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HOLDING HUMAN RESEARCH ETHICS COMMITTEES TO ACCOUNT: A ROLE FOR JUDICIAL REVIEW?

Abstract

Decision-making by Human Research Ethics Committees ('HRECs') is subject to significant criticisms, many of which relate to the extent to which decisions are made within their authority or to the provision of reasons for such decisions. This suggests that judicial review of decisions made by HRECs may contribute to improving adherence to administrative law norms and the quality of decision-making processes. This article assesses this proposition by examining current opportunities for review and then assessing the extent to which expanding the role of judicial review might better hold HRECs to account. It argues that only some types of HREC decisions are currently open to judicial review, and that the purported benefits of enhanced decision-making processes arising from judicial review are less than the risks of impairment to efficient administration. Alternative mechanisms are suggested. Decisions that are neither clearly within or outside the scope of judicial review provide useful case studies for interrogating both the purpose of judicial review and the extent to which it achieves its aims.

I Introduction

Research involving human participants underpins health and medical advances and is a significant contributor to the Australian economy.[1] Human Research Ethics Committees ('HRECs') act to balance these substantial societal benefits against the potential risks to individuals in making their decisions about proposed

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1 KPMG, *Economic Impact of Medical Research in Australia* (Report, Association of Australian Medical Research Institutes, October 2018) 1 <https://aamri.org.au/wp-content/uploads/2018/10/Economic-Impact-of-Medical-Research-full-report.pdf>.

research projects.[2] Decisions made by HRECs take two main forms: (1) assessing proposed projects for compliance with the *National Statement on Ethical Conduct in Human Research* ('*National Statement*');[3] and (2) assessing applications for waivers of consent under the *Privacy Act 1988* (Cth) ('*Privacy Act*').[4] Complaints from researchers about HRECs are common. The most frequent complaints relate to: the lack of transparency in decision-making; excessive processing time for applications; inconsistencies in decision-making between HRECs; and changes to projects required by HRECs that are not supported by the *National Statement*.[5] Where substantiated, these failings increase the costs and inefficiencies of research, without facilitating greater protection of human participants.

Except for excessive time complaints, these concerns can largely be characterised as relating to the extent to which decisions are made within the scope of granted authority and the appropriate provision of reasons. Judicial review is concerned with exactly these issues. It might therefore be hypothesised that judicial review represents a viable mechanism for addressing some or all of the criticisms levelled at HRECs. This article seeks to test this hypothesis in three parts. First, it will outline the establishment and composition of HRECs, and identify possible sources of HREC power. Second, it will examine current opportunities for review, and establish whether judicial review is likely to be available for HREC decisions. It is argued that only some ethics approval decisions are likely to be justiciable under

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2 HRECs became a feature of the Australian research ethics landscape after the National Health and Medical Research Council ('NHMRC') started requiring, from 1985, that institutions undertaking research establish ethics committees for the review of research proposals as a condition of receiving NHMRC funding: see Susan Dodds, 'Human research Ethics in Australia: Ethical Regulation and Public Policy' (2000) 19(2) *Monash Bioethics Review* 4, 5–6. Towards the end of the 20th century, HREC oversight expanded to include social sciences research: see, eg, Gary D Bouma and Kristin Diemer, 'Human Ethics Review and Social Sciences: Several Emerging Ethical Issues' (1996) 15(1) *Monash Bioethics Review* 10, 16. While the discussion here likely applies to social sciences research as well, the focus is on health and medical research, reflecting the origin of many of the relevant documents under the auspices of the National Health and Medical Research Council and their originally intended scope.

3 National Health and Medical Research Council, Australian Research Council and Universities Australia, *National Statement on Ethical Conduct in Human Research 2007* (Statement, July 2018) ('*National Statement*').

4 *Privacy Act 1988* (Cth) ss 95, 95A ('*Privacy Act*').

5 See, eg: David M Studdert et al, 'Ethics Review of Multisite Studies: The Difficult Case of Community-Based Indigenous Health Research' (2010) 192(5) *Medical Journal of Australia* 275; Tim Battin, Dan Riley and Alan Avery, 'The Ethics and Politics of Ethics Approval' (2014) 56(1) *Australian Universities' Review* 4; Wendy A Brown et al, 'Streamlining Ethics Review for Multisite Quality and Safety Initiatives: National Bariatric Surgery Registry Experience' (2016) 205(5) *Medical Journal of Australia* 200; Amber L Johns et al, 'The Path to Reducing Duplication of Human Research Ethics Review in Australia' (2017) 36(1) *Medicine and Law* 7; Rebekah E McWhirter and Lisa Eckstein, 'Moving forward on Consent Practices in Australia' (2018) 15(1) *Journal of Bioethical Inquiry* 243.

the *Administrative Decisions (Judicial Review) Act 1977* (Cth) ('*ADJR Act*') and at common law, but that decisions regarding waivers of consent under the *Privacy Act* are likely amenable to judicial review. Third, this article will assess the extent to which expanding the role of judicial review to include both types of decisions might better hold HRECs to account and address the criticisms levelled against HRECs as they currently operate. It is argued that there are significant barriers preventing the benefits of judicial review for HREC decision-making being realised in practice, and that alternative approaches might achieve the same ends more efficiently. Decisions made by HRECs are an example of decisions at the limits of the judicial review regime and provide a case study for assessing the goals of judicial review and the extent to which they are achieved.

II Sources of HREC Power

In order to determine the justiciability of HREC decisions, it is important to understand how HRECs are constituted and under what authority they make decisions. This information is critical to identifying whether HREC decisions can be characterised as government decisions or as an exercise of public power.

Identifying the source and nature of HREC powers is not a straightforward exercise. There are over 200 HRECs registered with the National Health and Medical Research Council ('NHMRC') which are collectively responsible for reviewing more than 15,000 new research proposals each year.[6] Most HRECs are attached to public institutions such as hospitals and universities, many of which have been established by statute,[7] while others are affiliated with private hospitals or research institutions. Bellberry Limited is an example of an unaffiliated and non-institutional based HREC service, in the form of a private not-for-profit dedicated HREC organisation.[8] If institutional affiliation is taken as determinative, then it would appear that some HRECs exercise public power and others private, despite undertaking identical roles. However, it is not obvious that this is the correct approach to take.

For HRECs to be registered with the NHMRC, they need to notify the NHMRC of their existence and confirm that they meet the requirements contained within the *National Statement*. This document details how HRECs are to be established, their composition, processes for review, and procedural requirements. Membership of HRECs must include at least two laypeople, two people with current research experience, at least one lawyer, one person who performs a pastoral care role, and one person with current experience in the professional care, counselling or treatment

6 National Health and Medical Research Council, *Report on the Activity of Human Research Ethics Committees and Certified Institutions for the Period: 1 January 2019 to 31 December 2019* (Report, November 2020) 6, 12 ('*2019 Report*') <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/att_b_-_2019_activity_report.pdf>.

7 See, eg, *Australian National University Act 1991* (Cth).

8 'About Us', *Bellberry Limited* (Web Page) <https://bellberry.com.au/about-us/>.

of people.[9] Notably, at least one third of the members are required to be unaffiliated with the institution for which the HREC is reviewing research,[10] and all members are 'appointed as individuals for their knowledge, qualities and experience, and not as representatives of any organization, group or opinion'.[11] These conditions suggest that an HREC is intended to operate, as far as possible, independently of any institution with which it is affiliated, in order to fulfil its ethical review and monitoring roles appropriately.

