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Evidence-Based Guidelines for Low-Risk Ethics Applicants: A Qualitative Analysis of the Most Frequent Feedback Made by Human Research Ethics Proposal Reviewers

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Abstract
Human Research Ethics Committee (HREC) reviewers often provide similar feedback across applications, which suggests that the problem lies in researcher awareness of key issues rather than novel, unsolvable challenges. If common problems can be addressed before lodgement by applicants referencing clear evidence-based supports (e.g., FAQs on common application shortcomings), it would improve efficiency for HREC members and expedite approvals. We aim to inform such supports by analysing the patterns in the most frequent feedback made by HREC members during review processes. We collected every instance (N=4,195) of feedback made on N=197 'low-risk' protocols by all HREC staff (N=16) at one institution over the course of a full year (2019). Reflexive thematic analysis to identify themes (and content analysis to determine relative frequency) revealed that the top three themes are consistent with existing literature: Consent, Administrative, and Methodological concerns. However, we identified important new themes that are not captured in previous research, including 'Risk to Researchers', 'Commercial benefit, scope and scale', 'Diversity' (covering issues of cultural sensitivity, language and accessibility), as well as fair right to a complaints process. Our thorough exploration of information-rich primary data marks an important methodological improvement over previous studies and offers a theoretical contribution to understanding themes that have heretofore been overlooked in the ethics review process. By identifying the common challenges experienced in HREC review we can better inform tailored supports to applicants (by extension reducing workload burdens on HREC systems) and reduce their perceived barriers to engaging in challenging but meaningful research.

Keywords Ethics applications · Research ethics · Ethical considerations · Ethics approval · Review boards · Research ethics committee

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Introduction

The ethics application process is complex even for experienced researchers. Around the world several studies have documented that submitted protocols have a high likelihood of being returned for minor modifications through to a complete overhaul. In Switzerland for example, when Bergstraesser and colleagues (2020) reviewed feedback on ethics applications they found that 62% of submissions ($N=74$) required modifications, whilst in South Africa, Silaigwana and Wassenaar (2019) found that not even a single application ($N=180$) received immediate approval in their first round. This high rate of returned ethics applications demonstrates the need for a clear guide to the types of questions applicants should consider, such as a list of common problems to enable self-checks prior to submission. The latter will be directly addressed in the present study as we explore patterns in the feedback made by reviewers of low-risk ethics applications.

In Australia, universities are responsible for assessing the ethical merit of all research on people conducted by their staff and students. A university will typically have a Human Research Ethics Committee (HREC) comprised of academics and community members with relevant expertise enabling them to assess and provide feedback on research ethics applications (Page & Nyeboer, 2017). However, HREC members encounter common problems and must issue the same feedback time and time again when reviewing applications (Allen & Flack, 2015). This not only creates extra work for HREC members, but often leads to a longer turnaround for researchers, many of whom are working on time-limited projects. Reilly et al. (2016) mention the clear need for support in preparing ethics applications, whilst Davis et al. (2022) suggest that a curriculum be developed to help students understand the importance of research ethics.

Taplin and colleagues' (2022a, 2022b) review of ethics application feedback in Australia found that researchers were usually able to address most issues to the HREC's satisfaction. Together with the earlier points it suggests that the problem lies in general awareness of issues rather than novel, unsolvable problems. If the same feedback is issued time and time again but can be easily resolved, then common problems should be able to be addressed before lodgement via clear guidelines so that researchers can submit an already optimised application. This would improve efficiency for HREC members and researchers.

The aim of the present study is to identify common themes in HREC feedback on 'low risk' ethics protocols; through recognition of common pitfalls for applicants we inform the development of research ethics supports and training resources. This issue has implications for the progression of knowledge because important and beneficial research may be left unexplored due to the perceived hurdles presented by ethics approval processes.

Although our study does not actively explore the moral reasoning in the HREC feedback itself, it is important to recognize that those making the decisions and giving feedback operate within and are informed by ethics theories. For example, HREC reviewers may make a feedback decision on ethics applications by weighing up both deontological and teleological rationales, and research ethics is often about identifying conflicting ethical dimensions (Thompson & Thompson, 1989). Therefore, in our study we adopt ethical pluralism (Resnik, 1998), which is also important because applications at our institution are both: (1) reviewed by staff from diverse backgrounds; and (2) concern research in a variety of disciplines each with its own ethical standards and codes of practice. While this might suggest that we can rely on basic human rights and normative ethics that underlie all research,

we would argue that the present study operates within an applied ethics framework since we seek to apply the principles of ethics to real-world problems (Allhoff, 2011). The key advantage of conducting our study with a broad applied ethics lens is that we do not need to reach agreement between moral theories, but rather seek consensus between researchers on the best resolution to an ethical dilemma in a discrete scenario by evaluating the facts, risks, and potential harms (Aita & Richer, 2005). This further underlines the importance of the present study as a way of better educating and training researchers on the key considerations when planning their own studies to reduce and better manage risks.

