statement fails to specify any mechanism through which researchers should evidence presumed consent (eg, requirements for public engagement activities). Nor is it clear what level of assent (if any) among potential participants is consistent with the criteria: A simple majority? A clear majority? All or nearly all?[87]

Interpretive challenges may be heightened by a lack of the necessary legal and technical expertise to make decisions about waiver of consent applications. The composition of HRECs is intentionally broad: a diversity that makes sense in the context of reviewing the ethical acceptability of research. However, HREC membership may be insufficient for tasks of complex legislative interpretation. In particular, often only one HREC member will be legally trained, and this training may not include in-depth knowledge of privacy laws. Roger S Magnusson has further noted that HREC members more generally have expertise in 'assessing the impact of medical decisions upon individual welfare' as compared with 'weighing competing public interest considerations in order to determine where the balance of public welfare lies' – the task required of them under privacy laws.[88] Finally, members are appointed by institutions, largely on a voluntary basis: an anomalous set-up for a group empowered to waive legal responsibilities.[89] The result is a committee whose composition is arguably insufficient to satisfy its privacy law functions, particularly given the interpretive challenges with which HRECs must grapple.

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84 *Macquarie Dictionary* (online at 12 March 2023) 'impracticable' (def 1).

85 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, 'Tri-council Policy Statement: Ethical Conduct for Research Involving Humans' (Statement, 2018) 196.

86 Angela Ballantyne and G Owen Schaefer, 'Taxonomy of Justifications for Consent Waivers: When and Why Are Public Views Relevant?' (2019) 45(5) *Journal of Medical Ethics* 353, 353 <https://doi.org/10.1136/medethics-2018-105318>.

87 Ibid.

88 Roger S Magnusson, 'Confidentiality and Consent in Medical Research: Some Recurrent, Unresolved Legal Issues Faced by IECs' (1995) 17(4) *Sydney Law Review* 549, 569.

89 Colin JH Thomson, 'Records, Research and Access: What Interests Should Outweigh Privacy and Confidentiality? Some Australian Answers' (1993) 1(2) *Journal of Law and Medicine* 95, 105 (citations omitted).

D Non-transparency

Adding to the challenge of the ambiguity of many criteria for authorising a waiver of consent is the lack of knowledge about how HRECs are interpreting these terms, or strategies for generating precedent on how these terms *should* be interpreted. Despite compelling arguments that HRECs should be considered public bodies, and thereby subject to requirements (among others) to publish reasons for their decisions,[90] HREC deliberations are commonly assumed to be confidential.[91] The National Statement requires institutions to 'make publicly accessible (for example in annual reports) summary descriptions of all its research projects for which consent has been waived'. However, this responsibility only arises once the research has been completed and does not require that the HREC provide any reasons for its decisions.[92] Institutional compliance with this requirement also appears to be limited.

A small number of Freedom of Information applications have been lodged to seek additional information on HREC processes and procedures. Tribunals and information commissioners have varied in their willingness to release this information. The Western Australian Acting Information Commissioner, in the determination of *Re Whitely and Curtin University of Technology*,[93] set a standard of openness for the HREC deliberative process under the *Freedom of Information Act 1992* (WA). In this case, a member of the Western Australian Parliament sought information about a research project being run at Curtin University investigating medicines for children with attention deficit hyperactivity disorder. In requiring the University to release the HREC application and deliberations, the Acting Information Commissioner noted the 'strong public interest in favour of the public being able to scrutinise an HREC approval and make its own judgment as to whether the HREC is discharging its functions properly'.[94] Disclosure also was required based on public interest grounds in *Battin v University of New England*,[95] in which a researcher sought access under the *Government Information (Public Access) Act 2009* (NSW) ('*GIPA Act*') to information about complaints that had been made about their research project.

On the other hand, the 2015 decision of the NSW Civil and Administrative Tribunal, *Raven v The University of Sydney* demonstrated a reluctance to release information about an HREC approval process.[96] The matter involved a dispute about the safety of a clinical trial approved by the University's HREC. The complainant applied under the *GIPA Act* for access to the trial protocol, information sheets, HREC minutes, and expert reviews. With the exception of the revised information sheet, the Administrative Decisions Tribunal supported non-disclosure, based, in

90 Grant Davies and Lynn Gillam, 'Articulation and Transparency of Decision-Making by Human Research Ethics Committees' (2007) 26(1–2) *Monash Bioethics Review* 46 <https://doi.org/10.1007/BF03351465>.

91 Lynn Gillam, 'Secret Ethics Business?' (2003) 22(1) *Monash Bioethics Review* 52, 53 <https://doi.org/10.1007/BF03351387>.

92 'Updated 2018 National Statement' (n 4) 22 [2.3.12].

93 [2008] WAICmr 24.

94 Ibid 24 [94] (Acting Commissioner Lightowlers).

95 [2013] NSWADT 73.

96 [2015] NSWCATAD 104.

particular, on concerns about the potential for disclosure to prejudice the supply of confidential information to HRECs in the future. The Acting Freedom of Information Commissioner followed similar reasoning in declining to require the release of information relating to the submission of the University Sexual Assault and Sexual Harassment Project to the University of New South Wales HREC under the *Freedom of Information Act 1982* (Cth).[97]

The level of transparency required for HREC deliberations about waiver of consent applications is yet to be tested. Arguably, the public interest in disclosing information relating to an HREC's decision to authorise a waiver of consent is greater than for other kinds of research reviews given the public nature of the interests at stake. As Thomson has noted,

> it is anomalous that decisions that have the potential to conflict with the public's expectations about privacy – by approving use or disclosure of health information without consent – are made by private citizens, whose public accountability is indirect at the very best.[98]

E Limited Substantive Oversight or Appeals Mechanisms

The National Statement places the responsibility on an establishing institution to ensure that its human research is 'ethically reviewed and monitored in accordance with [the] National Statement'.[99] Institutions must register their HRECs with the NHMRC, and report annually on HREC operations. Yet any accountability required as a condition of NHMRC registration is procedural and based on institutional self-regulation. Institutions must report, for example, on their HRECs' composition, processes for considering research proposals, reporting arrangements, and complaint-handling mechanisms. However, no external independent auditing applies to an HREC's substantive decisions.[100] Under chapter 5.6 of the National Statement, institutions must establish mechanisms to deal with complaints about research, the conduct of research, and the conduct of HRECs.[101] Where necessary, this should include access to an independent person to handle the complaint.[102] Additional accountability applies to those HRECs certified under the NMA and HoMER. Certified HRECs must demonstrate the availability of terms of reference and standard operating procedures, provision of annual reports, and so forth.[103] Yet, there is no independent assessment of the applications an HREC has approved. In fact, the National Statement expressly precludes appeals of HREC decisions

97 *Seven Network Operations Ltd and Australian Human Rights Commission* [2021] AICmr 66 [144]–[150] (Acting Commissioner Hampton).