HRECs are required by statute to be registered with the NHMRC in order to review clinical trials,[12] human embryo research[13] and research requiring application of the guidelines under ss 95 and 95A of the *Privacy Act*. Further, institutions receiving funding from the NHMRC for research activities are required under the funding agreement to comply with NHMRC Approved Standards and Guidelines and any applicable NHMRC policies.[14] This requirement extends to other institutions partnering on the funded research. The definitions section of the funding agreement confirms that NHMRC Approved Standards and Guidelines include the *National Statement*.[15] Significantly, the *National Statement* requires that '[i]nstitutions must see that any human research they conduct or for which they are responsible is … ethically reviewed and monitored in accordance with this National Statement'.[16]

The combined effect of the funding agreement and this section of the *National Statement* is that if an institution receives *any* research funding from the NHMRC, then *all* of its research activity involving humans, and that of its partner institutions, must comply with the *National Statement*.

Significantly, the *National Statement* traces the line of accountability in relation to human research in the following way:

- from researchers to review bodies and institutions;
- from review bodies and institutions to funders and other agencies;
- from agencies to government; and
- from government to the Australian public.[17]

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9 *National Statement* (n 3) 87 [5.1.30].

10 Ibid 87 [5.1.29].

11 Ibid 87 [5.1.35].

12 *Therapeutic Goods Act 1989* (Cth) ss 19, 32CM.

13 *Research Involving Human Embryos Act 2002* (Cth) s 21.

14 'NHMRC Funding Agreement', *National Health and Medical Research Council* (Web Page) <https://www.nhmrc.gov.au/funding/manage-your-funding/funding-agreement>.

15 Ibid cl 1.1.

16 *National Statement* (n 3) 83 [5.1.1].

17 Ibid ch 5.7.

This places review bodies (that is, HRECs) and institutions at the same level, making it clear that HRECs are not accountable to their institution. In identifying funders and other agencies as the bodies to which HRECs are directly accountable, the *National Statement* reflects the fact that the requirement to comply with it derives its legal force either from contract (in the form of funding agreements) or statute (as in the case of clinical trials, human embryo research or waivers of consent). On this approach, it is the type of decision that determines the nature of the power being exercised, rather than the institutional affiliation of an HREC. This approach provides less arbitrary outcomes, leading to like decisions being treated alike, and therefore should be preferred.

III Opportunities for Review

HRECs play a critical role in the regulation of research with human participants by assessing research proposals for ethical acceptability and compliance with relevant guidelines and standards. They are responsible for making two main types of decisions: (1) whether ethics approval may be granted on the basis that the proposed project complies with the *National Statement*; and (2) whether a waiver of consent may be granted, authorising researchers to use personal or sensitive information collected by Commonwealth agencies or private sector organisations without the consent of the individuals to whom the information pertains, for the purposes of medical research, in accordance with guidelines issued under ss 95 and 95A[18] of the *Privacy Act*.[19]

Both individuals and institutions may be affected by these decisions. Affected individuals include researchers, whose careers depend on being able to undertake research with human participants and their data; and potential participants, whose privacy, bodily integrity and health may all be adversely affected by incorrectly made or non-guideline-compliant decisions. Affected institutions include universities, research institutes and funding bodies, who have invested in researchers and the proposed research. Less directly, the broader Australian public is also adversely affected by inappropriately made decisions of HRECs, as these contribute to wasted public funds, loss of trust in the research endeavour, and a consequent reduction in health and medical benefits. Conversely, correctly made decisions to approve research have the potential to contribute to the advancement of health and

18 National Health and Medical Research Council, *Guidelines under Section 95 of the Privacy Act 1988* (November 2014) <https://www.nhmrc.gov.au/sites/default/files/2018-02/Guidelines%20under%20section%2095%20of%20The%20Privacy%20Act.pdf> ('*Section 95 Guidelines*'); National Health and Medical Research Council, *Guidelines Approved under Section 95A of the Privacy Act 1988* (March 2014) <https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988> ('*Section 95A Guidelines*').

19 Waivers may also be granted for use or disclosure of personal information held by state or territory agencies under the applicable privacy regime. This article focuses on the application of the Commonwealth legislation which is, broadly speaking, representative of decision-making regarding waivers of consent more generally.

medical science. Understanding the review landscape requires an examination of three factors. First, the opportunities for merits review of these decisions. Second, whether judicial review is available. Finally, the utility of freedom of information legislation as an accountability mechanism within this review landscape is assessed.

A *Merits Review*

1 *Review of Ethics Approval Decisions*

Interestingly, the *National Statement* specifically states that it 'does not provide for appeals by researchers against a final decision to reject a proposal' on the grounds that '[t]here can be justifiable differences of opinion as to whether a research proposal meets the requirements of this National Statement'.[20] This indicates that opportunities for merits review of HREC decisions are non-existent. In practice, most HRECs are motivated by a desire to facilitate ethical research and will frequently enter into dialogue with researchers to assist them in improving their application to a point where it can be approved.[21] The lack of provision for appeals against final decisions can therefore be interpreted as an intentional measure designed to assist HRECs to end repetitive or unsuccessful discussions with researchers. Contributing to administrative efficiency is likely a driving force behind the decision to withhold merits review, given the volume of research proposals reviewed each year.

However, this is not to say that review is impossible. Chapter 5.6 of the *National Statement* provides that 'complaints about the process of review' may be made 'by participants, researchers, staff of institutions, or others'.[22] These complaints processes are applicable to all decisions made by HRECs, including those made under the *Privacy Act*. Such complaints are to be directed to the institution that established the HREC — usually a university, hospital or research institute — and which has responsibility for oversight of the HREC's operations.[23] The *National Statement* requires institutions to 'establish procedures for receiving, handling and seeking to resolve … complaints'.[24] Additionally, a person should be identified to receive complaints,[25] and 'a person or agency external to the institution' should be identified to receive complaints not resolved by internal processes.[26] Although the wording indicates that this complaints process is intended to focus on issues with the process of review, the distinction between procedural and substantive concerns is not necessarily a bright line. It is unlikely that the persons identified to handle complaints, both internally and externally to the institution, will be as concerned

20 *National Statement* (n 3) ch 5.6.

21 Ibid 6. This approach aligns with the purpose of the *National Statement*, which is 'to promote ethically good human research': at 6.

22 Ibid ch 5.6.

23 Ibid.

24 Ibid 98 [5.6.1(b)].

25 Ibid 98 [5.6.1(a)].

26 Ibid 98 [5.6.6].

with differentiating the procedural from the substantive as might be expected from a judicial review process. This issue, combined with the lack of detail provided in how complaints should be handled, suggests that it is likely that substantive changes to the decision could result from the complaints process, despite appeals being ostensibly unavailable.

Registered HRECs provide annual reports to the NHMRC concerning their compliance with specific requirements of the *National Statement*, including mechanisms for handling complaints. Oversight of HRECs' complaints processes by the NHMRC is limited to requiring that HRECs make their procedures for receiving and handling complaints and concerns publicly available, and that HRECs report on the number and nature of complaints received. In 2019, 6% (n=12) of HRECs 'received a combined total of 14 complaints *from researchers* about the consideration of their research proposal(s)' by the HRECs.[27] This is slightly lower than the previous year, in which a combined total of 22 complaints from researchers about HRECs were received by 9% (n=18) of HRECs.[28] The NHMRC reports that these complaints related to issues associated with the review process, communication, and outcomes, including:

- dissatisfaction or disagreement with the HRECs' feedback or decision;
- submission procedures and timelines, including time delays or multiple rounds of feedback;
- exemption from ethical review;
- a perceived lack of expertise in the composition of HRECs; and
- inadequate opportunity to justify and explain research.[29]

A larger number of complaints were received *about researchers* or the conduct of approved research projects, with 37% (n=74) of HRECs receiving a total of 231 complaints in 2019, and 40% (n=80) receiving a total of 224 complaints in 2018.[30] While the majority of these complaints appear to relate to conduct by researchers, at least some of the complaints potentially relate to HREC decision-making, including complaints about the ethical acceptability of the research, privacy and confidentiality concerns, conflicts of interest, and the validity of the research.[31] It is not clear from the reports whether these complaints were lodged by researchers, participants or other members of the public, but it is likely to have been a combination of these.

