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Australian Attitudes Towards Waivers of Consent Within the Context of Genomic Data Sharing

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Abstract

This research identifies the circumstances in which Human Research Ethics Committees (HRECs) are trusted by Australians to approve the use of genomic data – without express consent – and considers the impact of genomic data sharing settings, and respondent attributes, on public trust. Survey results ($N = 3013$) show some circumstances are more conducive to public trust than others, with waivers endorsed when future research is beneficial and when privacy is protected, but receiving less support in other instances. Still, results imply attitudes are influenced by more than these specific circumstances, with different data sharing settings, and participant attributes, affecting views. Ultimately, this research raises questions and concerns in relation to the criteria HRECs use when authorising waivers of consent in Australia.

Keywords

genomic data sharing, public trust, human research ethics committees, waiver of consent, Australia

Introduction

Data sharing underpins advances in genomics and is associated with improvements in both medicine and healthcare through the potential to strengthen understandings, and the treatment of, diseases and health conditions (e.g., cancer [Beane et al., 2017)], infertility [Capalbo et al., 2021]). Still, this practice – and genomics more broadly – presents new challenges, especially for the key decision-making bodies that provide the necessary authorisation for research projects involving genomic data sharing. In Australia, these bodies are Human Research Ethics Committees (HRECs). Given the challenges that genomics brings, information about community expectations is needed to understand the extent to which people have and can have trust in decision-making processes, and criteria for genomic data sharing, within this research context.

Many of the challenges associated with genomics are due to a culture of data sharing (Byrd et al., 2020), and long-term, or even indefinite data storage capabilities, which complicate capacity to inform participants about what could and will happen to their data at the time of collection (Horton & Lucassen, 2023; Shabani & Borry, 2015). Data storage systems and the places and people responsible for them are also subject to varying interests and regulations (Wan et al., 2022), which can make future data use difficult to predict. Meanwhile, the unique and largely static nature of genomic data increases the potential threat to the privacy of those who donate data, and those related to them (Wang et al., 2017), and as such, works to exacerbate data sharing risks.

Previous research has shown potential donors are motivated to donate by the benefits of genomic data sharing, with importance attributed to helping those with specific illnesses and/or health concerns, as well society more broadly (see Oliver et al., 2012; Shabani et al., 2014). Nicol and Critchley (2012) found this tendency could be linked to the norm of reciprocity, with many of their participants willing to participate in, and to trust biobanks, so long as health benefits could be delivered to others, and themselves. Still, the challenges to privacy raised by genomic data sharing and storage are an important consideration for some. For example, an Australian study examining expectations of genetic biobanks showed many participants valued the potential healthcare benefits produced by these entities, but prioritised biobanks' capacities to protect the privacy of donors (Critchley et al., 2017). Similarly, in their investigation of attitudes towards DNA data donation in Australia, America, Canada, and the United Kingdom, Middleton et al. (2019) found 40.3% of participants unwilling to

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donate genomic data for research were worried about government agencies accessing data they had not opted to share with them, while 23.8% were concerned about police agencies having this capacity. A later publication demonstrated a similar level of uncertainty was shared by people from an additional eighteen nations, with many participants expressing their reluctance to donate anonymous genomic data to researchers – particularly those classified as 'for-profit researchers' – and to have their data accessed by multiple users (Middleton et al., 2020a).

Attitudes towards genomic data sharing have also been linked to trust in researchers, and the institutions perceived to be involved in the practice, with trust in these actors enhancing, or diminishing, trust in genomic data sharing (see Shabani et al., 2014). This sentiment was reflected in Kasperbauer et al.'s (2022) research, which showed participants trusted the Indiana Biobank located in the United States of America, to store their data, because they had trust in the health and academic bodies affiliated with it. While discussed with reference to trust, these findings raise questions in relation to the importance, and impact of 'trustworthiness'. Trust and trustworthiness can be understood and defined in different ways and are often framed as distinct concepts (see O'Neill, 2018). Whereas trust can refer to both "… a psychological state consisting of positive expectations… [and] a willingness… to be vulnerable or to risk being dependent in some way…" (Critchley & Nicol, 2017, p. 355), trustworthiness pertains to qualities that can be possessed, and/or demonstrated by entities (or individuals), which enable and show they can be trusted; for instance, having integrity, and/or acting with transparency (see Samuel et al., 2022). As such, though some scholars suggest trustworthiness is, in part, a consequence of the domain in which an entity or individual is operating (see Mayer et al., 1995), others explain there is a difference between trusting an entity or person in certain circumstances, and finding those actors inherently *trustworthy* (Sheehan et al., 2021).