98 Thomson, 'Protecting Health Information Privacy in Research' (n 13) 309.

99 'Updated 2018 National Statement' (n 4) 83 [5.1.1(b)].

100 Susan Dodds, 'Is the Australian HREC System Sustainable?' (2002) 21(3) *Monash Bioethics Review* 43, 47 <https://doi.org/10.1007/BF03351274>.

101 'Updated 2018 National Statement' (n 4) 98.

102 Ibid [5.6.5].

103 National Health and Medical Research Council, *Certification Handbook: National Certification Scheme of Institutional Processes Related to the Ethical Review of Multi-centre Research* (Handbook, November 2012) <https://www.nhmrc.gov.au/about-us/publications/certification-handbook>.

to reject a proposal given '[t]here can be justifiable differences of opinion as to whether a research proposal meets the requirements of this National Statement'.[104]

Privacy laws provide an additional avenue for accountability via state and federal commissioners. In each annual report, HRECs must advise the NHMRC on waivers of consent under the privacy guidelines that they have received and details of the outcomes of the requests. At the federal level, the Australian Information Commissioner is empowered to investigate complaints about acts or practices that may be an interference with the privacy of an individual.[105] Based on the outcome of any such investigation, the Commissioner may make a non-binding determination, including that an agency or organisation must take steps and/or provide compensation to redress any loss or damage that an individual has suffered due to an infringement of their privacy.[106]

The only determination that has been issued by the Privacy Commissioner in regard to the privacy guidelines is *'PA' and Department of Veterans' Affairs (Privacy)*.[107] This dispute arose from a complaint against the Department of Veterans' Affairs ('DVA') for releasing personal information to the Australian Institute of Health and Welfare for the purposes of a 'Study Roll' to aid the recruitment of ex-service personnel into research projects. The question for the Commissioner was specified (and accepted) as one of *scope*: to what extent did generating the Study Roll satisfy the definition of an act of disclosure made 'in the course of medical research', which would thereby fall within section 95(4)(b) of the *Privacy Act*. The Commissioner ultimately answered this question in the affirmative, and satisfied himself that the HREC and DVA had complied with the procedural requirements of the guidelines. However, no further review was undertaken of the *merits* of the HREC's approval decision under the waiver of consent criteria (for example, whether there was 'no known or likely reason for thinking that participants would not have consented if they had been asked').[108]

Further, individuals may apply to the Administrative Appeals Tribunal under section 96 of the *Privacy Act* for merits review of determinations made by the Commissioner. In practice, this avenue is likely only available to individuals who are unhappy with the collection, use or disclosure of their information, and therefore objecting to an HREC's decision to grant a potentially inappropriate waiver, rather than researchers objecting to an HREC's *refusal* to grant a waiver.[109] After exhausting these avenues, it is possible that a complainant may be able to apply for judicial review, either by state Supreme Courts or under the *Administrative Decisions (Judicial Review) Act 1977* (Cth).[110] This has never been tested in Australian courts, however, and would depend upon whether HREC decisions are found to be exercises of public power, and whether waiver decisions are found

104 'Updated 2018 National Statement' (n 4) 98.
105 *Privacy Act 1988* (Cth) s 36A.
106 Ibid s 52.
107 [2018] AICmr 50.
108 'Updated 2018 National Statement' (n 4) 20 [2.3.2].
109 Rebekah McWhirter, 'Holding Human Research Ethics Committees to Account: A Role for Judicial Review?' (2022) 43(1) *Adelaide Law Review* 377, 384.
110 Ibid.

to be decisions 'of an administrative character made … under an enactment'.[111] While a reasonably strong case can be made that waiver decisions are justiciable, the fact that no such case has come before the courts is evidence of the practical difficulties in doing so – because HREC reasons are not published, most potential complainants will not have sufficient access to the relevant information to contest an unfavourable HREC decision using judicial review mechanisms.

Once an HREC has approved the waiver of consent, a research institution's responsibility is essentially to satisfy itself that the research involving the use of the personal information has been approved by an HREC. Presumably, this can be achieved simply through the receipt of an approval letter. For publicly collected health data, a data custodian (typically a high-level employee of a government agency) also will need to exercise their own discretion on the facts and merits prior to disclosure based on the authorising statute for the data collection. This may require (among other criteria) the data custodian to make an assessment of the public interests involved in releasing the data without consent.[112] For example, section 284 of the *Public Health Act 2005* (Qld) states:

> (1) The chief executive must consider the application for health information held by a health agency as soon as practicable and either grant or refuse the application.
>
> (2) The chief executive may grant the application only if the chief executive is satisfied –
>
> (a) the giving of the health information held by a health agency is in the public interest, having regard to –
>
> (i) the opportunities the research will provide for increased knowledge and improved health outcomes; and
>
> (ii) the privacy of individuals to whom the health information relates; and
>
> (b) the identification of any person by the information is necessary for the relevant research.

Where a data custodian is required to make a public interest determination under the authorising statute, legal scholars have argued that the responsibility cannot simply be delegated by, for example, accepting an HREC decision on what is in the public interest.[113] However, data custodians have raised questions about how well they are equipped to make assessments of the public interests in research, as compared with HRECs. As one data custodian stated in an interview for the data custodian study, conducted in 2017 by Judy Allen, Carolyn Adams and Felicity Flack:

> There's not really a good set of guidelines around what constitutes public interest. So, the legislation refers to the concept and the fact that there's a delegation or an approval point for the Minister to do that but, yeah, as often as not we lean more upon the consideration of ethics for looking at public interest.[114]

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111 *Administrative Decisions (Judicial Review) Act 1977* (Cth) s 3(1).