27 *2019 Report* (n 6) 19 (emphasis added).

28 National Health Medical Research Council, *Report on the Activity of Human Research Ethics Committees and Certified Institutions for the Period: 1 January 2018 to 31 December 2018* (Report, July 2019) 18 <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/2018-activity-report.pdf> ('*2018 Report*').

29 Ibid 19; *2019 Report* (n 6) 20.

30 *2019 Report* (n 6) 19; *2018 Report* (n 28) 18.

31 *2019 Report* (n 6) 19–20; *2018 Report* (n 28) 18–19.

Complaints about HRECs are handled with a minimal degree of transparency and accountability. The nature of these processes is such that information about their outcomes is not publicly available. It is unclear how these complaints were resolved, whether any changes were made to the HRECs' processes as a result, or whether the parties involved were satisfied with the outcomes. They are also undertaken in a piecemeal fashion, with little or no communication between committees about complaints or their outcomes, such that complaints are unlikely to effect broader improvements in processes beyond the affected HRECs.

2 *Review of Decisions about Waivers of Consent*

As an alternative, or in addition, to complaints to the HRECs, complaints about waiver of consent decisions may also be made to the Information Commissioner under s 36 of the *Privacy Act*, who can make determinations on privacy complaints under s 52 of the *Privacy Act*. Information about waiver of consent decisions made by HRECs is collected by the NHMRC on behalf of the Australian Information Commissioner ('Information Commissioner') but is not reported. Complaints about waiver of consent decisions are most likely to originate from individuals who object to their information being used or disclosed without their consent, and for practical reasons are likely to be directed towards the data custodian who released the information rather than the HREC that authorised its use or disclosure. However, an HREC's decision to grant a waiver may be examined as part of a wider investigation, as occurred in *'PA' and Department of Veterans' Affairs (Privacy)*.[32] In this case, the complainant alleged that the Department of Veterans' Affairs ('DVA') had improperly disclosed his information to the Australian Institute of Health and Welfare.[33] A waiver of consent under s 95 of the *Privacy Act* had been granted in relation to this disclosure by the DVA HREC,[34] and the Information Commissioner examined whether the HREC's decision to grant the waiver had been made in accordance with the guidelines issued under s 95, or whether a breach of the *Privacy Act* had occurred.[35]

Further, under s 96 of the *Privacy Act*, a complainant who was dissatisfied with a determination made by the Information Commissioner under ss 52(1) or 52(1A) could apply to the Administrative Appeals Tribunal ('AAT') for a merits review. This means that individuals concerned about the inappropriate collection, use or disclosure of their information have more comprehensive opportunities for merits review of a waiver decision than individuals concerned about ethics approval decisions. However, it is less clear if researchers wishing to have a rejected application for a waiver reviewed will have the same opportunities. A decision not to grant a waiver does not give rise to privacy concerns of the type that fall clearly within the Information Commissioner's purview. This represents a gap that potentially reinforces conservative HREC decision-making with respect to the granting of waivers.

32 [2018] AICmr 50.

33 Ibid [11]–[12].

34 Ibid [82].

35 Ibid [29].

B *Judicial Review*

If a complainant was still dissatisfied with the outcome of the complaints processes described above, could they then apply for judicial review? There are multiple avenues available for pursuing judicial review, and — although it is not certain that review of HREC decisions is readily available under any of these options — some are more likely than others.

The individuals who comprise HRECs are a diverse group appointed to act in their personal capacity and not on behalf of particular organisations or groups.[36] They are not 'officers of the Commonwealth', as required for review under s 75(v) of the *Constitution* and s 39B of the *Judiciary Act 1903* (Cth), and if they are 'officers' in another capacity, they are not acting in that capacity when making HRECs decisions. The Australian Law Reform Commission noted that

> HRECs are institutional, rather than statutory committees, established on an administrative basis in accordance with the National Statement. Members are generally volunteers, drawn from a range of community sectors. At least one third of the members of an HREC are required to be from outside the institution for which the HREC is reviewing research, including two lay people who have no affiliation with the institution. Even where an HREC is established by a public sector agency, therefore, the committee is not composed entirely of officers of that agency. Members are asked to make decisions on the basis of their own judgement.[37]

Given the uncertainty surrounding the scope of review under s 75(v) of the *Constitution*, it is possible that the HREC itself, rather than the individuals comprising the HREC, could be found to be an officer of the Commonwealth. This is perhaps unlikely, however, given the High Court's reluctance to apply the *Datafin* public function test[38] and its tendency, noted by Janina Boughey and Greg Weeks, to find alternative sources of jurisdiction for review of decisions by private bodies rather than explicitly expanding the scope of phrase 'officer of the Commonwealth'.[39] Further, most HRECs are affiliated with state instrumentalities, such as universities and public hospitals.

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36 *National Statement* (n 3) 87 [5.1.35].

37 Australian Law Reform Commission, *For Your Information: Australian Privacy Law and Practice* (Report No 108, May 2008) vol 3, 2189–90 [65.135] ('*For Your Information*').

38 That is, the principle in English law that judicial review will be available when a private body is exercising public power: *R v Panel on Take-Overs and Mergers; Ex parte Datafin plc* [1987] QB 815 ('*Datafin*').

39 Janina Boughey and Greg Weeks, '"Officers of the Commonwealth" in the Private Sector: Can the High Court Review Outsourced Exercises of Power?' (2013) 36(1) *University of New South Wales Law Journal* 316, 317.

Complaints considered by the Information Commissioner and then reviewed by the AAT can be appealed to the Federal Court,[40] but this constitutes a review of the AAT's decision, rather than the initial decision made by the HREC, and is limited to only those decisions falling within the Information Commissioner's purview. Whether HREC decisions are open to judicial review either by state Supreme Courts or under the *ADJR Act* depends on the nature of these decisions. That is, whether these decisions have a governmental character or, more specifically in relation to the *ADJR Act*, whether decisions made by HRECs are decisions 'of an administrative character made … under an enactment'.[41] To answer this question, the two types of HREC decisions will be considered separately in relation to the availability of judicial review under the *ADJR Act*, followed by an assessment of whether review by State Supreme Courts might be available.

1 *Ethics Approvals*

HRECs are responsible for deciding whether any proposals submitted meet the requirements of the *National Statement* when granting ethics approvals.[42] There is little doubt that the final decision to approve or reject a proposal is 'operative and determinative', as found to be required by Mason CJ in *Australian Broadcasting Tribunal v Bond* ('*Bond*').[43] It is also clearly an administrative decision, in that it is neither judicial nor legislative, and it is more akin to governmental decision-making than the sort of decision made day-to-day within private organisations, in terms of the large numbers of people affected by the decision and in its core objective of protecting the public. Whether such a decision is made under an enactment is less obvious. At the very least, it is not a decision explicitly excluded under sch 1 of the *ADJR Act*, nor by the *Administrative Decisions (Judicial Review) Regulations 2017* (Cth).[44]

Some ethics approval decisions engage with statutory frameworks such that they may be characterised as being made under an enactment. The clearest example of this category of decision is any decision to grant ethics approval for a clinical trial involving an unapproved therapeutic good, required under the *Therapeutic Goods Act 1989* (Cth).[45] It is likely that decisions made pursuant to human embryo legislation[46] may also fall into this category. Such decisions are likely open to judicial review under the *ADJR Act*, although no examples have occurred to date. Most ethics approvals, however, are not made as a result of statutory obligations, but rather as a result of institutional compliance with the *National Statement* — the precise status of which merits attention.

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40 *Administrative Appeals Tribunal Act 1975* (Cth) s 44.

41 *Administrative Decisions (Judicial Review) Act 1977* (Cth) s 3(1) (definition of 'decision to which this Act applies' para (a)) ('*ADJR Act*').

42 *National Statement* (n 3) 89 [5.2.2].