Despite the distinctions that characterise trust and trustworthiness, certain types of trust, like public trust, appear to emphasise the links between these concepts. In fact, as Samuel et al. (2021) point out, public trust can be considered somewhat related to, or *reliant* on, the presence and/or impression of trustworthiness. The kind of relationship that can exist between trust and trustworthiness is evident in Kasperbauer et al.'s (2022) findings, with some participants indicating that their trust in the Indiana Biobank was due to its operation within a trustworthy health system, and the trustworthiness that this association implied. Still the relationship between trust and trustworthiness is less certain in other studies, such as that undertaken by Warren et al. (2023), which found participants' willingness to share genomic data depended on the context in which sharing would take place, with dramatic differences in intention to share between clinical, research, and commercial settings.

Other studies illustrate the role individual attributes, like age and gender, can have in relation to views on genomic data sharing. In their examination of donor preferences regarding data security in research repositories, Goodman et al. (2017) demonstrate the association between age and attitudes, showing older participants were significantly less likely than younger participants to think that there should be no links retained between their identity and de-identified data. Meanwhile, Middleton et al. (2020b) highlight the way in which gender may be related to trust, showing male respondents were more likely to demonstrate high levels of trust in the individuals and organisations they were asked to consider in relation to genomic data sharing (e.g., medical doctors, researchers, governments).

Knowledge of factors associated with willingness to participate in genomics may be useful for making decisions about genomic data sharing in the absence of explicit or specific consent. In Australia, there are different levels of decision-making. For example, in some instances, data custodians may determine whether data can be accessed, and how this data is provided (Palamuthusingam et al., 2019). More generally, authorisations of genomic data sharing are provided by HRECs, with the committees assessing the scope of consent associated with Australian projects. Researchers may obtain consent that is 'specific' (relevant only to a specific project), 'extended' (relevant to a similar or resulting project, or a project that fits within a certain area of research), or 'unspecified' (relevant to any future research). In some instances, HRECs can also grant researchers an alternative to consent, such as a waiver of consent. This enables researchers to access and use stored data without the express permission of the individuals that provided it (Eckstein et al., 2018).

As a result of Commonwealth, state, and territory privacy laws, there is some variability when it comes to the requirements that must be met to secure a waiver (Otlowski & Nicol, 2013). Still, certain conditions are consistently important, and required, for HRECs to grant a waiver of consent. These are provided in the *Guidelines approved under Section 95 and 95A of the Privacy Act 1988* (Australian Government National Health and Medical Research Council, 2014), and in the *National Statement on Ethical Conduct in Human Research* (Australian Government National Health and Medical Research Council, 2007, updated 2023), ('*National Statement*'). Under the *National Statement*, the following criteria are used to determine whether the requirement for consent can be waived:

(a) involvement in the research carries no more than low risk… to participants
(b) the benefits from the research justify any risks of harm associated with not seeking consent
(c) it is impractical to obtain consent…
(d) there is no known or likely reason for thinking that participants would not have consented if they had been asked

(e) there is sufficient protection of their privacy;
(f) there is an adequate plan to protect the confidentiality of data
(g) in case the results have significance for the participants' welfare… information arising from the research [will be made] available to them…
(h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits…
(i) the waiver is not prohibited by State, federal, or international law. (Australian Government National Health and Medical Research Council, 2007, updated 2023)

As expressed in the *National Statement*, "[g]enomic research is frequently considered to be greater than low risk, especially in the context of research involving Indigenous peoples" (Australian Government National Health and Medical Research Council, 2007, updated 2023, p. 47). Though this limits the potential for issuing waivers of consent for genomic data sharing, chapter 3.3 of the *National Statement*—which specifically pertains to genomic research—specifies that a HREC may consider authorising a waiver of consent if:

(a) the data or information to be accessed or used was previously collected and either aggregated or had identifiers removed, or
(b) prior consent for the use of the data or information was provided under the scope of a research programme that encompasses the proposed research project, or
(c) 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
(d) unspecified consent has been provided. (Australian Government National Health and Medical Research Council, 2007, updated 2023)