112 Judy Allen, Carolyn Adams and Felicity Flack, 'The Role of Data Custodians in Establishing and Maintaining Social Licence for Health Research' (2019) 33(4) *Bioethics* 502, 508 <https://doi.org/10.1111/bioe.12549>.

113 Flack, Adams and Allen (n 72) 657.

114 Allen, Adams and Flack (n 112) 509.

Another data custodian, when asked about the role of ethics approval in their own decision-making, advised:

> Probably, [ethics approval provides] the confidence that the research they are undertaking is in the public interest … and I could never, I can't say never, but I don't think I'd ever receive an application that had HREC approval where we'd knock them back. That would be the first time, I think.[115]

The result is the ability of individual HRECs to assess the waiver of consent criteria, and make determinations based on these assessments, often with few additional checks and balances. Although data custodians will exercise their independent discretion prior to releasing the public datasets, with such release decisions being subject to standard administrative law appeals channels, these decisions are based on different criteria and often lean heavily on HREC approvals.[116] In some respects, HRECs' ownership in this space is understandable – and perhaps even optimal in the current research governance landscape. As noted by Allen, Adams and Flack, HRECs have better guidance, training, and composition to make public interest assessments when it comes to the release of data without consent.[117] Yet, the question remains whether there are other models from which lessons can be drawn to improve authorisations of waivers of consent in research, which could retain the strengths of HRECs (consultative, diverse expertise, community members) while also adopting the checks and balances of administrative law.

VI THE FORK IN THE ROAD FOR HRECS' ROLES IN AUTHORISING WAIVERS OF CONSENT

Evident from the above discussion are gaps in the ability to ensure that HRECs make well-founded and accountable decisions to authorise waiver of consent applications under privacy legislation. Some of these gaps – whether in accountability or performance – may be rectified through incremental changes to the HREC system itself. Others suggest a more fundamental disconnect between the peer review foundations of HRECs and their more recent quasi-tribunal role. Governance strategies that may be pertinent in the context of ethical deliberation – for example, a proscription on substantive appeals from HREC decision-making – are counterintuitive in the context of a body empowered to waive substantive legal rights. In Part VI, we outline some general changes that could be made to strengthen HRECs' roles in authorising waivers of consent. We go on to suggest, however, that any such fixes will be insufficient. Instead, a broader rethink is required of the suitability of HRECs as the authorising body for waivers of consent. We use the systems that have been established in the United Kingdom ('UK') and the Republic of Ireland as exemplars of the kind of demarcation between HREC review and waivers of consent that may warrant consideration in the Australian context. We will see they operate in ways more conducive to achieving national consistency

115 Flack, Adams and Allen (n 72) 668.
116 Ibid 669.
117 Allen, Adams and Flack (n 112) 509.

and transparency. They also provide greater opportunity for coordinated public engagement. We conclude by outlining in more detail what such an Australian system could look like.

A Strengthening HREC Operations

To some extent, HREC authorisations of waivers of consent will be improved through strategies to better support their regulatory role.

1. *Precedent-building activities*: A core feature of Australian common law is judicial precedent. Precedent has a less formalised position when it comes to merits review in Australian tribunals, given their overriding duty of ensuring that 'the correct or preferable decision is made in the individual case before the tribunal'.[118] Acknowledging, however, that precedent may not be binding in tribunal systems, Trevor Buck has explained that:

> Inevitably, however, general principles do emerge, for the very good reason that an each-case-on-its-own-facts (or merits) approach leads before very long to an inconsistency problem. Demands too for predictability of decision, both from lawyers and from those engaged in the business or industry affected by the tribunal's decisions, contribute to the eventual establishment of an informal de facto system of precedent.[119]

   In this way, general principles operate alongside the individual merits of a case 'to reach the right decision in the circumstances of the moment'.[120] A similar system could support HRECs operating as quasi-tribunals, including in the review of waivers of consent for the use and disclosure of personal information. A system for making previous decisions available to US IRBs has recently been piloted. Despite some practical challenges that arose in seeking to establish the pilot, the researchers noted that:

> If a group of IRBs could form a shared commitment to work through these issues, one could envision the IRB review process becoming not only more consistent but also more transparent, robust, and effective in protecting research subjects. Through the ongoing dialogue of a shared body of precedent, IRBs could evaluate one another's decisions by considering, in the context of another study under review, whether to agree with them, refine them, or disagree with them – and why.[121]

2. *Substantive oversight of HREC decision-making*: The generation of bodies of precedent could be further supported through the availability of substantive oversight of HREC decision-making. This is not presently included in the Australian framework, limiting the scope for HREC accountability; that is, the need for HRECs to justify their decisions based

118 Peter Cane, 'Judicial Review and Merits Review: Comparing Administrative Adjudication by Courts and Tribunals' in Susan Rose-Ackerman and Peter L Lindseth (eds), *Comparative Administrative Law* (Edward Elgar, 2010) 426, 437 <https://doi.org/10.4337/9781849808101>.

119 Trevor Buck, 'Precedent in Tribunals and the Development of Principles' (2006) 25 (October) *Civil Justice Quarterly* 458, 463.