Problems Creating Ethics Applications

Many researchers are insufficiently prepared when it comes to creating an ethics application (Bergstraesser et al., 2020), and the perceived difficulty of ethics protocols can result in researchers focussing more on the superficial submission processes rather than fundamental issues of research integrity. This is especially pertinent for postgraduate students, whose development as researchers requires them to navigate this complex process while under degree-related time pressures. Lengthy HREC processes and anxiety may deter them from pursuing research that is deemed "too hard" to get approval (Davis et al., 2022).

Davis and colleagues (2022) also identified that lack of experience and familiarity with research ethics procedures was a key concern, especially for students. Even experienced researchers and staff report long and project-jeopardising wait times for their own studies when numerous amendments are required (Milosavljevic et al., 2022; Page & Nyeboer, 2017; Scott et al., 2022; Silberman & Kahn, 2011). This is perhaps understandable since ethics applications vary greatly across different projects and over time, particularly as new technologies and research practices emerge, such as online data collection and Artificial Intelligence. Researchers can also change discipline areas and methods, giving rise to new ethical issues requiring the development of original ethical research strategies.

While applicant experience is clearly important in creating a good ethics application, having a streamlined process benefits the HREC and applicants alike. The review of ethics applications creates a significant administrative load for HREC members, and by extension, the institutions they represent (Gillam et al., 2006). However, the present study is not an effort to review problems with application systems themselves because every infrastructure is different.

Perceived difficulties with gaining ethics approval can polarise the views of researchers and HREC reviewers (Gillam et al., 2006). Research has found that student researchers' attitudes towards ethics applications are heavily influenced by negative experiences recounted by peers (Brindley et al., 2020; Davis et al., 2022), and students have described the ethics application process as emotional, distressing, and draining (Brindley et al., 2020; Davis et al., 2022). Rather than focussing on the potential benefits and implications of possible research, applicants may be deterred by the process itself, meaning that academic and research integrity may regress if novel and generative research is avoided in favour of archival or metanalytical studies that do not require ethics review. Therefore, it is important to realign researcher views with those of ethics reviewers, underlining the need for a guide to the most important ethical issues that should be considered when designing a research project.

What We Know From Previous Research on Completing Ethics Applications

Previous studies from institutions around the world have used a variety of methods to find out more about issues with ethics applications, most commonly via interviews with HREC staff. We conducted a review of existing literature in online databases including JSTOR, Google Scholar, and Wiley Online Library, as well as journals specific to the topic material, such as the Journal of Empirical Research on Human Research Ethics. Keywords were used for the initial search (e.g., human research ethics; ethics committee; review / evaluation) as well as snowballing inquiries via reference lists to seek out relevant primary sources. Abstracts were screened to remove irrelevant studies, after which full text articles were read to finalise inclusion. A total of 17 different peer reviewed articles provided information that was directly relevant to identifying the themes that arise in the comments and feedback provided by ethics reviewers. The studies were predominantly in biomedical settings and consisted of interviews or focus groups with HREC members or Chairs ($n=6$) while a few others tapped into meeting minutes, notes, or shadowing of HREC staff at meetings ($n=4$). The remaining seven studies analysed trends in decision letters returned to applicants ($n=2$), comments on participant information sheets ($n=1$), with only $n=4$ studies actually extracting all observations, feedback, and revisions requested from the HREC database of applications during a specified period. It is important to note that almost all of those studies conducted qualitative analysis based on *predefined* coding categories so researchers sought out specific characteristics.

From the 17 studies we synthesised 10 consistent themes which are displayed for ease of reference in Fig. 1, and then expanded in Table 1. These are listed in order of prevalence, from most frequently cited to least: (1) consent; (2) methodology; (3) administrative errors; (4) risk; (5) the research team; (6) data security; (7) research merit; (8) respect for participants; (9) appropriate compensation, and; (10) financing of the research (see Table 1 for elaboration on each theme and citations).