The above conditions mean researchers may face difficulties obtaining waivers for research that involves genomic data sharing. Still, some conditions are particularly problematic. For instance, it can be challenging to establish whether research is 'low risk' if the future use of the data is unknown, or open to change. In addition, as McWhirter et al. (2021) show, the circumstances in which it is 'impractical' to obtain consent are not always clear cut; for example, the *National Statement* does not specify whether costs associated with consent qualify as impracticability (see also Eckstein et al., 2018). Furthermore, as Ballantyne and Schaefer (2019) point out, whether the requirement for 'no known or likely reason for thinking the participants would not have consented if they had been asked' must apply to all participants (which would be almost impossible to satisfy), or most, or some other threshold, remains uncertain. In countries like the United Kingdom (UK), measures have been taken to address these issues. For instance, the UK's recent *Data Protection Act 2018* has introduced a public interest test that removes the requirement for individual consent when research involving personal health data is deemed to be in the public interest (Taylor & Whitton, 2020). In addition, those applying for consent waivers in the UK must demonstrate they have adequately engaged with the public for a waiver of consent to be granted (Eckstein et al., 2023).

Given the opportunities that medical research involving genomic data presents, and the fundamental role data sharing has in this research, it is important that genomic data is available to researchers. However, given the risks associated with this type of research, and with genomic data sharing more generally (Shabani and Borry, 2015; Wan et al., 2022; Wang et al., 2017), it is essential that protective mechanisms – such as the criteria provided in the *National Statement* (Australian Government National Health and Medical Research Council, 2007, updated 2018) – are in place. It is also important that attitudes towards these mechanisms are recognised and considered, so governance that is trusted, can be established, and maintained. As such, this article aims to identify the circumstances in which members of the Australian public would trust HRECs to approve the use of their genomic data without express consent. In addition, it aims to examine how specific genomic data sharing settings, and respondent attributes, contribute to trust in HREC decision-making.

Method

The study comprised a 22-question online survey with a between-groups design. It was approved by the University of Tasmania's Human Research Ethics Committee in November 2021 (Ethics Number: H0026098). In December 2021, a pilot version of the survey was administered using the Qualtrics XM cloud-based platform. It was completed by 90 individuals for comprehensibility, and to ensure a logical survey structure. A finalised version of the survey was then established on the platform.

The survey comprised three sections and included 21 multiple choice questions and one open-ended question (see Table S1). The first section centred on respondent demographics. The second section introduced respondents to genomic data via a short YouTube video (Garvan Institute of Medical Research, 2019), and gauged their understanding through a series of 'true or false' questions. The final section focused on respondents' knowledge of, and attitudes towards, HRECs.

Before answering questions in the final section, respondents were assigned one of three scenarios depicting a genomic data sharing setting, and a HREC's role within this process (Table S2 provides a summary of the

Table 1. Scenario Outlines.

Scenario	Description
1	A hospital doctor also has a research position at the local university. Patients seeing this doctor have agreed to allow different researchers (including those in other countries) to use their information and tissue samples for a variety of future studies. Patients will not know which researchers will use their information, or how their information will be used. Personal identifiers like name, date of birth and address have been removed from all information files and tissue containers. The doctor has been using the information and samples for a research project, which includes obtaining genetic information from the samples through a technique called genotyping. To save money, the doctor engages an overseas laboratory to conduct this test. The doctor wants to share some of their genotyping and medical information with a group of international researchers for a collaborative project. The information will be shared with other researchers through a cloud-based platform. Researchers will only be able to view and analyse the data within this system, they cannot copy the data to their own computers and use their own software to analyse it. Although information has been stripped of personal identifiers, there is a very slight chance it could be re-identified. The doctor has approval from their Human Research Ethics Committee (HREC) to share the patients' information with international researchers for the collaborative project.
2	A cancer researcher has a tissue bank of pancreatic cancer tumours, and surrounding normal tissue, which were collected from Aboriginal and Torres Strait Islander participants. Whole genome sequencing was performed on both the tumour and normal tissue in 2013. The researcher now wants to publish the results of the research, but the journal requires the whole genome sequence data to be deposited in a public repository. The repository allows only approved researchers to access and analyse the information. The information will be shared to approved researchers through a cloud-based platform. Although information has been stripped of personal identifiers, there is a very slight chance it could be re-identified. The original participants agreed to allow the original researcher to keep their tissue for use in further research on pancreatic cancer. The consent did not say anything about sharing their data for other purposes, or whether individual results of any future research would be returned to participants. The researcher has decided that it will be difficult and impractical to recontact the participants to obtain their consent to share their information, especially since the researcher estimates that half of the participants are likely to have already passed away. The researcher therefore gets approval from their HREC to waive the requirement for consent to share the anonymous genomic data. This means the HREC makes the decision as to whether the researcher can share the genomic data without the approval of the original research participants.
3	After obtaining approval from their HREC, a researcher recruits participants with a particular disease for a clinical trial of a new and original treatment/medication. The trial is funded by a private for-profit company. As a part of the trial, participants will need to provide blood samples for genotyping. The blood samples are stored in a centralised biobank operated by the same company funding the clinical trial. The biobank maintains a database of genomic information that is linked to the individual donors' medical information. Personal identifiers like name, date of birth and address have been removed from all of the information files and blood sample containers. Although information has been stripped of personal identifiers, there is a very slight chance it could be re-identified. The biobank will be maintained by the company with unclear future storage and sharing practices. Participants may withdraw from the clinical trial at any time but the company states that this does not include the ability to withdraw from the future use of their samples since they will already have been added to the biobank in a de-identified form. Any future use or sharing of participants' samples will require HREC approval.