120 Ibid 464, quoting HWR Wade and CF Forsyth, *Administrative Law* (Oxford University Press, 9th ed, 2004) 931–2.

121 Seykora et al (n 65) 15.

on an agreed set of norms of conduct.[122] Some other countries have public authorities with responsibility for sharing and enforcing such norms. In the US, for example, the Office for Human Research Protections has the legislative responsibility of overseeing IRB compliance with regulations for the protection of research participants. This includes investigating allegations of noncompliance as well as a program of not-for-cause surveillance evaluations.[123] In the UK, the Health Research Authority ('HRA') has responsibility for developing quality assurance programs for research ethics committees, including regular monitoring in auditing.[124]

While measures to strengthen the operation of HRECs will provide important benefits for medical research and participant welfare, they fail to resolve the fundamental disconnect that lies at the heart of delegating, for all practical purposes, waiver of consent reviews to HRECs. That is, a shift in HREC function from their intended role of ethical deliberation to one of 'privacy policing'.[125] This subverts HREC responsibility from one primarily focused on protecting participants to one that also must take into account protecting institutions from legal liability. Interviews with Australian health researchers have raised these very concerns. One researcher and HREC member reportedly stated:

> I think ethics committees have become so bound up in the procedure part of it and the legal ramifications of not doing their jobs that they've actually forgotten what research is about. So they've forgotten about the research ethics ... I don't think they're sort of really concerned about the ethics, I think they're concerned about the legal constraints or the legal implications of what research might mean. You know, the possibility of being sued or whatever, rather than their responsibilities to researchers and participants and the ethics of both.[126]

The researchers came to the view that tensions stemming from ethics committees working to protect institutions (as compared with protecting participants) 'lead to poor relationships between ethics committee members and researchers'.[127] The damage to relationships between researchers and HRECs that may result from HRECs taking on a policing function were recognised as early as 1998 by Donald Chalmers and Philip Pettit, when they warned against a review process

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122 Jane Nielsen et al, 'Integrating Public Participation, Transparency and Accountability into Governance of Marketing Authorisation for Genome Editing Products' (2021) 3 (October) *Frontiers in Political Science* 1, 5 <https://doi.org/10.3389/fpos.2021.747838>.

123 Office for Human Research Protections, 'Compliance & Reporting', *Department of Health and Human Services (US)* (Web Page, 11 February 2016) <https://www.hhs.gov/ohrp/compliance-and-reporting/index.html>.

124 Health Research Authority, National Health Service (UK), 'Governance Arrangements for Research Ethics Committees: 2020 Edition' (Policy Document, 20 July 2021) annex E <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/>.

125 Gaze (n 73) 416.

126 Marilys Guillemin et al, 'Human Research Ethics Committees: Examining Their Roles and Practices' (2012) 7(3) *Journal of Empirical Research on Human Research Ethics* 38, 42–3 <https://doi.org/10.1525/jer.2012.7.3.38>.

127 Ibid 45.

> presented as a struggle between those of a single scientific mind, who want to pursue their research ambitions at any cost, and those of a single ethical mind, who have to try to keep the researchers honest. There is no room left in the scenario for the possibility of the two sides coming to a common mind on relevant matters.[128]

Paul McNeill expanded on these concerns, stressing the need to reframe the relationship between HRECs and researchers to one based on principles rather than rules, and discussion and exploration rather than control. He advocates, in particular, for

> committees freed from the burden of excessive detail, in order to develop an understanding of ethics as part of an overall ethical enterprise. This means supporting good research and researchers, playing a part in the education of researchers, being alert to systemic issues and problems in the institution, and having the time to discuss and explore difficult ethical issues in the relatively few cases where they arise. … To continue to treat ethics committees as instruments of bureaucratic regulation and control is to misunderstand the nature and meaning of ethics.[129]

More recently, Angus Dawson and colleagues have called for a shift away from a legalistic approach to research ethics, wherein guidelines are framed as rules to be applied without exception. They go on to suggest that

> it is time to return *ethics* to the heart of research ethics review. This alternative view sees ethics as being very different, not so much an application of rules, which primarily seem to provide legal protection for the institution, but rather being about developing people's capacity to be sensitive to the relevant moral features of the particular research context, and taking responsibility for the moral judgments that arise from responding to the dynamic nature of each individual piece of research.[130]

It is time to fundamentally reconsider the breadth of roles with which HRECs have been assigned; in particular, entrusting HRECs with what can best be characterised as legal and compliance responsibilities. It is far preferable to allow HRECs to do the job for which they were instituted – collegial deliberations on the ethical acceptability of human research – and instead to delegate compliance activities to other entities.

B Looking to Alternative Models: The United Kingdom and Republic of Ireland

Processes and institutions that have been implemented in the UK and the Republic of Ireland to authorise waivers of consent provide an alternative model for consideration. Authorisation to waive consent requirements, and to enable research to proceed in circumstances where it may not otherwise be lawful, is provided via different processes in the jurisdictions.[131] Both have processes for

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128 Donald Chalmers and Philip Pettit, 'Towards a Consensual Culture in the Ethical Review of Research' (1998) 168(2) *Medical Journal of Australia* 79, 81 <https://doi.org/10.5694/j.1326-5377.1998.tb126720.x>.

129 Paul M McNeill, 'Research Ethics Review and the Bureaucracy' (2002) 21(3) *Monash Bioethics Review* S72, S73 <https://doi.org/10.1007/BF03351280>.

130 Angus Dawson et al, 'Why Research Ethics Should Add Retrospective Review' (2019) 20(1) *BMC Medical Ethics* 68:1–8, 2 (emphasis in original) (citations omitted) <https://doi.org/10.1186/s12910-019-0399-1>.

131 In Scotland and Northern Ireland, there is no specific statutory basis for authorising use or disclosure without patient consent.

granting waivers that are governed and empowered by statute.[132] There are different approaches to waiver of consent in the Republic of Ireland to those in the UK. The UK has different schemes operating in Northern Ireland,[133] Scotland,[134] and England and Wales.[135] Here we focus on two statutory schemes relevant to the CAG in England and Wales in the UK, and the Health Research Consent Declaration Committee ('HRCDC') in the Republic of Ireland, which have particular relevance in illustrating alternative approaches available to Australia.

The English scheme for consent waiver is shaped, to some extent, by its history and provenance in the response to scandalous uses of patient data and tissue without consent at the turn of the century.[136] The Irish scheme is more recent and has been crafted with knowledge and understanding of how such a scheme might fit with modern data protection legislation, in particular the European Union *General Data Protection Regulation*.[137] However, common to the operation of both statutory schemes is a commitment to transparency, an opportunity for consistency, and a centralised and coordinated approach to public engagement. Each also has a formal process of appeal. In light of the gaps identified with the current Australian system, these are significant features which provide important insight into how our system could be improved.