These broad themes are a good start to answering questions about the major issues with human ethics applications, but there are numerous limitations of the existing research which we will try to overcome in the present study. First, the terms used in previous studies actually cover a multitude of issues, so the most prevalent might simply be topics with more diversity and therefore cover a myriad of implicit issues. For example, 'consent' might be the most raised issue only because there are so many variations on consent procedures to consider, and previous studies have elected to cluster all these diverse issues together. Whether an issue is commonly reported or not probably depends upon the level of categorization used by the researcher in qualitative coding, rather than anything more substantial.

Second, the prevalence of an issue does not reflect the ease with which that group of issues might be resolved or better taught and supported. For example, administrative or regulatory errors were wide-ranging and common throughout the literature, but they are also likely the easiest to fix with simply better cross-checking and proofreading. Third, most previous research hinges on interview data, with researchers conducting interviews with HREC staff and deriving themes from their responses (e.g., see Barnard et al., 2021; Brindley et al., 2020; Davis et al., 2022; Hibbin et al., 2018; Morton, 2022). However, this raises numerous problems, such as interviewees being subject to a bias in recall. This could lead to an oversaturation of the most readily recalled themes (such as easily addressed administrative or consent-form-related changes), or over representation of the most frustrating issues, or

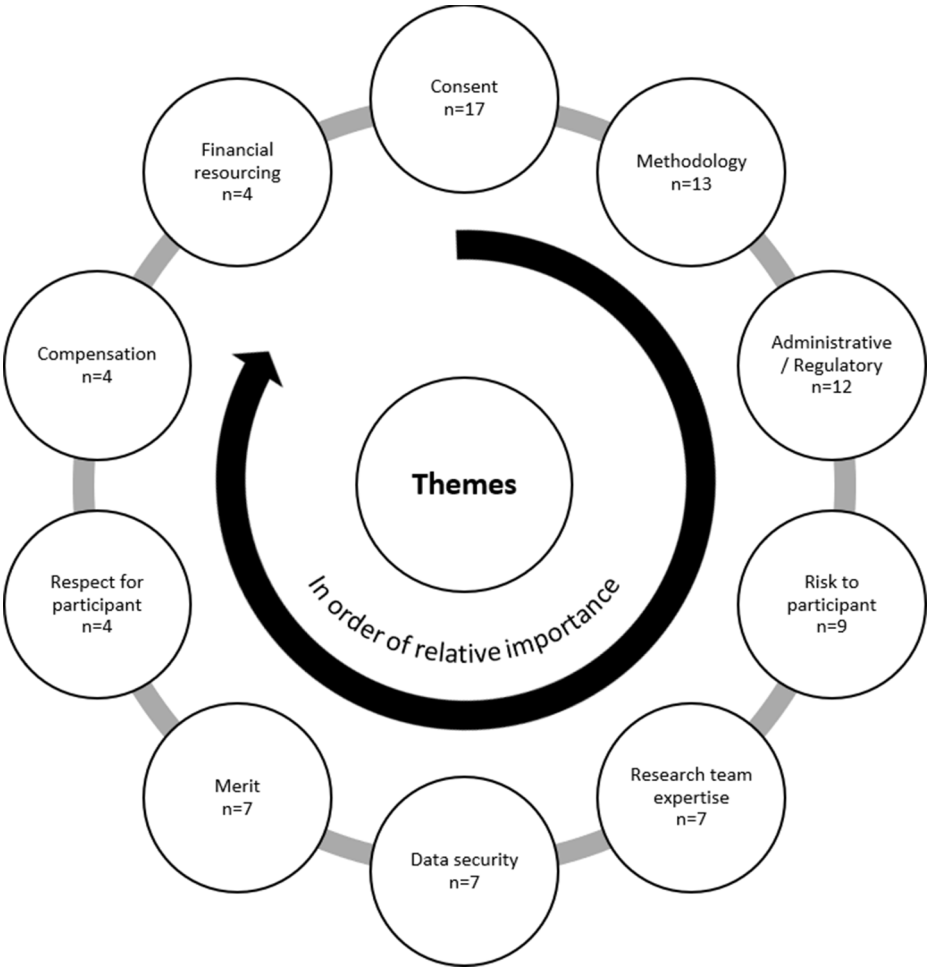

Fig. 1 Overview of the ten themes cited by existing studies ($N=17$) that suggest potential priorities in ethics review feedback

those that make the best or easiest story to tell an interviewer. Together, these methodological limitations may mean that individually nuanced concerns remain unreported.