respondents that viewed each scenario). The scenarios were adapted from those developed by McWhirter et al. (2020). To facilitate respondent understanding, the language used in the scenarios was simplified from the originals, and definitions of complex concepts and processes were made available by hyperlink. The selected scenarios were chosen as they depicted three realistic waiver of consent situations and included a range of salient features (public and private interests, use of Indigenous samples, clinical and research settings, inter alia) (see Table 1).

Members of the Australian public were recruited by Qualtrics XM to participate in the survey. All respondents were online panel members at the time they completed the survey. This method of recruitment was chosen because it provides straightforward access to a diverse range of people who can be easily engaged through quota sampling, and compensated for their time. Furthermore, we chose to undertake recruitment via Qualtrics XM because the company is affiliated with more than twenty sample providers (Qualtrics, 2021), which aids in capturing a more diverse sample of the Australian population. To participate in the survey, respondents had to be over the age of 18, reside in Australia, and meet specific age, gender, and geographical location parameters. Individuals were invited to participate via email, online portal advertisements, and text message. A detailed information sheet was located at the start of the survey, and available to all potential respondents before they began. Prior to starting the survey, respondents were asked if they consented to participate in the survey (see Table S1). At the end of the survey, respondents were reminded that by clicking 'Submit', they were consenting to participate in the survey.

Data was collected from December 15, 2021, to January 17, 2022. IBM SPSS Statistics version 28.0.1.1 (15) was used to conduct descriptive and inferential statistics. Binary logistic regression models were employed to identify

Table 2. Circumstances Wherein HRECS Would be Trusted to Determine Future Use of Genomic Data.

Circumstance type	Frequency (n)	Percentage (%)
If future research was beneficial	1892	62.8
If I was confident my privacy would be protected	1847	61.3
If I was going to be told about results significant to my welfare	1518	50.4
If I had the ability to opt-out of future projects	1368	45.4
If I am not going to lose any potential financial benefits from the data	1039	34.5
If the HREC classified the future project as 'low risk'	1037	34.4
If people like me had been asked their views of the proposed research, and thought it was reasonable	828	27.5
If obtaining my consent was impractical	616	20.4
If the HREC thought I was likely to have consented if I had been asked	488	16.2
Other	34	1.1
I would not trust the HREC to decide this	284	9.4

associations between respondent trust in circumstances surrounding HREC decision-making, genomic data sharing scenarios, and respondent attributes (age, gender, education level, and country of birth). Other important attributes such as ethnic and cultural group were excluded from the analysis because of the wide variety of backgrounds described by respondents, which made meaningful groups difficult to establish. As these models were engaged to explain rather than predict associations between variables, all remaining relevant covariates were included in all models.

Results

The survey received a total of 4209 responses. Upon excluding those with missing data, a sample of 3013 respondents remained. All respondents were living in Australia at the time they completed the survey. Most respondents were born in Australia (76.3%, $n = 2298$), with 4.3% ($n = 129$) identifying as Aboriginal, 0.5% ($n = 14$) identifying as Torres Strait Islander, and 1.0% ($n = 30$) identifying as both Aboriginal and Torres Strait Islander. Respondents came from more than thirty ethnic and cultural backgrounds. However, the largest portion (49.9%, $n = 1503$) reported that they had an 'Australian' ethnic and cultural background.