43 (1990) 170 CLR 321, 337 (Mason CJ) ('*Bond*').

44 *Administrative Decisions (Judicial Review) Regulations 2017* (Cth) reg 6 ('*ADJR Regulations*').

45 *Therapeutic Goods Act 1989* (Cth) ss 19, 32CM.

46 *Research Involving Human Embryos Act 2002* (Cth) s 21.

An enactment, as defined in the *ADJR Act*, can include 'an instrument (including rules, regulations or by-laws) made under … an Act'.[47] This definition does not specify that the instrument should be a legislative instrument for the purposes of the *Legislation Act 2003* (Cth),[48] although the examples given in the (non-exhaustive) list fit within the character of delegated legislation, and would generally fall within the definition of legislative instruments. Further, a legislative instrument 'determines the law or alters the content of the law, rather than determining particular cases or particular circumstances in which the law, as set out in an Act or another legislative instrument or provision, is to apply, or is not to apply' and in this way, their inclusion within the definition of 'enactment' is clear.[49] Conversely, an instrument not of this character would fall outside the definition of enactment for the purposes of the *ADJR Act*.

The *National Statement* is the set of human research guidelines developed by the Australian Health Ethics Committee (a statutory Principal Committee of the NHMRC) and issued by the Chief Executive Officer ('CEO') of the NHMRC under s 10 of the *National Health and Medical Research Council Act 1992* (Cth) ('*NHMRC Act*'). However, the *NHMRC Act* explicitly states that guidelines developed by the NHMRC and issued by the CEO are not legislative instruments.[50] Looking at the history of the *NHMRC Act*, it is notable that this provision was introduced as part of a suite of amendments in 2006,[51] following the identification of governance issues by three major reviews.[52] The purpose of the amendments was to address concerns about the governance of the NHMRC and to clarify accountability mechanisms.[53] With such a focus, and viewed in the context of a detailed analysis of the mechanisms for accountability, it appears likely that the effect of this deliberate distinction between 'recommendations and guidelines' and 'legislative instruments' was appreciated at the time. Efforts to limit the potential for judicial intervention in this way can be driven, as Simon Young notes, by 'a desire for finality or certainty, a concern about sensitivity or controversy, a wish to avoid delay and expense, or a perception that a matter requires specialist expertise and/or awareness of executive context'.[54]

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47 *ADJR Act* (n 41) s 3(1) (definition of 'enactment' para (c)).

48 *Legislation Act 2003* (Cth) s 8.

49 Ibid s 8(4)(b)(i).

50 *National Health and Medical Research Council Act 1992* (Cth) s 9(3) ('*NHMRC Act*').

51 National Health and Medical Research Council Amendment Bill 2006 (Cth) sch 1 item 33.

52 Australian National Audit Office, *Governance of the National Health and Medical Research Council* (Audit Report No 29, 2004); *Sustaining the Virtuous Cycle for a Healthy, Competitive Australia: Investment Review of Health and Medical Research* (Final Report, December 2004); *Review of the Corporate Governance of Statutory Authorities and Office Holders* (Report, June 2003).

53 Explanatory Memorandum, National Health and Medical Research Council Amendment Bill 2006 (Cth) 1.

54 Simon Young, 'Privative Clauses: Politics, Legality and the Constitutional Dimension' in Matthew Groves (ed), *Modern Administrative Law in Australia: Concepts and Context* (Cambridge University Press, 2014) 276, 276.

In *Griffith University v Tang* ('*Tang*'),[55] Gummow, Callinan and Heydon JJ outlined a two-step test for determining whether a decision is made 'under an enactment':

> first, the decision must be expressly or impliedly required or authorised by the enactment; and, secondly, the decision must itself confer, alter or otherwise affect legal rights or obligations, and in that sense the decision must derive from the enactment.[56]

For this reason, it is important to note that the *National Statement* derives its legal force, not from the *NHMRC Act*, but from contract, as discussed in Part II above. This means that the first step of the two-part test articulated in *Tang*, that 'the decision must be expressly or impliedly required or authorised by the enactment', cannot be satisfied.[57] As Gummow, Callinan and Heydon JJ explained in *Tang*, '[i]f the decision derives its capacity to bind from contract or some other private law source, then the decision is not "made under" the enactment in question'.[58] An important implication of the approach taken by the majority in *Tang* was identified by Mark Aronson, who noted that it made judicial review of decisions made under 'soft law', including 'practice manuals, procedure pamphlets, guidelines and so forth' very unlikely.[59]

Alternatively, if the source of HREC power is found to derive from their institution rather than the *National Statement*, review under the *ADJR Act* is likely still unavailable given both: (1) the fact that many such institutions are established by state legislation or by incorporation, rather than by a Commonwealth Act; and (2) the lack of express or implied authorisation of HREC decisions in the establishing statutes of universities and research institutions, as required following *Tang*.

On this basis, ethics approval decisions made without engaging a specific statute, such as those relating to clinical trials or human embryo research, are almost certainly not open to judicial review under the *ADJR Act*.

2 *Waiver of Consent Decisions*

Decisions to grant waivers of consent are made in compliance with guidelines issued under ss 95 and 95A of the *Privacy Act*.[60] Unlike the *National Statement*, however, these guidelines are legislative instruments, present on the Federal Register of Legislative Instruments. The decisions are expressly mandated by the guidelines, and affect the legal rights and obligations of researchers by causing an act that would

55 (2005) 221 CLR 99 ('*Tang*').

56 Ibid 130 [89] (Gummow, Callinan and Heydon JJ).

57 Ibid. See also: *Australian National University v Burns* (1982) 43 ALR 25; *Australian National University v Lewins* (1996) 68 FCR 87.

58 *Tang* (n 55) 128 [81].

59 Mark Aronson, 'Private Bodies, Public Power and Soft Law in the High Court' (2007) 35(1) *Federal Law Review* 1, 23.

60 *Section 95 Guidelines* (n 18); *Section 95A Guidelines* (n 18).

otherwise breach an Australian Privacy Principle ('APP') to be regarded as not breaching the APPs.[61] In this way, these decisions meet both criteria for a decision made under an enactment articulated in *Tang*. They are also not excluded under the *ADJR Act* or the associated regulations.[62] Waivers of consent, then, appear prima facie to fit the definition of a decision under the *ADJR Act*.[63]

It is noteworthy that equivalent decisions in the United Kingdom are not made by their Research Ethics Committees, but rather by the Health Research Authority. This is a public body, constituted under the *Care Act 2014* (UK),[64] and its decisions regarding access to patient information without consent are made under the *National Health Service Act 2006* (UK),[65] on advice from the Confidentiality Advisory Group,[66] which is only set aside under exceptional circumstances. More firmly located within the executive branch of government, it is uncontroversial that these decisions are open to accountability mechanisms through judicial review.

The High Court of Australia has evinced a reluctance to extend the availability of judicial review to private bodies exercising public power, which would include at least some kinds of HRECs. In *NEAT Domestic Trading Pty Ltd v AWB Ltd* ('*NEAT*'),[67] the High Court declined the opportunity to adopt a functional approach to determining the scope of judicial review.[68] The High Court was limited in its ability to apply the functional approach taken in *Datafin* in a straightforward manner by the nature of the statutory test of a 'decision' which requires that it be made 'under an enactment'. Instead, the High Court characterised the issue in *NEAT* as whether it was necessary or appropriate to read the relevant statutory provision as authorising the decision. As a result, the majority in *NEAT* emphasised the structure of the provision in question and the roles given to the two main actors by the *Wheat Marketing Act 1989* (Cth), as well as the private, commercial nature of

61 *Privacy Act* (n 4) s 95(4).

62 *ADJR Act* (n 41) sch 1; *ADJR Regulations* (n 44) reg 6.