Last, the small cohorts recruited for interview may have led to a narrowing of themes that arose because feedback is commonly influenced by the preferences and experiences of other committee members (Handal et al., 2021; Hibbin et al., 2018). While these are all problems for interview methodologies, even studies that did not use interviews came with their own challenges. For example, Taplin et al. (2022a) used vignettes that were less detailed than typical ethics applications, thus limiting the generalisability of findings.

Beyond the above methodological shortcomings, much of the previous research came from data gathered in the early 2000s or older (Decullier et al., 2005; Hemminki et al., 2015; Jones et al., 1996), and themes may have evolved with the significant shift toward digital application forms. For our interest, there is also a paucity of research on ethics in an Austra-

Table 1 Ten themes cited by existing studies ($N=17$) that suggest potential priorities in ethics review feedback

Theme (Appearing in n Studies)	Description (with Citations)
Consent ($n=17$)	• Failure to discuss appropriate consideration of informed consent, or consent processes absent (Allen & Flack, 2015; Barnard et al., 2020; Bergstraesser et al., 2020; Decullier et al., 2005; Hemminki et al., 2015; Hibbin et al., 2018; Martin-Arribas et al., 2012) • Inadequate participant information sheets so informed consent not possible (Angell & Dixon-Woods, 2009; Bergstraesser et al., 2020; Buchanan & Hvizdak, 2009; Dal-Re et al., 2004; Decullier et al., 2005; van Lent et al., 2014; Tsoka-Gwegweni & Wassenaar, 2014) • The consent forms were unsuitable (Bueno et al., 2009; Jones et al., 1996; Silaigwana & Wassenaar, 2019) • A lack of consideration of consent for research with children and adolescents (Bergstraesser et al., 2020; Taplin et al., 2022a) and vulnerable people (Silaigwana & Wassenaar, 2019) • Overly technical or confusing language so no assurance of fully informed consent (Bergstraesser et al., 2020; Jones et al., 1996; Morton, 2022; Taplin et al., 2022a)
Research methodology ($n=13$)	• Missing specification of age groups or inclusion/exclusion criteria; unclear or undefined treatment parameters; sampling issues; inadequate validity or general suitability of methodology (Barnard et al., 2021; Bergstraesser et al., 2020; Bueno et al., 2009; Buchanan & Hvizdak, 2009; Decullier et al., 2005; Hemminki et al., 2015; Jones et al., 1996; Morton, 2022; van Lent et al., 2014; Silaigwana & Wassenaar, 2019; Taplin et al., 2022ab; Tsoka-Gwegweni & Wassenaar, 2014). • No plans to convey research results (Suzuki & Sato, 2016)
Administrative or regulatory errors ($n=12$)	• Errors of writing and wording (Angell & Dixon-Woods, 2009; Bergstraesser et al., 2020; Jones et al., 1996; Silaigwana & Wassenaar, 2019) • Incomplete or missing paperwork (Angell & Dixon-Woods, 2009; Bueno et al., 2009; Decullier et al., 2005; Hemminki et al., 2015; van Lent et al., 2014; Martin-Arribas et al., 2012; Morton, 2022) • Difficult or improper declaration of conflicts of interest (Allen & Flack, 2015; Jones et al., 1996; Suzuki & Sato, 2016), legal issues (Angell & Dixon-Woods, 2009; Decullier et al., 2005; Jones et al., 1996) • Failure to properly register trials (Angell & Dixon-Woods, 2009; Jones et al., 1996)
Risk to participants ($n=9$)	• Underestimation or underappreciation of risks (Bergstraesser et al., 2020; Hibbin et al., 2018) • Omission of risk management or emergency plans (Barnard et al., 2021; Jones et al., 1996) • Unclear instructions for participants (Bergstraesser et al., 2020) • The presence of unacceptable risks (Barnard et al., 2021; Jones et al., 1996; Martin-Arribas et al., 2012; Taplin et al., 2022a; Taplin et al., 2022a) • Researchers neglected to demonstrate a favourable risk to benefit ratio (Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014)
The research team ($n=7$)	• HREC not satisfied with the calibre of the research team, typically that researchers were inexperienced or had lower-than-desired qualifications (Allen & Flack, 2015; Hemminki et al., 2015; Jones et al., 1996; Morton, 2022) • Suggestion that research teams engage with others prior to commencing the study, such as subject-matter experts, policymakers, or the community (Barnard et al., 2021; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014)
Participant data security ($n=7$)	• Privacy, such as encryption and anonymization (Allen & Flack, 2015; Bergstraesser et al., 2020; Hibbin et al., 2018; Silaigwana & Wassenaar, 2019; Taplin et al., 2022a) • The improper storage of data (Allen & Flack, 2015; Bergstraesser et al., 2020; Buchanan & Hvizdak, 2009; Hemminki et al., 2015)
Research merit ($n=7$)	• Ensuring that all research had social value and was worth doing, usually because objectives and reasons were not properly explained (Barnard et al., 2021; Decullier et al., 2005; Hemminki et al., 2015; Jones et al., 1996; Morton, 2022; Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014)