1 Transparency

In England and Wales, section 251 of the *National Health Service Act 2006* (UK) re-enacted statutory authority for the Secretary of State to make regulations in relation to the processing of patient data.[138] The *Health Service (Control of Patient Information) Regulations 2002* (UK) SI 2002/1438 ('*COPI Regulations*') provides lawful grounds for the processing of confidential information for medical purposes, defined to include 'medical research … and the management of health and social care services'.[139] Approval for such processing is given, in the case of medical research by the HRA, and in any other case (ie, non-research use) by the

132 In England and Wales, the relevant statutory instrument is the *Health Service (Control of Patient Information) Regulations 2002* (UK) SI 2002/1438 ('*COPI Regulations*'), laid under section 251 of the *National Health Services Act 2006* (UK) (originally section 60 of the *Health and Social Care Act 2001* (UK) ('*Health and Social Care Act*')). In Ireland, it is the *Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018* (Ireland) SI 2018/314 ('*Health Research Regulations 2018*').

133 The *Health and Social Care (Control of Data Processing) Act (Northern Ireland) 2016* (UK) provides for establishment of a committee that is to supersede the non-statutory Privacy Advisory Committee.

134 Public Benefit and Privacy Panel in Scotland. See 'NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP)', *Information Governance* (Web Page) <https://www.informationgovernance.scot.nhs.uk/pbpphsc/>.

135 The CAG in England and Wales. See 'Confidentiality Advisory Group', *Health Research Authority* (Web Page) <https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/>.

136 Joan Higgins, 'The Patient Information Advisory Group and the Use of Patient-Identifiable Data' (2003) 8(1) (Supplementary) *Journal of Health Services Research and Policy* 8, 8–11 <https://doi.org/10.1258/135581903766468819>.

137 *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation)* [2016] OJ L 119/1.

138 Previously, power had been conferred under section 60 of the *Health and Social Care Act 2001* (UK).

139 *National Health Service Act 2006* (UK) s 251(12).

Secretary of State. In both cases, authorisation effectively sets aside the duty of confidentiality and provides a lawful basis for the disclosure of confidential patient information without patient consent in circumstances where it may not otherwise be lawful.

The HRA may not give approval for a consent waiver under the *COPI Regulations* unless a Research Ethics Committee ('REC', an HREC equivalent) has approved the medical research concerned, but a REC's consideration is restricted to ethical aspects of an application unrelated to the legal power to set aside the duty of confidentiality. The HRA must appoint a committee for the purposes of giving advice to the HRA and the Secretary of State in relation to the exercise of the power to set aside duties of confidentiality.[140] The HRA has appointed the CAG to provide this advice and the CAG prioritises transparency in its operations.[141] The deliberations and advice of the CAG are published online by the HRA in the form of detailed meeting minutes. Details of all approved applications are also published in a register of approvals, updated monthly. This provides summary information about the activity, details of the identifiers approved for release, and the applicant's contact details with the *COPI Regulations* detailing particulars that must be included in the register.[142]

In the Republic of Ireland, regulation 12 of the *Health Research Regulations 2018* creates the possibility for what is known as a 'consent declaration'.[143] Such a declaration may be made by the HRCDC where it is satisfied that the public interest in carrying out health research significantly outweighs the requirement for explicit consent that would otherwise apply. Again, there must be ethical approval of any health research carried out under the *Regulations*,[144] but the HRCDC (rather than the REC) is constituted to make consent declarations. The HRCDC itself, similarly to the CAG, includes members 'representative of the health research community, including patient and public representatives'.[145] The regulations under which they operate expressly require that 'arrangements to ensure that personal data are processed in a transparent manner are identified and in place'.[146] Furthermore, again as with the CAG, the minutes of all HRCDC meetings are published online

140 *Care Act 2014* (UK) sch 7 pt 1 para 8.

141 V Ranieri, H Stynes and E Kennedy 'To CAG or Not to CAG? Difficulties in Determining Submission to the Confidentiality Advisory Committee: A Commentary' (2021) *Research Ethics* 17(1) 120, 122 <https://doi.org/10.1177/174701612092006>.

142 *COPI Regulations* (n 132) reg 6.

143 *Health Research Regulations 2018* (n 132) reg 12.

144 Ibid reg 3(1)(b)(i).

145 'About Us', *Human Research Consent Declaration Committees* (Web Page) <https://hrcdc.ie/about-us/>.

146 *Health Research Regulations 2018* (n 132) reg 3(1)(d). Guidance to researchers notes '[a]ppropriate transparency arrangements (eg notices on websites, in public areas etc) must be identified and put in place to inform individuals of how their data is being used for health research purposes. Such notices must be in clear and understandable language.': 'Suitable and Specific Measures', *Health Research Board* (Web Page) <https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/suitable-and-specific-measures-for-health-research/> (emphasis in original).

and the status of all applications submitted for consideration can be found in a published log.[147]

2 Precedent

The fact that a single committee operates in both jurisdictions, with a relatively small membership,[148] lends itself toward similar cases being treated similarly. The presumption of consistency was sufficient to motivate thematic analysis of feedback provided to applicants in England and Wales by researchers who hoped to support future applications.[149] Indeed, the significance of precedent to the operation of the CAG is evident in the existence of a 'precedent set review pathway', expediting the review process where applications 'share the same issues as previous applications that have been reviewed by CAG'.[150] There is every reason to suppose that the HRCDC in the Republic of Ireland will similarly strive for consistency within their own decision-making. The *Health Research Regulations 2018* that structure and empower the committee's work have been described as ensuring 'that there is certainty, consistency and clarity for those carrying out health research'.[151]

3 Patient and Public Engagement ('PPE')

There are two ways that the CAG and the HRCDC promote PPE and embed it within decision-making processes. The first is by consistent expectations of engagement by applicants. The second is by taking advantage of opportunities to engage directly themselves with stakeholders. In England and Wales, the CAG has clearly promoted the first aspect as an important indicator of public and patient perception of the public interest in a proposed use of patient data. As noted in relation to consideration of a recent application:

> Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations and to help support public trust and confidence in the use of patient data without consent.[152]

147 'Decisions', *Health Research Consent Declaration Committee* (Web Page) <https://hrcdc.ie/decisions/#b-3>.