63 *ADJR Act* (n 41) s 3(1) (definition of 'decision to which this Act applies' para (a)). Note that in his submission to the Australian Law Reform Commission inquiry into Australian Privacy Law, Colin Thomson expressed concern about a proposal to elevate the requirement for HRECs review of waiver requests from the guidelines to the *Privacy Act*, on the basis that it may expose these decisions to judicial review. The Australian Law Reform Commission correctly commented that would not alter the availability of judicial review, given that the guidelines are legislative instruments. See *For Your Information* (n 37) vol 3, 2181–2 [65.107], 2190 [65.137].

64 *Care Act 2014* (UK) sch 7.

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

66 Terence W Wiseman, 'Confidentiality Advisory Group Already Regulates Use of Non-Anonymised Patient Data' (2014) 348 (March) *British Medical Journal* 2321; 'Confidentiality Advisory Group', *Health Research Authority* (Web Page, 4 May 2022) <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/>.

67 (2003) 216 CLR 277 ('*NEAT*').

68 Ibid 319 [134]. Cf the approach taken by courts in other jurisdictions: *Datafin* (n 38).

AWB (International) Ltd, as 'a company incorporated under companies legislation for the pursuit of the objectives stated in its constituent document'.[69] The perceived difficulty in reconciling public law obligations with the pursuit of private interests in this case led to a decision that, in Aronson's words, 'ruled that the statutory privileges of Australia's monopolist bulk wheat exporter were unrestrained by any considerations of public interest'.[70]

The decision in *NEAT* did not purport to answer the question of whether private bodies making administrative decisions could ever be subject to judicial review under the *ADJR Act*, although it provides guidance on when review will be excluded. Significantly, decisions about waivers of consent can be distinguished from the situation in *NEAT* in an important respect: HRECs are not corporations with attendant profit-maximising goals. The key role of HRECs in granting waivers of consent is to balance the public interest in health and medical research against the public interest in the protection of privacy.[71] The discordant interests that were so determinative in *NEAT* are not present here and, while the High Court did not embrace a functional approach, the decision in *NEAT* was closely tied to the specific facts of that case, leaving it open for the courts to find that a decision has been made under an enactment even when it is made by a private body. The nature of decisions about waivers of consent, the guiding interests, and the significance of these decisions for those affected are all such that a court would likely find waiver decisions amenable to judicial review under the *ADJR Act*.

3 *Common Law Judicial Review*

The issue as to whether HREC decisions are justiciable at common law has not been tested, which is likely a consequence of the complexity and technical nature of judicial review at common law.[72] Remedies in the nature of prerogative writs may be sought in relation to decisions that can be shown to be affected by jurisdictional error. The extent to which this approach is open to parties wishing to challenge the decisions made by bodies such as HRECs is, however, unclear. As detailed in Part II, some HRECs are private bodies and others could be characterised as public, if the power they exercise is found to derive from their institutional affiliation. This approach would result in the decisions of some HRECs being open to review by state Supreme Courts, while others would not, even though the HRECs may make similar decisions of similar importance. Alternatively, if the type of decision is taken as determinative of the source of power being exercised, then decisions involving waivers of consent, clinical trials of unapproved therapeutic goods, and human embryo research are all likely to be justiciable at common law, while other ethics approval decisions are not.

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69 *NEAT* (n 67) 297 [51] (McHugh, Hayne and Callinan JJ).

70 Aronson (n 59) 1.

71 *Privacy Act* (n 4) ss 95(2), 95A(3); *Section 95 Guidelines* (n 18); *Section 95A Guidelines* (n 18).

72 Australian Law Reform Commission, *Traditional Rights and Freedoms: Encroachments by Commonwealth Laws* (Final Report No 129, December 2015) 415–16 [15.11].

Further, even in instances when an HREC is incontrovertibly a private body, it is likely that its decision-making will be subject to the rules of procedural fairness for some decisions. Significantly, as recognised in *Kioa v West*,[73] 'there is a common law duty to act fairly, in the sense of according procedural fairness, in the making of administrative decisions which affect rights, interests and legitimate expectations, subject only to the clear manifestation of a contrary statutory intention'.[74] The 'legitimate expectations' aspect of this threshold test was subsequently described as 'superfluous and confusing'.[75] This position was clarified by Kiefel, Bell and Keane JJ in *Minister for Immigration and Border Protection v WZARH*,[76] noting that

> [t]he 'legitimate expectation' of a person affected by an administrative decision does not provide a basis for determining whether procedural fairness should be accorded to that person or for determining the content of such procedural fairness. It is sufficient to say that, in the absence of a clear, contrary legislative intention, administrative decision-makers must accord procedural fairness to those affected by their decisions.[77]

Both the *NHMRC Act* and the *Privacy Act* are silent on the content of the procedural fairness to be accorded to those affected by decisions made under their respective guidelines. Nonetheless, the *NHMRC Act* explicitly includes breach of the rules of natural justice as a ground for complaint in relation to funding decisions, and procedural justice in the review of research is identified as a key principle in the *National Statement*.[78] However, while procedural fairness has not been excluded, a court may determine whether an individual has been 'affected' by a decision with reference to the impact of the decision on their rights and interests. As established above, waivers of consent affect the legal rights of researchers, but the extent to which ethics approvals affect an individual's rights and interests is likely to vary and to be fact-specific, depending on the research being proposed, the source of the funding (if any), and the institutional affiliations of the researchers. Failure to progress beyond this threshold question represents a potentially significant barrier to obtaining judicial review of ethics approval decisions.

A cohort of cases has developed in which decisions made by private bodies, such as sporting clubs and associations, have been reviewed and the rules of procedural fairness or natural justice applied. For example, in *Forbes v New South Wales Trotting Club Ltd*,[79] a private trotting club was found to be required to accord procedural fairness in relation to decisions to exclude a person from its courses. As Murphy J noted:

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73 (1985) 159 CLR 550.

74 Ibid 584.

75 *A-G (NSW) v Quin* (1990) 170 CLR 1, 55 (Dawson J).

76 (2015) 256 CLR 326.

77 Ibid 335 [30] (Kiefel, Bell and Keane JJ).

78 *NHMRC Act* (n 50) s 58(a); *National Statement* (n 3) 9.

79 (1979) 143 CLR 242.

> There is a difference between public and private power but, of course, one may shade into the other. When rights are exercised directly by the government or by some agency or body vested with statutory authority, public power is obviously being exercised, but it may be exercised in ways which are not so obvious. In my opinion, a body, such as the respondent, which conducts a public racecourse at which betting is permitted under statutory authority, to which it admits members of the public on payment of a fee, is exercising public power. It may not arbitrarily exclude or remove such a person from the lands during a race meeting.[80]

An analogy can be drawn here with HRECs, being bodies which make decisions about the expenditure of (usually) public money in the public interest, in accordance with guidelines issued by a statutory body under the relevant Act, suggesting that HRECs too could be considered to be exercising public power. Although the majority in *NEAT* did not address the issue of 'public power', the focus on the incompatibility of private interests and public obligations in their reasoning leaves it open for more public-focused private bodies to be open to review.[81]

As the site of contentious decision-making moves away from loci of government action, the rationale for expecting adherence to administrative norms becomes less obvious. In *McClelland v Burning Palms Surf Life Saving Club*,[82] Campbell J considered suggestions that 'in relation to bodies which have no statutory basis but whose decisions can affect the rights of members or others, rules of natural justice are implied as a matter of public policy',[83] but concluded that

> [i]n Australia, the preferable view is that natural justice comes to operate in private clubs and associations by the rules of those private organisations being construed on the basis that fair procedures are intended, but recognising the possibility that express words or necessary implication in the rules could exclude natural justice in whole or part.[84]

However, these obligations can also be found in contracts, as can be seen in a number cases involving sporting and other clubs in which private law actions analogous to those pursued in administrative law have sought to imply terms into contracts requiring procedural fairness.[85] The applicability of such an approach is of limited utility in the HREC context, as the parties to the relevant contract (that

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80 Ibid 275.