Table 1 (continued)

Theme (Appearing in n Studies)	Description (with Citations)
Respect for participants ($n=4$)	• Specifying whether or not an intervention will be available for participants post-trial (Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014) • Researchers did not identify a process in case of incidental or unexpected findings (Bergstraesser et al., 2020) • General concerns surrounding the treatment of participants (Morton, 2022; Silaigwana & Wassenaar, 2019)
Appropriate compensation ($n=4$)	• Not enough explanation on participant compensation (Suzuki & Sato, 2016) • Some reviewers wanted to ensure that research participants were reimbursed or compensated properly (Silaigwana & Wassenaar, 2019) • Financial incentives sometimes led to applications being rejected (Taplin et al., 2022a, 2022b • Participant compensation also included conflicting views in the literature
Financial resourcing ($n=4$)	• Concern that some projects did not have sufficient funding (Bueno et al., 2009; Hemminki et al., 2015; Jones et al., 1996; Suzuki & Sato, 2016)

lian context, with most studies being conducted in South Africa (Silaigwana & Wassenaar, 2019; Tsoka-Gwegweni & Wassenaar, 2014), the UK (Hibbin et al., 2018; Morton, 2022), the United States (Buchanan & Hvizdak, 2009), or Switzerland (Bergstraesser et al., 2020).

Therefore, our goals were to look at data from actual ethics applications themselves, and to use a bigger sample of instances each of which offered more detail, i.e., not sacrificing nuance for broad categorization. Rather than rely on the retrospective recall of reviewers, we were able to collect all instances of written feedback to applicants made by one group of HREC members over the course of a full year and conduct a thematic analysis (rather than using preconceived categories or checklists) to identify the complete range of themes that arose across the ethics protocol review process. Through this thorough exploration we aim to find ways to better inform researchers on strategies for addressing ethical issues before they submit their ethics application.

Method

This project was approved by the Human Research Ethics Committee of an Australian Technology Network (ATN) university; the name of the HREC body is redacted for confidentiality of participating research ethics advisors, professional staff, and Chair. Each participant in the human research ethics system under review provided explicit permission to release all the comments that they made on negligible and low-risk protocols in 2019. Protocols of a higher risk category are handled in a separate cohort that involves face-to-face meetings and community discussion; for consistency we elected to limit the analysis to the well-documented body of applications that were not deemed high enough risk to go to full committee sittings. The implications of this are covered further in the Discussion. Last, the resulting database was de-identified (both name of commenter and name of applicant removed) prior to being supplied to the research team.

Participants

Staff engaging in reviews at an ATN university's HREC community in 2019 were invited to participate. Participants served in one of three different roles; Ethics Compliance Officer (ECO; $n=5$); Research Ethics Advisor (REA; $n=10$); or HREC Chair ($n=1$). The role of the first relates to a professional staff review of all applications in relation to regulatory requirements, while the REAs undertake low-risk discipline-specific reviews and some also sit on the broader Human Research Ethics Committee which reviews moderate to high-risk applications. REAs were academics drawn from the disciplines of allied health; architecture; business and marketing; education; human performance; law; psychology; sociology; and STEM. The Chair role provides final reviews of all applications which includes oversight of REA recommendations as well as the responses that applicants make after they receive the guidance and changes requested via the HREC process. With a participation rate of 100%, the dataset accurately reflects the full range of reviewer comments on all negligible and low-risk applications submitted to the ethics review process at one institution, over the course of a whole year.