148 At the time of writing, there are 26 members of CAG and 17 members of the HRCDC.

149 Lauren Cross et al, 'Guidance for Researchers Wanting to Link NHS Data Using Non-consent Approaches: A Thematic Analysis of Feedback from the Health Research Authority Confidentiality Advisory Group' (2020) 5(1) *International Journal of Population Data Science* 34:1–8 <https://doi.org/10.23889/ijpds.v5i1.1355>.

150 'What Is the CAG Precedent Set Review Pathway?', *Health Research Authority* (Web Page, 17 October 2022) <https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/cag-precedent-set-review-pathway/>.

151 Muiris O'Connor, 'Health Research Regulations 2018: Context and Purpose' (Seminar, 19 October 2018).

152 Health Research Authority, 'Minutes of the Meeting of the Confidentiality Advisory Group' (Minutes, 21 January 2021) 5 <https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/13._Full_CAG_Minutes_-_21_January_2021.pdf>.

Where the CAG does not think that applicants undertake patient and public engagement activity proportionate to the scale and use of the information, they will require it. This was also a theme in CAG outcome letters that was identified in the thematic analysis mentioned above. In addition to requiring applicants to engage with proportionate PPE, the CAG have also run events to directly solicit patient and public views on issues relating to the advice that CAG is asked to give to 'directly inform and influence CAG members' thinking'.[153]

Stakeholder consultation has also been significant in the Republic of Ireland. In January 2021, the Department of Health identified substantive amendments to the *Health Research Regulations 2018* following 'a process of engagement with stakeholders to identify genuine and meaningful challenges in implementation of the *Regulations* that have impacted health research and health researchers'.[154] The national character of the decision-making processes makes it relatively easy to manage expectations with regards to PPE by those seeking consent waivers and also the processes of seeking PPE with regard to the principles and processes of waiver themselves. Having one committee in each jurisdiction, with one source of relevant guidance to researchers, is conducive to consistency in messaging. The committees can also themselves run events to invite public check and challenge of their own operations.[155]

4 Review and Appeal

Recalling that the CAG is an advisory body, in England and Wales, the HRA is statutorily required to put in place and operate a system for reviewing decisions it makes in relation to waiver of consent.[156] The process that it has established for review initially invites applicants seeking a different decision to resubmit an application, presumably providing an opportunity for further information or alternative argument. A dissatisfied applicant may still request a review of a decision, in which case, the CAG is invited to reconsider its advice to the HRA.[157] The committee may either reaffirm or modify previous advice. The HRA will then review the decision and determine whether to change the decision. The decision in relation to the request for review is final, with no appeals process against the final

153 'Confidentiality Advisory Group Patient Involvement Workshop', *Health Research Authority* (Web Page, 31 January 2017) <https://www.hra.nhs.uk/about-us/news-updates/confidentiality-advisory-group-patient-involvement-workshop/>.

154 'Guidance: Amendments to the Health Research Regulations', *Health Research Consent Declaration Committee* (Web Page, 22 January 2021) <https://hrcdc.ie/guidance/>.

155 For example, workshops were run by the CAG with members of the public and other stakeholders in 2017: see 'Confidentiality Advisory Group: Understanding Public Views on Using Personal Data', *Health Research Authority* (Web Page, 16 March 2017) <https://www.hra.nhs.uk/about-us/news-updates/confidentiality-advisory-group-understanding-public-views-using-personal-data/>.

156 *COPI Regulations* (n 132) reg 5(3), as amended by *Care Act 2014* (UK) s 117(4).

157 'The *Health Service (Control of Patient Information) Regulations 2002*: Regulation 5 Decision Procedure for Research Applications', *Health Research Authority* (Web Page, 20 August 2019) [5.14]–[5.17] <https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/health-service-control-patient-information-regulations-2002-regulation-5-decision-procedure-research-applications/>.

HRA decision.[158] It may be that HRECs in Australia are subject to similar processes, but much will depend on how an institution understands its responsibilities under the National Statement.[159] The process for review and appeal in the Republic of Ireland is rather different. In the Republic of Ireland, a data controller (applicant) may appeal a refusal of the HRCDC to make a consent declaration or any of the conditions attached (and the revocation of a consent declaration). The appeal is decided by an independent appeal panel appointed by the Minister for Health and no member of the HRCDC may sit on an appeal panel.[160]

C Moving Forward with Australian Waivers of Consent

We do not seek to imply that Australia could or should import a CAG or equivalent model in its entirety. Given the federated nature of Australia's privacy laws, one statutory body would almost certainly lack the legal authority to waive requirements for consent for the use and disclosure of personal information across Australian states and territories. Even if national buy-in could be achieved, the small but significant differences among the various privacy regimes would fatally complicate the work of any such committee. However, the basic features of the UK and Republic of Ireland models warrant consideration as a basis for reformulating how Australia, and its constituent states and territories, approach waivers of consent for medical research.

Most fundamentally, we suggest that the following criteria should be incorporated into waiver of consent processes in Australia:

1. *The authorisation of waivers of consent under Australian privacy laws should be complementary to the HREC review process, rather than integrated within it*. This reinstates ethical deliberation, rather than legal compliance, as HRECs' key mandate. It also allows for independent review bodies, separate from HRECs for waiver of consent decisions, with specialist competence in areas such as law, data security, and data linkage technologies. An independent review body of this nature would be consistent with the limited available data on views of the Australian public on who should be trusted to make decisions on the release of personal information for medical research without consent: an important aspect of any trustworthy system. In particular, in two citizens' juries in NSW, jurors wanted an independent body to make decisions about data access.[161] Although jurors were not directly asked whether such a body should be an HREC or something else entirely, the juries did recommend that members

158 Although of course, along with other public bodies, the decisions of the HRA may be subject to judicial review. See, eg, *R (Richmond Pharmacology) v Health Research Authority* [2015] EWHC 2238 (Admin).

159 See 'Updated 2018 National Statement' (n 4) 98 [5.6.4].

160 See Department of Health (Ireland), 'Health Research Regulations: Appeals Process from Decisions of the Health Research Consent Declaration Committee' (Document, 1 August 2019) 1 <https://hrcdc.ie/wp-content/uploads/2019/08/Appeals-Process-Health-Research-Regulations-DOH.pdf>.