Almost a third of respondents were aged between 18 and 34 years (30.4, $n = 916$), 34.1% ($n = 1028$) were aged between 35 and 54, and the remaining 35.5% ($n = 1069$) were over 55. Just over half of the respondents identified as 'woman or female' (51.1%, $n = 1539$), and 48.2% ($n = 1453$) identified as 'man or male'. The remaining respondents had a gender identity that fell outside of these groups (0.7%, $n = 21$). While 40.7% ($n = 1227$) of respondents had an undergraduate, or postgraduate degree, most did not (59.3%, $n = 1786$).

Trust in HRECs to Determine Future Use of Genomic Data

To determine attitudes towards the use of a waiver of consent in relation to genomic data, respondents were asked to pretend they were a participant in the scenario they viewed. They were then asked to consider the circumstances in which they would trust a HREC to decide if their genomic data could be used for future projects. For the purposes of the survey, trust was defined as the belief that HRECs are competent, respectful of rights, and can be depended on (Critchley & Nicol, 2017). The circumstances respondents were asked to consider were derived from the criteria outlined in paragraph 2.3.10 of the *National Statement* (Australian Government National Health and Medical Research Council, 2007, updated 2018) that must be satisfied for a HREC to authorise a waiver of consent in relation to research.

Over half of the respondents reported that they would trust HRECs to determine whether their data could be used if the future research was beneficial (62.8%, $n = 1892$), they were confident their privacy would be protected (61.3%, $n = 1847$), and/or they were going to be told about results significant to their welfare (50.4%, $n = 1518$) (see Table 2). Less than half indicated they would trust HRECs to decide whether their data could be used if they had the ability to opt out of future projects (45.4%, $n = 1368$). Around a third said they would trust HRECs to determine the future use of their data if they were not going to lose potential financial benefits (34.5%, $n = 1039$), or if the future project was classified as 'low risk' (34.4%, $n = 1037$). Table 2 also shows just over a quarter of respondents indicated that they would trust HRECs to make decisions around data use in future projects if people like them had been asked about the research, and thought it was reasonable (27.5%, $n = 828$). Only 20.4% of respondents agreed they would trust HRECs to decide whether their data could be used if obtaining their consent was impractical, and 16.4% ($n = 488$) trusted HRECs to determine future use of data if the HREC thought it likely they would have consented if asked.

'Other' circumstances that would lead to respondents trusting HRECs to decide if genomic data could be used were highlighted by some respondents (1.1%, $n = 34$). For many of these respondents, having knowledge about what future research would involve, and how data would be

protected, was important to trust. For others, information about where and with whom data would be shared, mattered. Several respondents also implied they would trust HREC decision-making only if they were no longer living. Despite most respondents identifying circumstances wherein they would trust HRECs to make decisions around their genomic data, a small but notable proportion of respondents indicated that there were no circumstances under which they would trust a HREC to decide this (9.4%, $n = 284$).

Factors Contributing to Public Trust in HREC Decision-Making

Table 3 presents results of the binary logistic regression models in which statistically significant associations were identified. Non-significant results from the models pertaining to two circumstance types: 'If I am not going to lose any potential financial benefits from the data'; and 'If the HREC classified the future project as 'low risk'' (see Table 2), are not shown. The circumstance types 'Other', and 'I would not trust the HREC to decide this', are also not provided in Table 3. Analysis was not able to be undertaken in relation to 'Other' due to heterogeneity. Meanwhile, the use of a different reference category in relation to 'I would not trust the HREC to decide this' meant the results from this model could not be given in Table 3. As a result, this model is discussed without reference to Table 3 below.

Some circumstances in which HRECs were trusted to decide if genomic data could be used for future projects were associated with the scenario viewed. As Table 3 shows, Scenario 1 – which involved patients agreeing that their doctor could allow other researchers to use their information and tissue samples for a variety of future studies – was used as the reference category for all models. It was chosen because it outlines the simplest genomic data sharing setting. In comparison to respondents that viewed Scenario 1, those that viewed Scenario 2 were significantly less likely to trust a HREC to determine whether their data could be used if they had the ability to opt-out of future projects (odds ratio (OR) 0.78; 95% confidence interval (CI) 0.65, 0.93; p .005), but significantly more likely to trust a HREC to decide whether their data could be used if obtaining their consent was impractical (OR 2.24; CI 1.80, 2.78; $p < .001$), or if the HREC thought they were likely to have consented if asked (OR 1.90; CI 1.50, 2.41; $p < .001$).