Materials

All human research ethics protocols at the participating institution are submitted via an online portal which uses algorithms to classify them into negligible risk (E1; 43.4% of applications), low-risk (E2; 44.0% of applications) and above low-risk (E3; 12.6% of applications). These digital submissions are initially reviewed by an ECO. E1s are then reviewed by the Chair, E2s are reviewed by an REA and the Chair, whilst E3s are reviewed by the full HREC and finalised by the Chair. Review comments for E1 and E2 applications are recorded on the online protocol in the form of communication 'Comments' between ECOs, REAs, and the applicant, whereas E3 review involves meetings and verbal exchange with community members of a broader HREC cohort. Since E1 aren't reviewed by an REA, E2 applications tend to have the most extensive text-based documentation (whereas E3 minutes are only a summary of the full verbal dialogue at committee meetings), therefore the decision was made to extract all comments made on E2 'low-risk' protocols. These comments from ECOs, REAs, and the Chair predominantly contain feedback directed toward the applicant regarding issues to be addressed prior to approval. The 2019 comments in the system ($N=4{,}195$) were extracted and deidentified, to form the dataset for the present qualitative analysis. 2019 was specifically selected as the last full year prior to the COVID-19 pandemic, which led to a sharp drop-off in research projects involving interaction with human participants in subsequent years. This also allowed a focus on analysing ethics themes without the COVID-19 confounder which still lingers in applications to date.

Procedure

In our analysis we aimed to explore the construct of 'feedback made by HREC members', so our qualitative research paradigm uses a factist perspective (Sandelowski, 2009), i.e., we view our data as accurate approximations of reality (Ten Have, 2004), and we can be confident of this because the database consisted of all possible comments that were made by HREC members in 2019. An initial thematic analysis was conducted to identify all areas

of commentary and not exclude themes solely based on frequency of occurrence. This is similar to the approach taken by other ethics researchers, such as Taplin et al. (2022a) albeit on HREC member feedback rather than responses to open-ended questions. Braun and Clarke's (2006) thematic analysis approach was further layered using reflexive thematic analysis (Braun & Clarke, 2019) to account for the subjective experience of ethics reviews and differences in reviewer perspectives. One author conducted the literature review, and we were conscious that their knowledge of the existing themes pervasive in the literature may similarly influence the perception of patterns that arise in coding. Therefore a combined reflexive process included procedural notes on each author's approach to coding and rationales for key decisions. Importantly, author relationship to those data was documented in those decisions, such as whether they were informed by our individual characteristics, background, or personal experience based on their role in the HREC. These were shared with the research team at regular meetings to better understand meaning-making from data and open a dialogue to guide key coding decisions.

Once theoretical saturation was reached and all unique themes in the dataset were identified, we then conducted a content analysis to quantify the relative importance of each of the themes (Vaismoradi et al., 2013). A key goal of the study was to identify the most frequently occurring feedback from reviewers to better inform supports for applicants. In sum, reflexive thematic analysis was first used to extract the themes whilst understanding potential bias, then subsequent content analysis identified the relative importance of those themes.

In the first pass of the full dataset ($N=4{,}195$ comments on E2 applications), a subset of $n=100$ comments were randomly selected to serve as a coding baseline and assist in early meetings between coders. A codebook was developed, and continually updated as new themes arose. The analysis consisted of $n=751$ comments from the chairperson (100% of chair feedback), $n=759$ comments from research ethics advisors (100% of REA feedback), and $n=1{,}352$ comments from compliance officers (54.4% of compliance comments before theoretical saturation). Saturation was achieved earlier in compliance officer comments due to the nature of the topic because feedback commonly pertained to administrative and consent processes (incidentally, two of the most commonly cited themes, see Results). Although saturation was reached faster when coding ECO comments, all instances of Chair and REA comments were included for analysis. This split between administrative/regulatory compliance comments and broader ethical considerations is a structure that has been recognised in other research (e.g., Hemminki et al., 2015). Therefore, saturation was achieved after a total of $n=2{,}962$ comments, representing comments made across a total of $n=197$ HREC applications made in 2019.

Results

Table 2 presents a detailed summary of each theme extracted in our reflexive thematic analysis, whilst Fig. 2 provides a quick overview of the content analysis (including the percentage of total comments to denote relative frequency). Note that as the thematic analysis unfolded, we decided that themes should be grouped under a 'parent node'. These clusters assisted with organisation, and overarching parent nodes were classified according to the implications or consequences for research participants. For example, a sub-theme relating to the dissemination of results to participants, as well as another sub-theme regarding the pres-

ervation of participants' anonymity, would together both represent a failure to uphold participant rights, and therefore clustered under the parent theme "Rights of the Participant".