161 Jackie Street et al, 'Sharing Administrative Health Data with Private Industry: A Report on Two Citizens' Juries' (2021) 24(4) *Health Expectations* 1337, 1344 <https://doi.org/10.1111/hex.13268>.

should constitute a cross-section of the community with the expertise necessary to make informed decisions. One jury specified that this includes 'university researchers, IT and data experts, ethics and privacy experts, private industry representatives, health department representatives, and consumers and community members'.[162] Jurors also recommended that members should be paid a nominal hourly rate to indicate the value of their work and enable participation by low-income persons.[163]

Separating compliance responsibilities under privacy laws from HREC deliberations is also consistent with broader international advocacy for rethinking HREC reviews to promote 'an effective promulgation of substantive ethics'.[164] Townend and Dove suggest that this could come from committees focusing less on the 'correct' answer to an ethics question, and more on 'including all the relevant stakeholders in high-quality debate to find consensus about what the right answers might be (or at least about what "wrong" answers to avoid)'.[165] This deliberative model would accord with concerns explained in Part VI(A) about the increasingly legalistic bent of Australian HREC reviews, and its implications for relationships with researchers.[166]

2. *Waiver of consent decisions should feed into pathways for administrative review*. Despite the statutory footing of privacy rights at the Commonwealth level and in most Australian states and territories, waivers of these rights are authorised by voluntary groups of citizens with limited avenues for recourse. Under present arrangements, this is attributable to 'justifiable differences of opinion' when it comes to interpretations of ethical guidelines.[167] However, retaining trust in, and trustworthiness of, the research ethics system requires some limits to the zone of acceptable HREC decision-making. This could be based on whether the HREC has drawn on appropriate expertise and 'objectively assess[ed] the proposal against the principles in the National Statement'.[168] Decisions that researchers or members of the public consider to fall outside these acceptable parameters should give rise to opportunities for appeal. Avenues for appeal may be bespoke – as in the UK and the Republic of Ireland – or may be situated within existing Australian merits and judicial review pathways. Opportunities need to be available both to researchers seeking to appeal a rejected application as well as potential data donors seeking to appeal an authorisation to disclose. To ensure this right is more than merely

162 Ibid 1343 tbl 5.
163 Ibid 1344.
164 Townend and Dove (n 1) 80.
165 Ibid 82.
166 Chalmers and Pettit (n 128); McNeill (n 129); Dawson et al (n 130).
167 'Updated 2018 National Statement' (n 4) 98.
168 Ian Pieper and Colin JH Thomson, 'Justice in Human Research Ethics: A Conceptual and Practical Guide' (2013) 31(1) *Monash Bioethics Review* 99, 109 <https://doi.org/10.1007/BF03351345>.

theoretical, members of the public must have clear, easily accessible and timely information about projects seeking waivers of consent.

3. *A body of precedent for interpreting waiver criteria should be established*. Despite the detailed criteria that presently exist for HREC authorisations of waivers of consent, very little is known about the manner in which HRECs are interpreting these criteria. However, as scholars have pointed out, the guidelines allow for quite varied interpretations.[169] This includes the relevant and sufficient factors to constitute 'impracticability' and thresholds for 'presumed consent' of participants. Although scholars have started to grapple with strategies for building precedent within and between HRECs, implementation has been challenging.[170] Establishing a new body for waiver of consent decisions would allow precedent-building opportunities to be integrated from the outset – identified as a key implementation issue in the context of HRECs and their international equivalents.[171]

VII CONCLUSION

Since the mid-20th century, HRECs and their international equivalents have been a cornerstone of modern frameworks for promoting the welfare of human research participants. There are important benefits in ensuring that the ethical acceptability of research is assessed by a diverse and independent group. However, the assessments with which HRECs are tasked have become increasingly detailed, complex, and legalistic – far removed from their peer review roots. Moreover, the *outcomes* of HREC decision-making now include granting and waiving legal rights and responsibilities, including authorising waivers of consent for the use of personal information in medical research under federal and state privacy laws. This distorts the important demarcation between ethics and law and increases the likelihood of unduly conservative HREC decision-making.

Despite changes in HREC roles and responsibilities, the way in which HRECs are constituted, funded, and regulated has barely budged from their peer review origins. We need to take steps to support a trustworthy HREC system, including strategies for increased transparency, accountability and precedent-building. But we also need to recognise the limits of the HREC's role. The core mission of an HREC is to ascertain the ethical acceptability of a research proposal, rather than its compliance with legal requirements. Although there will be some crossover between the criteria for legal and ethical acceptability, conflation of the two can

169 See, eg, Rebekah McWhirter et al, 'Essentially Ours: Assessing the Regulation of the Collection and Use of Health-related Genomic Information' (Occasional Paper No 11, Centre for Law and Genetics, 2021) <https://www.utas.edu.au/__data/assets/pdf_file/0005/1576940/Essentially-Ours-Report-11-Final_.pdf>; Ballantyne and Schaefer (n 86).

170 Seykora et al (n 65); Martin Tolich and Emma Tumilty, 'Making Ethics Review a Learning Institution: The Ethics Application Repository Proof of Concept' (2014) 14(2) *Qualitative Research* 201 <https://doi.org/10.1177/1468794112468476>.

171 Seykora et al (n 65) 15.

lead to a loss of trust in, and trustworthiness of, the human research enterprise in Australia. In particular, granting and waiving legal rights and responsibilities should be managed by administrative bodies with established links to mechanisms for accountability and review. The frameworks in the UK and the Republic of Ireland provide templates for how this could be managed in the Australian context.