81 *NEAT* (n 67). Note that Kirby J, in dissent, appeared to view public power as 'helpful in analysing whether particular decisions are of an "administrative character"', but declined to put forth a view as to whether it was 'sufficiently precise to be accepted as the basis for review of decisions under the common law': at 314 [115].

82 (2002) 191 ALR 759.

83 Ibid 784 [96] (Campbell J).

84 Ibid 785 [97] (Campbell J).

85 *Dickason v Edwards* (1910) 10 CLR 243; *Carlton Football Club Ltd v Australian Football League* (Supreme Court of Victoria, Hedigan J, 29 May 1997); *Australian Football League v Carlton Football Club Ltd* [1998] 2 VR 546. See also: Andrew

is, the funding agreement requiring compliance with the *National Statement*) are usually — though not always — the funding body and the institution to which the lead researcher belongs (most often a university or research institute) rather than individual researchers. This restricts the ability of researchers and members of the public affected by the decision to bring an action for breach of contract.

It appears that the rules governing a private body are critical in determining whether procedural fairness should be accorded, rather than its identity; although compatibility with public law obligations and the presence of alternative review options will also be relevant. It is likely that waivers of consent would be justiciable at common law and open to review under the *ADJR Act*. Additionally, ethics approval decisions might be amenable to judicial review at common law in the absence of a requirement that the decision be made under an enactment, although this is far from clear cut. This lack of clarity, combined with the modest remedies on offer, are likely to play a part in complainants being dissuaded from pursuing judicial review of HREC decisions at common law, contributing to a lack of accountability and consistency in HREC decision-making.

C *Freedom of Information as an Accountability Mechanism*

Freedom of Information ('FoI') legislation is 'intended to deliver more effective and efficient access to government information and promote a culture of disclosure across government'.[86] That is, it provides a mechanism for accountability through improved transparency. There have been a number of disputed FoI applications made by researchers to universities,[87] requesting information about the ethics review of research projects.[88] These requests demonstrate the lack of transparency in HREC decision-making.

For example, in *Re Whitely and Curtin University of Technology* ('*Whitely*'),[89] the complainant sought access to documents held by the university relating to a research program into Attention Deficit Hyperactivity Disorder, including the researchers' ethics application, documents relating to the funding of the study, as well participant

Buckland and Jayne Higgisson, 'Judicial Review of Decisions by Private Bodies' [2004] (42) *AIAL Forum* 37; Ian Fullagar, 'Australian Football League v Carlton Football Club Ltd' (1997) 21(2) *Melbourne University Law Review* 703.

86 Commonwealth, *Parliamentary Debates*, House of Representatives, 26 November 2009, 12971 (Anthony Byrne).

87 Note that these applications treat HRECs as committees of the university, and that ethics documentation was viewed as the property of the university — applications are made to the university rather than to the HREC as an independent body.

88 Mary Wyburn, 'Freedom of Information Applications and the Confidentiality of University Research and Research Review Processes' (2018) 18(2) *QUT Law Review* 171. See, eg: *Battin v University of New England* [2013] NSWADT 73; *Raven v University of Sydney* [2015] NSWCATAD 104.

89 [2008] WAICmr 24.

information documents.[90] The university withheld some of the documents on the basis of exemptions under sch 1 of the *Freedom of Information Act 1992* (WA) including, inter alia, exemptions under cl 6(1) for revealing information pertaining to deliberative processes that would be contrary to the public interest, and cl 11(1) for disclosure that would impair effective operation of the agency.[91] In particular, the university argued that 'damage may be done to university research if the deliberative processes that have taken place in coming to an agreed research protocol are made available to the public'.[92] The Acting Information Commissioner found the disputed documents not to be exempt, noting that the documents in question neither revealed information about deliberative processes nor that disclosure would be against the public interest:

> There is a strong public interest in agencies being accountable for their decision-making and in the public having access to information about university research projects, particularly where, as here, the Project involves academic research involving the medication of children with drugs. I agree with the complainant's submission that obtaining information about research of the kind being undertaken in relation to the Project is a strong public interest factor in favour of the public being able to scrutinise the approval given by the HREC of the agency and make its own judgment as to whether the HREC is discharging its functions properly.[93]

A public interest in the disclosure of HREC documents was also found in *Battin v University of New England* ('*Battin*').[94] In this case, researchers who had their ethics approval for a research project suspended after complaints were made about their research, sought to access information relating to those complaints under the *Government Information (Public Access) Act 2009* (NSW) ('*GIPA Act*'). Of the 44 relevant documents, the researchers were granted access to six, with the remainder refused on the basis that they were subject to legal professional privilege or that the public interest consideration against disclosure outweighed that in favour of disclosure.[95] The university's decision was reviewed by the Information Commissioner, following which the researchers applied to the Administrative Decisions Tribunal for review. The Tribunal set aside the decision and remitted it for reconsideration, observing that

> [d]isclosure of the information could reasonably be expected to promote open discussion of public affairs, enhance the Agency's accountability, and contribute to positive and informed debate on decision making by the Agency's [HREC], an issues [sic] of public importance. It is also clear that the efficient, effective,

90 Ibid [2]–[5].

91 Ibid [7].

92 Ibid [67].

93 Ibid [94].

94 [2013] NSWADT 73.

95 Ibid [3].

> and ethical fair consideration of human research proposals is of importance to the community general, and to the academic and research community in particular.[96]

Against these significant considerations, the public interest 'against disclosure of identifying information relating to complainants' was balanced,[97] but the Tribunal noted that 'identifying information relating to complainants could be readily deleted from those documents, without rendering them nonsensical' and that this would shift the balance of public interest towards disclosure.[98]

While the public interest in access to information about HREC decision-making was emphasised in *Whitely* and *Battin*, this was downplayed relative to the public interest in the confidentiality of HREC deliberations in *Raven v The University of Sydney*.[99] Five academics made a complaint to the University of Sydney's HREC about its approval of a clinical trial.[100] In response, the HREC suspended the trial while the complaint was investigated by independent experts.[101] The clinical trial researchers were given the opportunity to respond to the expert report, and their responses were reviewed by an independent biostatistician.[102] On the basis of these materials, the HREC reinstated approval for the trial with some additional conditions.[103] Melissa Raven, one of the original complainants, then applied for access to documents relating to the ethics approval and external review process under the *GIPA Act*.[104]

The university refused access to all documents apart from the revised participant information sheet, on the basis that there was an 'overriding public interest in not disclosing information created or received in confidence'.[105] Raven then applied to the Information Commissioner for review of this decision, who did not accept that disclosure would undermine the supply of information to it, and recommended that the university reconsider its decision not to disclose the documents. The university reaffirmed its original decision, and Raven subsequently applied for review which was undertaken by the New South Wales Civil and Administrative Tribunal ('NSWCAT'). There is a presumption in favour of disclosure in s 5 of the *GIPA Act*, unless an overriding public interest against disclosure can be established. NSWCAT accepted that 'disclosure of the information could reasonably be expected to enhance the accountability of the HREC and the University (being,

96 Ibid [43].

97 Ibid [58].

98 Ibid [77].

99 [2015] NSWCATAD 104.

100 Ibid [4].

101 Ibid [5].

102 Ibid [6].

103 Ibid [8].

104 Ibid [10].

105 Ibid [12].

in this context, the Government …)'[106] but that this benefit was nevertheless outweighed by the public interest against disclosure:

> There is a strong public interest in preserving the confidentiality of ethics applications and of the University's processes for considering such applications, so as to ensure that researchers continue to provide full and frank information when seeking ethics approval, that they continue to seek such approval at public institutions, that reviewers are prepared to conduct reviews and do so candidly and that HREC members are not inhibited in what they say about ethics applications in meetings. The prejudice to the supply of confidential information, and the effective exercise of the functions the University exercises through the HREC, could reasonably be expected to be significant.[107]

Taken together, these disputed FoI requests highlight the limited extent to which information about HREC decision-making is available, and the uncertainty of access even through FoI mechanisms, leading to significant issues in HREC accountability.