Table 2 provides more detail than previous studies on each overarching theme and subtheme; we are able to present demonstrative quotes extracted directly from the dataset, as opposed to other studies which predominantly make use of retrospective memories of HREC interviewees. A major criticism made in our review of previous literature was the highly variable nature of categories, so we offer more thorough detail and examples of each theme to aid in the development of guidelines and supports for future applicants.

It was determined that some comments may fit into more than one theme. For example, reviewers occasionally wrote feedback for multiple elements of the ethics application in a single comment, meaning that some individual passages had to be separated into numerous codes, or double-coded when appropriate. The findings are explored further below, in particular comparing what we know from previous studies (Table 1) with what we have discovered in an exhaustive analysis of all HREC feedback over the course of one year (Table 2).

Discussion

We set out with an applied ethics perspective to explore the full range of HREC comments made on actual ethics applications (not limited to a specific area such as biomedical research) and conduct thematic analysis without preconceived categories, in order to better inform researchers on strategies for addressing ethical issues before they submit their ethics application. We can now see that many of the high priority concerns in the existing literature (Table 1) appear to be more a reflection of the working role of the HREC member, perhaps signalling impacts to their daily work, or components that are most memorable in interviews. In comparison, our findings in Table 2 offer more variation in themes, as well as nuance within each, which is particularly clear in the prevalence of sub-themes. We will discuss these differences shortly, but first it is important to note that there are some overarching similarities in the themes extracted.

Similarities Between Existing Literature and the Present Findings

Both our literature review of 17 existing studies (Table 1) and the results of our empirical analysis of one year's worth of HREC comments in one Australian institution (Table 2) demonstrate that 'Consent' is the most frequently cited ethical issue in applications. Both sources of data indicate that 'Administrative' and 'Methodological' concerns are the next two most common ethical concerns for reviewers, albeit the ranking for 2nd and 3rd are reversed. It should be noted however that we had to split one of the categories from the literature review ('Administrative and Regulatory Concerns'), into two separate themes for our dataset ('Administrative' and 'Regulatory and Legal') because they comprised a large portion of the dataset that warranted finer investigation.

More Granularity in Major Themes

Access to all comments made on every application over the year provided us the advantage of pressing further inquiry of the dataset. We discovered that not only was existing

Table 2 Results of the reflexive thematic analysis of 2,962 comments made by HREC reviewers at one Australian institution in 2019. The themes are listed from highest to lowest frequency (shown), and a definition and example quote are provided for each unique theme

Name of theme coded (with % Frequency)	Definition	Example quote
Consent (22.2%)	Comments relating to consent.	N/A – parent code
• Coercion and power dynamics	Comments that identify a risk of coercion (in the context of consent) due to power dynamics or unbalanced relationships.	*Given some potential participants are known to the researcher, provide details of the strategies the researcher will use to manage and/or minimise the potential for coercion in the recruitment process.*
• Consent process	Comments regarding the process that the protocol has outlined for establishing consent.	*Ensure that participants consent and that of any third party persons whose image made clear in the self-identity photographs taken by participants is obtained. If the research intends publishing the photographic material in the publication outcomes.*
• Extended consent	Comments about whether or not participants will be asked to provide extended consent and allow data to be used in future research.	*Consent Form - Add a statement to obtain participants* (sic.) *consent to use the data collected from them for future studies related to this project.*
• Informed consent	Where comments provided by HREC members refer to ensuring that participants have the right information and ability to truly opt in to the research.	*Participant information sheet and consent form - Amend the participant information sheet and consent form and ensure that the duration, location and forms in which data is stored at stated clearly.*
Administrative (16.2%)	Issues identified with the application's construction that derive from an administration error rather than a flaw with the study in question.	N/A – parent code
• Incorrect, incomplete, or inconsistent information	Where information is provided that is identified as inaccurate or incomplete, or inconsistent with another aspect of the application.	*The answer to this question should only be "yes" if the researcher will be travelling to the overseas country and collect data when in that country. If the researcher or colleagues are not travelling to the overseas country and participants from the overseas country complete an online questionnaire, the research is not being conducted overseas. Please consider and change the response if appropriate.*
• Personnel, organisations, and contact details	Comments that mention the exclusion of details about people or organisations involved in the research.	*Submit a list of the participating organisations when finalised.*
• Spelling, grammar, wording, and formatting	Where a HREC member has raised an issue with spelling, grammar, wording choice, or the formatting of any part of the application.	*Participant Information Sheet- Correct the typograhical* (sic) *error in the third sentence under the heading "What will I be asked to do". The word should be "six" not "ssix".*