Table 1: Examples of Guidelines of the National Statement (from High Level Principles to More Detailed Codes)

Chapter 2.1	Research is ethically acceptable only when its potential benefits justify any risks involved in the research.
Paragraph 2.2.2	Participation that is voluntary and based on sufficient information requires an adequate understanding of the purpose, methods, demands, risks and potential benefits of the research.
Paragraph 3.1.5	Where current and available treatments are known or widely believed to be effective and/or there is known risk of significant harm in the absence of treatment, placebo or non-treatment groups are not ethically acceptable. Non-treatment (including placebo alone) groups may only be used: (a) where the existing standard of care comprises or includes the absence of treatment (of the type being evaluated); or (b) where there is evidence that the harms and/or burdens of an existing standard treatment exceed the benefits of the treatment.
Paragraph 4.4.13	When neither the potential participant nor another on his or her behalf can consider the proposal and give consent, an HREC may, having taken account of relevant jurisdictional laws, approve a research project without prior consent if: (a) there is no reason to believe that, were the participant or the participant's representative to be informed of the proposal, he or she would be unwilling to consent; (b) the risks of harm to individuals, families or groups linked to the participant, or to their financial or social interests, are minimised; (c) the project is not controversial and does not involve significant moral or cultural sensitivities in the community; and, where the research is interventional, only if in addition: (d) the research supports a reasonable possibility of benefit over standard care; (e) any risk or burden of the intervention to the participant is justified by its potential benefits to him or her; and (f) inclusion in the research project is not contrary to the interests of the participant.

Table 2: Criteria for Waivers of Consent

1982 Statement on Human Experimentation	
Research on Children, the Mentally Ill and those in Dependent Relationships or Comparable Situations, including Unconscious Patients (Supplementary Note 2)	The intervention is intended or expected to benefit a patient and could reasonably be adopted 'in the interests of the patient'.
	Interventions neither intended nor expected to benefit a patient: • There are good reasons for why the experimental intervention cannot be limited to persons from whom, or on behalf of whom, consent can be obtained. • The intervention will involve no material risks beyond those procedures clinically indicated. • The requirements of research do not influence the procedures that are clinically indicated. • Confidentiality will be preserved.
1999 National Statement	
Epidemiological Research (Chapter 14)	The public interest in the research outweighs to a substantial degree the public interest in privacy and either: • obtaining consent would cause unnecessary anxiety for potential participants and these persons and their relatives would experience no disadvantage; OR • obtaining consent would be 'impossible in practice' due to the quantity, age or accessibility of the records to be studied.
Human Tissue (Chapter 15) and Human Genetic Material and Genetic Information (Chapter 16)	Prior to granting a waiver, HRECs must consider: • the nature of any existing consent relating to the tissue, sample or data; • the justification presented for seeking waiver of consent including the extent to which it would be impossible or difficult or intrusive to obtain specific consent; • the proposed arrangements to protect privacy, including through de-identification; • the extent to which the proposed research poses a risk to the privacy or wellbeing of the individual to whom the tissue, sample, or data relates; • whether the research proposal is an extension of, or closely related to, a previously approved research project; • the possibility of commercial exploitation; and • relevant statutory provisions.
Updated 2018 National Statement	
Research Involving Humans (Chapter 2.3, Paragraph 2.3.10)	Prior to granting a waiver, an HREC must be satisfied that: • involvement in the research carries no more than low risk to participants; • the benefits from the research justify any risks of harm associated with not seeking consent; • it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records); • there is no known or likely reason for thinking that participants would not have consented if they had been asked; • there is sufficient protection of their privacy;

Updated 2018 National Statement (cont)	
Research Involving Humans (Chapter 2.3, Paragraph 2.3.10) (cont)	• there is an adequate plan to protect the confidentiality of data; • in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media); • the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled; and • the waiver is not prohibited by state, federal, or international law.
Human Biospecimens (Chapter 3.2, Paragraph 3.2.14)	In considering requests for waivers of consent for research involving the use of human biospecimens, HRECs should consider, in particular: • whether there is a pathway to identify and re-contact the donor(s) in order to seek their informed consent; and • whether there is a known or likely reason for thinking that the donor(s) would not have consented if they had been asked.
Genomic Research (Chapter 3.3, Paragraph 3.3.14)	Consent specific to the research may not be required or a waiver of the requirement for consent may be considered by an HREC if: • the data or information to be accessed or used was previously collected and either aggregated or had identifiers removed; • prior consent for the use of the data or information was provided under the scope of a research program that encompasses the proposed research project; or • prior consent for the use of the data or information was provided in the clinical context for research that encompasses the proposed research project; or • unspecified consent has been provided.

Table 3: Weighing the Public Interests in Privacy and Research under the Section 95 Guidelines

In reaching a decision under [section] 3.2(b) [to determine if the public interest in the proposed research outweighs, or does not outweigh, to a substantial degree, the public interest in the protection of privacy,] an HREC should consider the following matters: a) the degree to which the medical research is likely to contribute to: (i) the identification, prevention or treatment of illness or disease (ii) scientific understanding relating to health (iii) the protection of the health of individuals and/or communities (iv) the improved delivery of health services (v) scientific understanding or knowledge b) any likely benefit to individuals, to the category of persons to which they belong, or the wider community that will arise from the medical research being undertaken in the manner proposed c) whether the medical research design can be satisfied without risking infringement of an APP and the scientific defects in the medical research that might arise if the medical research was not conducted in the manner proposed d) the financial costs of not undertaking the medical research (to government, the public, the healthcare system, etc)

e) the public importance of the medical research
f) the extent to which data being sought are ordinarily available to the public from that agency
   (i) whether the medical research involves use of data in a way which is inconsistent with the purpose for which the data was made public
   (ii) whether the medical research requires an alteration of the format of the data of a kind that would, if used by an agency, involve a breach of an APP
g) whether the risk of harm to a person whose personal information is to be used in proposed research is minimal, having regard to the elements of that research provided in response to paragraph 2.3 of these guidelines
h) the standards of conduct that are to be observed in the medical research, including:
   (i) the study design and the scientific credentials of the researchers
   (ii) if the research involves contact with participants, the procedures or controls which will apply to ensure that participants are treated with integrity and sensitivity, including whether questions to be asked or procedures to be employed are intrusive
   (iii) whether access to personal information is restricted to appropriate researchers
   (iv) the risk that a person or group could be identified in the published results
   (v) the procedures that are to be followed at the completion of the research to ensure that all data containing personal information are at least as secure as they were in the sources from which the data were obtained, including the date when the data will be destroyed or returned.[172]

172 '2014 Guidelines' (n 55) 5–6 [3.3].