Table 3 also shows that the circumstances in which HRECs were trusted to make decisions in relation to genomic data sharing were at times associated with respondent attributes. For example, older respondents (in this case, those aged 45 years and over), appeared more open to trusting the decision-making of HRECs if the research was beneficial (OR 1.63; CI 1.39 1.89; $p < .001$), and if they were confident their privacy would be protected (OR 1.85; CI 1.60, 2.16; $p < .001$). Furthermore, these respondents were significantly more likely to trust a HREC to determine whether their data could be used if they were going to be told about results significant to their welfare (OR 1.90; CI 1.64, 2.21; $p < .001$), and if people like them had been asked their views of the proposed research, and thought it was reasonable (OR 1.73; CI 1.46, 2.05; $p < .001$).

Gender too seemed to have a bearing on the circumstances in which HREC decision-making was trusted (see Table 3). In comparison to respondents who identified as women or female, those who identified as men or male were significantly less likely to trust a HREC to decide the fate of their data if they were confident their privacy would be protected (OR 0.74; CI 0.64, 0.86; $p < .001$), if they were going to be informed of results significant to welfare (OR 0.85; CI 0.73, 0.98; p .028), or if people like them thought the proposed research was reasonable (OR 0.79; CI 0.67, 0.93; p .005). At the same time, respondents who identified as men or male were significantly more likely to trust a HREC to determine data use if obtaining their consent was impractical (OR 1.30; CI 1.08, 1.56; p .005).

Other respondent attributes associated with circumstances were education level, and country of birth (see Table 3). Respondents that were not tertiary educated were significantly less likely to trust a HREC to decide whether their data could be used, even if their privacy would be protected (OR 0.82; CI 0.70, 0.95; p .011), or if obtaining their consent was impractical (OR 0.75; CI 0.63, 0.91; p .003). Respondents born outside Australia were also significantly less likely to trust a HREC to make decisions around their data if obtaining their consent was impractical (OR 0.75; CI 0.60, 0.94; p .011).

Only education and age were associated with the view that there were no circumstances in which a HREC would be trusted with decision-making. Those without tertiary qualifications were significantly more likely to report that they would not trust a HREC to determine whether their genomic data could be used in future projects (OR 1.83; CI 1.39, 2.40; $p < .001$). Older respondents were less likely than those younger to report that they would not trust a HREC to decide this (OR 0.77; CI 0.60, 0.98; p .048).

Discussion

Most participants in this study appear to prioritise an evaluation of potential benefits and risk mitigation when deciding whether they would trust a HREC to determine the future use of their genomic data. Two circumstance types: 'If future research was beneficial', and 'If I was confident my privacy would be protected', stand out as particularly – and almost equally – conducive to public trust in HREC decision-making (see Table 2). The emphasis respondents place on assessing benefit and risk in HREC waivers of consent considerations is consistent with participant responses to genomic data sharing more broadly

Table 3. Binary Logistic Regression Results for Circumstances Wherein HRECS Would be Trusted to Determine Future Use of Genomic Data.

	Circumstance type															
	If future research was beneficial		If privacy would be protected		If participants would be told about results		If there was the ability to opt-out		If other people thought the research reasonable		If obtaining consent was impractical		If the participant was likely to consent if asked	
Variable	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Scenario viewed														
Scenario 1 (ref)														
Scenario 2	0.96 (0.80, 1.15)	.659	1.02 (0.85, 1.22)	.868	1.06 (0.89, 1.26)	.542	0.78 (0.65, 0.93)	.005	1.08 (0.89, 1.32)	.428	2.24 (1.80, 2.78)	<.001	1.90 (1.50, 2.41)	<.001
Scenario 3	0.90 (0.75, 1.08)	.239	1.01 (0.84, 1.21)	.958	1.05 (0.88, 1.25)	.610	0.94 (0.79, 1.13)	.519	0.96 (0.79, 1.17)	.685	1.00 (0.79, 1.27)	.994	1.04 (0.80, 1.34)	.778
Country of birth														
Born in Australia (ref)														
Not born in Australia	1.20 (1.10, 1.43)	.053	1.02 (0.86, 1.22)	.794	1.16 (0.98, 1.38)	.091	0.88 (0.74, 1.05)	.150	1.01 (0.83, 1.22)	.958	0.75 (0.60, 0.94)	.011	0.89 (0.70, 1.13)	.346
Age														
18–44 (ref)														
45+	1.63 (1.39, 1.89)	<.001	1.85 (1.60, 2.16)	<.001	1.90 (1.64, 2.21)	<.001	1.00 (0.86, 1.16)	.979	1.73 (1.46, 2.05)	<.001	1.18 (0.98, 1.42)	.087	0.85 (0.69, 1.04)	.104
Gender														
Woman or female (ref)														
Man or male	1.02 (0.88, 1.19)	.770	0.74 (0.64, 0.86)	<.001	0.85 (0.73, 0.98)	.028	0.92 (0.79, 1.06)	.256	0.79 (0.67, 0.93)	.005	1.30 (1.08, 1.56)	.005	1.04 (0.85, 1.26)	.733
Other gender identity	1.17 (0.48, 2.85)	.731	0.76 (0.32, 1.80)	.527	1.92 (0.79, 4.69)	.152	1.55 (0.65, 3.72)	.323	1.17 (0.45, 3.04)	.753	0.46 (0.11, 2.03)	.306	1.51 (0.54, 4.21)	.432
Education														
Degree (ref)														
No degree	0.94 (0.81, 1.10)	.454	0.82 (0.70, 0.95)	.011	1.05 (0.91, 1.23)	.493	0.89 (0.76, 1.03)	.118	1.03 (0.87, 1.22)	.763	0.75 (0.63, 0.91)	.003	0.93 (0.76, 1.14)	.479