IV An Expanded Role for Judicial Review?

It is somewhat surprising that waiver of consent and ethics approval decisions — which are similar in nature (administrative), seriousness (breach of privacy regarding personal information, compared with unethical conduct of research with human participants) and purpose (protection of the public and maintenance of public trust in institutions and the research endeavour) — should not be open to the same opportunities for review. In assessing whether it would be desirable to extend the availability of judicial review to all ethics approvals, it is necessary to consider the extent to which this would be more broadly consistent with the goals of judicial review and administrative law norms. Further considerations include who would be likely to benefit from such a change, and whether similar benefits could be achieved more effectively through alternative mechanisms.

A *Aims of Judicial Review*

Administrative law is largely concerned with mechanisms for ensuring that government power is exercised 'in a fair rather than arbitrary manner'.[108] The *ADJR Act* was introduced to address the many shortcomings of the common law system

106 Ibid [41].

107 Ibid [131].

108 Matthew Groves and Janina Boughey, 'Administrative Law in the Australian Environment' in Matthew Groves (ed), *Modern Administrative Law in Australia: Concepts and Context* (Cambridge University Press, 2014) 3, 5.

identified in the Kerr[109] and Ellicott Reviews,[110] and aimed to improve administrative practice through increased accountability and transparency of executive action, by simplifying and codifying common law judicial review, and providing a right to written reasons for decisions.[111] It also, to some extent, extended the scope of judicial review. While initially successful in these goals,[112] difficulties have arisen in the application of the *ADJR Act* over time, exposing 'flaws and shortcomings', particularly with respect to the test for whether a decision is reviewable.[113] This has undone some of the early gains in respect of simplicity and, with it, resulted in some contraction of scope.

Writing extrajudicially, French CJ identified the key values of administrative justice as lawfulness, good faith, rationality and fairness, and argued that these are largely reflected in the statutory grounds for review articulated in s 5 of the *ADJR Act*.[114] Of particular interest are those grounds pertaining to breaches of the rules of procedural fairness, decisions not authorised by enactment, and improper exercises of power,[115] as well as the importance of access to reasons[116] — all of which clearly relate to the criticisms most frequently directed at HRECs.

Significantly, these administrative law norms are reflected within the *National Statement*. 'Procedural justice' in review of research is identified as a guiding value,[117] and this is further explicated in the requirements for handling conflicts of interest (reflecting the rule against bias) and for good communication and thorough review (reflecting the right to a fair hearing).[118] The guidelines also require that 'decisions are transparent, consistent, and promptly communicated' and that when a proposal is rejected, 'communication of the rejection must be in writing … and should include reasons linked to this National Statement'.[119] Further, Grant Davies

109 Commonwealth Administrative Review Committee, Parliament of Australia, *Commonwealth Administrative Review Committee Report* (Parliamentary Paper No 144, 1971).

110 Commonwealth Administrative Review Committee, Parliament of Australia, *Prerogative Writ Procedures: Report of Committee of Review* (Parliamentary Paper No 56, 1973).

111 Groves and Boughey (n 109) 8–11.

112 See, eg, Administrative Review Council, *Federal Judicial Review in Australia* (Report No 50, September 2012) 72–3.

113 Matthew Groves, 'Should We Follow the Gospel of the *Administrative Decisions (Judicial Review) Act 1977* (Cth)?' (2010) 34(3) *Melbourne University Law Review* 736, 771.

114 Chief Justice RS French, 'Administrative Law in Australia: Themes and Values Revisited' in Matthew Groves (ed), *Modern Administrative Law in Australia: Concepts and Context* (Cambridge University Press, 2014) 24, 37.

115 *ADJR Act* (n 41) s 5.

116 Ibid s 13.

117 *National Statement* (n 3) 9.

118 Ibid 86 [5.1.28(c)], 86 [5.1.28(f)], 86 [5.1.28(h)].

119 Ibid 86 [5.1.28(e)], 91 [5.2.24(c)].

and Lynn Gillam argued that HRECs are legally and ethically obliged 'to clearly articulate, document and be accountable for the reasons for their decisions, and to make their documentation available for external scrutiny'.[120]

This congruence of language and intent indicates that the aims and values underpinning HREC decision-making are largely consistent with the aims and values of judicial review. The criticisms of HRECs — relating to lack of transparency, inefficiency, inconsistencies between HRECs, and consideration of factors outside the *National Statement* — demonstrate that these aims are not being realised. These factors suggest that judicial review of HRECs, by promoting good decision-making, consistency and transparency, has the potential to provide an effective mechanism for addressing these concerns.

However, in determining the scope of judicial review, the court is balancing competing policy considerations. As Mason CJ observed in *Bond*:

> On the one hand, the purposes of the ADJR Act are to allow persons aggrieved by the administrative decision-making processes of government a convenient and effective means of redress and to enhance those processes. On the other hand, in so far as the ambit of the concept of 'decision' is extended, there is a greater risk that the efficient administration of government will be impaired.[121]

Although Mason CJ made these comments in the context of concerns about applications for review being brought prematurely, the policy considerations his Honour identified here — and the tension between them — have wider relevance to the goal of good administrative decision-making. Extending judicial review to all HREC decisions exemplifies this tension: while it would provide a mechanism for increasing HREC accountability and improving decision-making processes, it would also very likely decrease the efficiency of HRECs. This is because individual committees — worried about potential challenges to their decisions — would be less likely to participate in mutual acceptance of multisite research,[122] undoing

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120 Grant Davies and Lynn Gillam, 'Articulation and Transparency of Decision-Making by Human Research Ethics Committees' (2007) 26(1–2) *Monash Bioethics Review* 46, 46. Note, though, that their analysis appears to relate to an earlier version of the *NHMRC Act*.

121 *Bond* (n 43) 336 (Mason CJ).

122 As part of efforts to reduce duplication of review and to minimise the effects of inconsistent review between HRECs, the NHMRC instituted the National Certification Scheme of Institutional Processes Related to the Ethical Review of Multicentre Research, which is designed to support the National Approach to Single Ethical Review of Multicentre Research. HRECs certified under this scheme have demonstrated that their policies, processes and procedures meet the national criteria for the conduct of ethics review of multicentre human research. Certification is a requirement for participation in the (separate) National Mutual Acceptance scheme, run by the states and territories, which allows cross-jurisdictional acceptance of ethics review. However, not all HRECs are certified and, notably, Tasmania and the Northern Territory are not part of the National Mutual Acceptance scheme, and many of the

years of work and exacerbating existing duplicative review processes.[123] Indeed, in his submission to the Australian Law Reform Commission's privacy review, Colin Thomson suggested that judicial review would cause 'increasing concern among HREC members about the legal consequences of their decisions, leading to more conservative decision making'.[124] Such concerns about the potentially negative effects of judicial review on administrative efficiency and decision-making are not peculiar to HRECs, and can be seen across a wide range of administrative domains. Nevertheless, clear benefits — beyond mere congruence of goals — will need to be established to justify the risks. That is, while the goals of judicial review are consistent with the values underpinning HREC decision-making, the benefits of review must be weighed against the risks of potentially less efficient administration.

B *Potential Beneficiaries*

To assess whether judicial review may, in practice, address the issues plaguing HRECs, it is useful to identify who would be likely to make an application for review, and the extent to which they would be likely to benefit from judicial review. Researchers and research participants are those most likely to be able to establish themselves as persons aggrieved by a decision.[125] However, participants — or potential participants — would be unlikely to have (or to seek) access to information necessary for them to mount a challenge, until after a study has commenced and some harm has eventuated. For this reason, as well as the desirability of obtaining redress through an award of damages, participants might be more likely to pursue an action in tort rather than judicial review of the original decision.