Note. The reference category is 'would not trust the circumstance type'.

(Middleton et al., 2019; Oliver et al., 2012; Shabani et al., 2014; Wang et al., 2017), and aligns especially well with the findings of Critchley et al. (2017), which highlight both the desire to facilitate healthcare benefits, and to maintain privacy, within the context of biobanking. This emphasis could also be understood to reflect the norm of reciprocity (see Nicol & Critchley, 2012), with respondents' trust seemingly linked to the advantages that would come from the research, and/or the extent to which they would receive a level of personal protection.

Of the remaining circumstances listed (see Table 2), no others appear to be as dominant in determining public trust. For example, less than a quarter of respondents expressed they would trust a HREC with decision-making if obtaining their consent was deemed impractical, or if the HREC thought they would have consented if asked (see Table 2). While these are currently key requirements in determining a waiver of consent in relation to Australian research, based on this survey, neither reflects community attitudes. Challenges for HRECs in interpreting these provisions have previously been identified, including the lack of guidance in what constitutes 'impracticality' (see McWhirter et al., 2020), and how an acceptable threshold for potential participants that would consent or not consent if asked, can be determined (see Ballantyne & Schaefer, 2019). The result is a situation where considerable variability between HRECs in the granting of waivers is likely (see Kornhaber et al., 2012 on variability in multisite research approvals). This research adds to the weight of these concerns by suggesting that—in addition to their interpretive challenges—the provisions also may not represent meaningful sharing constraints to potential donors.

Respondent attitudes were influenced by more than the specific circumstances they were asked to consider; with other aspects of the research process, and genomic data sharing settings, appearing to affect views. For instance, although most respondents did not trust HRECs to decide whether their genomic data could be used if consent was impractical or presumed, this had greater acceptance among those that viewed Scenario 2. These results could suggest that when difficulties and impracticalities associated with recontacting participants and obtaining consent are explained, individuals may be more inclined to accept a HREC's role in the sharing pathway. Given the link between views regarding genomic data sharing and trust in those responsible for the practice (see Kasperbauer et al., 2022; Shabani et al., 2014), it is also possible that some differences in respondent views may be a consequence of greater trust in HRECs. For example, respondents with higher levels of education, or who were older, may have been more likely to trust HRECs, as these groups are perhaps more likely to be familiar with, and have faith in, health research and research ethics governance. At the same time, given the relationship that can exist between trust, and trustworthiness (Samuel et al., 2021), it is possible that these differences could additionally, or instead, reflect the level of trustworthiness that certain people associate with HRECs.

Aspects of respondents' identities – including age, gender, education, and country of birth – factored in their attitudes in other ways. As in Goodman et al.'s study (2017), age was especially influential. For instance, while over half of the respondents reported they would trust a HREC to determine whether their genomic data could be used if the future research was beneficial, and if they were confident their privacy would be protected, there was greater acceptance of this position from those that were over 45 years of age. It is possible that because of their age, and responsibilities that come with age (e.g., caring for children, parents), older people may give greater consideration to potential benefits to health for themselves and others; this notion is supported by the fact that these older respondents were also more likely to trust HRECs with decision-making if they were going to be told about results significant to their welfare. With respect to the relationship between age and privacy, changes to what privacy means and looks like in the digital age could be at play here, as information and communication technologies are considered to not only impact notions of privacy (Becker, 2019; Nissenbaum, 2020; Pyrrho et al., 2022), but to influence different generations' understandings of, and expectations around, this. For example, the introduction, presence, and risks associated with such technologies are often suggested to contribute to older population cohorts' concerns around, and desire for, privacy (Fox & Connolly, 2018; Wilson et al., 2023). In comparison, having grown up with these technologies, younger people are presumed to have different attitudes towards privacy (Halperin & Dror, 2016; Lustgarten et al., 2020).