Researchers, on the other hand, would be more likely to have access to sufficient information, as it would usually relate to their own application. Researchers are also more likely to know enough to be able to seek further information, evident in some of the FoI applications reviewed above, although access even through FoI mechanisms remains uncertain. Judicial review would be constrained in its ability to improve any deficit of accountability as a result of the problems arising from this lack of transparency, and the consequent difficulties that researchers might face in presenting evidence of legal error. While information would be discoverable in judicial review proceedings, potential applicants need to have sufficient information

problems of multisite review remain. See Tegan Cox, *Review and Evaluation of the National Certification Scheme for Institutional Ethical Review Processes* (Final Report, National Health and Medical Research Council, 21 November 2016) <https://www.nhmrc.gov.au/sites/default/files/documents/reports/ncs-evaluation.pdf>.

123 See, eg, Vasiliki Rahimzadeh and Bartha M Knoppers, 'How Mutually Recognizable Is Mutual Recognition? An International Terminology Index of Research Ethics Review Policies in the USA, Canada, UK and Australia' (2016) 13(2) *Personalized Medicine* 101.

124 *For Your Information* (n 37) vol 3, 2188 [65.129].

125 *ADJR Act* (n 41) s 3(4).

to initiate proceedings in the first place. Even in instances when researchers are sufficiently affected by HREC decisions and also possess sufficient access to information to pursue a grievance, applications for judicial review would likely be very rare: final decisions to reject proposals are a last resort, and usually follow a period of communication and negotiation between an HREC and the researcher.

Importantly, many researchers would not have the resources to pursue a legal challenge. Getting financial or legal support for such an action from their institution or funder would be challenging given the conflicting interests: NHMRC is the major funder of health and medical research, but also responsible for the regulation and registration of HRECs; and institutions often both employ the aggrieved researchers and hold responsibility for the constitution and operation of the HREC. Further, the consequences of adverse HREC decisions are generally not as serious for researchers (obstructed research, career implications) as for participants (breach of privacy, harm arising from unethical research), potentially reducing motivation for pursuing review. The lengthy court delays in some jurisdictions and limited remedial options on offer constitute additional reasons why judicial review may not represent an attractive mechanism for researchers, particularly if their research is time critical. These barriers are borne out by the dearth of cases relating to decisions about waivers of consent —although theoretically available, they seem not to have been pursued.

Judicial review would most likely be utilised by, and benefit, multinational randomised clinical trials ('RCTs'), or large multisite studies. With these groups, the stakes are higher, the funds are more plentiful (RCTs being frequently backed by pharmaceutical companies), and the effects of deficiencies — particularly relating to inconsistencies between HRECs — are potentially most acute. It is possible that a few review cases initiated by multisite RCTs would be sufficient to exert a moderating effect on HRECs, contributing to an overall improvement in adherence to administrative norms. However, it is also equally possible that it would lead to multisite RCTs being treated more conservatively than other proposals by HRECs, given that they represent only a distinct subset of proposals. The potential beneficial effects of judicial review on HREC decision-making are therefore far from obvious.

C *Another Way?*

The preceding analysis makes clear that increased adherence to administrative law norms is consistent with the guidelines underpinning the operation of HRECs, would be beneficial in HREC decision-making, and would potentially reduce criticisms of HRECs. However, it is not clear that judicial review is the most efficient mechanism for achieving increased adherence. Encouraging aggrieved parties to take their grievances about waiver decisions to the courts is perhaps more likely to result in burdensome and conservative practices than in improved adherence to administrative norms. This category of decisions involves assessing whether the proposal conforms to legal requirements, a function to which HRECs are perhaps not perfectly suited, given that they are constituted to assess ethical, rather than legal, acceptability of projects. For these reasons, consideration should be given to decisions about waivers of consent being made by a member of the executive and supported by a national body constituted for that purpose — analogous to the United

Kingdom's Confidentiality Advisory Group. Such a move would ensure concerns about capacity and consistency were addressed more effectively.

Improving administrative practice in relation to ethics approvals is more complicated. The *National Statement* already requires institutions to take responsibility for ensuring that their HRECs operate in accordance with the guidelines, that 'decisions are transparent, consistent, and promptly communicated', and that 'actual and potential conflicts of interest that may affect … review are identified and managed'.[126] This includes requirements to provide induction and continuing education to members of HRECs.[127] This is a significant burden on institutions, and one that has met with variable success. This variability is likely to be exacerbated in coming years, as the effect of the COVID-19 pandemic on universities and hospitals is such that funding is very unlikely to be directed towards the upskilling of HREC members or expensive improvement in the oversight of decision-making procedures.

Inconsistency between HRECs is one of the major criticisms levelled by detractors, and relying on individual institutions is unlikely to be effective at mitigating it. The NHMRC is the body most obviously placed to influence all HRECs in a consistent manner. Improvements to the existing guidelines, such as more explicit direction regarding reasons and review pathways, may go some way towards addressing this issue. Identification of an external body for handling complaints, rather than relying on institutions to identify and appoint independent investigators would also be beneficial. This might be achieved by either expanding the role of the Information Commissioner or establishing a body under the auspices of the Australian Health Ethics Committee and the NHMRC. Redistributing the burden of HREC oversight from institutions to the NHMRC would allow centralisation of training, professional development and monitoring, which would bring associated efficiencies and national consistency along with greater clarity in reporting and accountability. In short, there are a number of options available that collectively have great potential to improve adherence to administrative law norms, short of encouraging recourse to judicial review. Both the benefits of centralisation and the current challenges facing universities suggest that the NHMRC needs to take the lead in addressing consistency and accountability in HREC decision-making.

V Conclusion

The criticisms made in relation to HRECs strongly suggest the need for a mechanism to improve accountability and adherence to administrative law norms. Currently, the law regarding access to judicial review is complex, and it appears that only some HREC decisions are open to judicial review. While removing this inconsistency seems attractive, both in terms of improving accountability and simplifying access to judicial review, justifying an extension of the scope of judicial review

126 *National Statement* (n 3) 86 [5.1.28].

127 Ibid.

depends on the benefits of enhanced decision-making processes exceeding the risks of impairment to efficient administration. In the case of HRECs, this risk is not outweighed by the purported benefits, which appear equivocal at best. This suggests that alternative mechanisms should be explored instead and, in the current environment, the NHMRC is best placed to lead efforts to implement such mechanisms.

Considering cases on the margins that are neither clearly within or outside the scope of judicial review is useful for interrogating both the purpose of judicial review and the extent to which it achieves its aims. The decision in *NEAT* and the majority decision in *Tang* have been criticised, most notably by Kirby J, for adopting 'an unduly narrow approach to the availability of statutory judicial review', undoing the beneficial work achieved by the introduction of the *ADJR Act*, and 'occasioning a serious reduction in accountability for the exercise of governmental power'.[128] Yet examination of the liminal case of HREC decisions reveals that simple application of the *ADJR Act*, with a broad scope for judicial review, would not necessarily lead to the anticipated benefits of increased accountability and improved decision-making procedures, and may even have a negative effect by introducing inefficiencies. If judicial review is not going to achieve its helpful aims, then it is better to pursue more appropriate accountability mechanisms in its place, and allow judicial review options to be left as a final resort, should all else fail. While excluding review of certain administrative decisions removes an important safeguard, expansive judicial review is not necessarily an unalloyed good either. Particularly for these cases on the margins, we should be looking to promote the aims of administrative law with complementary accountability mechanisms to support improved decision-making.

128 *Tang* (n 55) 133 [99]–[100] (Kirby J). See also Christos Mantziaris, 'A "Wrong Turn" on the Public/Private Distinction: NEAT Domestic Trading Pty Ltd v AWB Ltd' (2003) 14(4) *Public Law Review* 197.