Gender also appeared to be particularly influential. While many respondents indicated they would trust HRECs to make decisions if they were confident their privacy would be protected, or if they were going to be informed of results significant to their welfare (see Table 2), this was less likely among respondents who identified as men or male (see Table 3). This tendency could be the result of men having higher levels of trust in HRECs; they may not feel that certainty around privacy mechanisms, or the return of results are important, because they have broad trust in HRECs regardless. Alternatively, it could be that they did not trust HRECs to make decisions in these specific circumstances *because* of their importance, preferring to retain individual autonomy instead. However, the finding that men have higher levels of trust is consistent with similar research (see Middleton et al., 2020b), and may explain why respondents who identified as men or male were also more likely to trust HRECs to approve the use of their data if obtaining their consent was impractical (see Table 3).

As respondents were not required to explain their reasoning in this survey it is difficult to definitively unpack these

associations. For instance, the connection that can characterise trust and trustworthiness makes it difficult to determine whether differences in respondent views – such as those that exist between respondents with different educational backgrounds, and those that belong to older and younger age cohorts – are due to trust in HRECs, the perceived and/or actual trustworthiness of HRECs, or a combination of the two. Additionally, it is possible that some responses reflect participants' assessment of the validity or relevance of the criteria themselves, rather than participant trust in HRECs to make decisions using these criteria. The results presented in this article are also subject to several limitations. Surveys only provide evidence of attitudes held at a particular point in time. This means that even if the same people are asked to answer the same questions at another time, there is a chance that their answers would be different. Furthermore, given the respondents were recruited using a non-probability sampling strategy, the generalisability of the results is limited. In addition, as particular individuals from online panels were invited to participate, it is likely that this sample represents the kinds of people that tend to be approached for, and involved in, studies. Still, with quota sampling, efforts have been made to ensure some sample diversity.

Educational Implications

Overall, the gaps identified in this study raise important questions when it comes to how some waiver requirements are being – and should be – drafted, interpreted, and utilised by HRECs. By highlighting the circumstances in which members of the public would trust HRECs with decision-making, the results demonstrate the degree to which waiver criteria can be justified, or fail to be justified, by public trust. Still, the results remind us that public trust is only one of the components that can be used to examine, validate, and uphold the frameworks that underpin regulatory systems. For this reason, it is important that the criteria continue to be considered and interrogated, particularly through the use of other lenses, such as a focus on respect for autonomy.

Best Practices

Survey results show there is a level of support for all criteria that HRECs use when determining scope of consent in Australia. Still, certain criteria – such as those pertaining to research benefits and privacy protections – appear especially relevant to public trust in Australia, while criteria concerning impracticality obtaining consent, and presumed consent, receive relatively weak endorsement. Results also suggest there may be people who will not be prepared to trust HRECs to make this decision, on their behalf, under any circumstances. Accounting for such perspectives adequately within the Australian regulatory framework will require, at the very least, clearer guidance for committee members on what it means for there to be no likely reason to think the participant would say no if asked for consent. More substantively, it may require the introduction of measures akin to that used in the UK, whereby researchers must demonstrate they have meaningfully and adequately engaged with stakeholders (see Eckstein et al., 2023).

Research Agenda

This article highlights the circumstances in which members of the Australian public trust HRECs to determine whether their genomic data is used without express consent. It demonstrates that public trust in HREC decision-making and support for waivers of consent can occur when benefits are associated with future research, and when privacy protection mechanisms are in place. However, it also shows that current waiver provisions may not adequately reflect community expectations, and therefore, could be unduly burdensome, and even work to impede research, without providing warranted protections. Consequently, these findings illustrate the need for greater focus to be given to the perspectives and understandings of individuals, and as such, for mixed-methods, or qualitative studies – that have the capacity to provide evidence of reasoning – to be undertaken. For waivers to be effective, and ethical, the criteria these are based on must adequately represent community expectations and values.

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Author Note

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Supplemental Material

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