Table 2 (continued)

Name of theme coded (with % Frequency)	Definition	Example quote
Methodology (14.2%)	Critiques on the proposed methodology for a study - HREC members suggest alternative approaches or point out that something does not work or make sense.	*provide greater detail about the research design and methodology. More detail about what will be undertaken on the blood - the tests and measures that will be conducted to collect data to answer the research questions stated in 5.3*
Rights of the participant (11.6%)	Where the rights of the participant have not been considered. HREC members may want the researchers to take steps to improve the way participants are treated.	N/A – parent code
• Anonymity	Comments relating to the anonymity of participants or others who may be mentioned in the research (such as clients or students of participants).	*Explain what is meant by "Only the researcher and supervisors have access to this data." The questionnaire appeared to be anonymous so how will* [you] *be able to identify people who have responded and submitted the questionnaire?*
• Complaints process	Comments relating to the inclusion of complaints process instructions.	*Participant information sheets. Add the following statement to all participant information sheet: "Participants or third parties who wish to lodge a complaint about either the study or the way it is being conducted should contact the Executive Officer of [redacted] HREC in the first instance, email: [redacted] or tel: [redacted]."*
• Dissemination of data and findings	Comments that address how findings will be provided to participants - with reference to final reports or transcripts.	*Please note that the minimum requirement is provision of a summary of the research findings.*
Regulatory and legal (10.4%)	Comments that address concerns related to compliance with laws, regulations, and ethics requirements.	N/A – parent code
• Agreements or approvals	Where HREC members have identified a missing or incomplete agreement or approval from external parties - includes industry partners, students, educational institutions, and government organisations.	*Arrange for the transcriber to sign a confidentiality agreement, if other than the researchers.*
• Compliance	Comments that mention an application's compliance with a policy or legal requirement.	*Clarify whether the researcher has a current National criminal history clearance (police check) to work with children.*
• Conflict of interest	Where HREC members are concerned that a conflict of interest is present and not declared or improperly declared.	*This relationship may require clarification. Is the researcher in an employment (paid) relationship to the host school within which the research is to be conducted? Should this be the case, its is recommended steps be taken to make clear to participants that this relationship exists.*

Table 2 (continued)

Name of theme coded (with % Frequency)	Definition	Example quote
• Insurance	Where a HREC member flags that the researcher has not considered insurance, or wants to verify that insurance has been secured for the project. Tiny category to date, so may merge with another code.	*Obtain confirmation of insurance cover from the [institution] Insurance Office – please refer to the following website for details and send your Research Project Insurance Application Form to [redacted]*
• Intellectual property	Comments about intellectual property and ownership of data, including concerns about obtaining IP protection or checking IP for a concept to be employed in the study.	*Students generally own the intellectual property they develop during their research, unless you have an agreement in place with the university or a staff member. If an agreement exists, please attach at 'Attachments' within this application. If no agreement, please change your selection at 8.3.*
Data security and storage (7.0%)	Comments on storage of data, or how secure it will be during the study - who can access it, where it will be physically stored, and when it will be deleted.	*Please note the HREC does not consider storing data on a USB stick (or external hard drive and/or CD) to be secure as these mobile devices are not only vulnerable to theft but deterioration with time. Wherever possible Research Data, Primary Materials and Research Records should be stored on the local school/research concentration server drive as this data is backed up nightly. Standard practice should be to store all data on the local server.*
Back-end and communication (6.6%)	Parent code for comments pertaining to the software and where reviewers have logged communications from applicants and those between HREC members.	N/A – parent code
• Acknowledge a procedural step	A reviewer providing feedback that something is okay, as long as the researcher takes note that they will need to complete some procedural step prior to enacting a certain stage of their research	*Note that ethics review queries generally indicate a need to amend the application to reflect the requested information, rather than simply to inform the reviewer. The application needs to reflect the final form of your intended activity, thus comments need to be responded to AND the application amended as indicated. Thanks*
• Communications between HREC members	Private notes from compliance officers to reviewers, or other messages to HREC members to the effect of "take note of this aspect in the process of your review".	*Highlighted for the Review Panel. You may wish to follow-up with the researcher.*
• Communications from applicants to HREC members	Applicants might submit clarification or notify HREC members of revisions.	*The school will not be identified in the data. The staff and children of the school will know who is the Principal and who is the school well-being leader. The public and readership of reports will not be able to identify the school or the individual leaders.*
• Systemic complications	The applicant or reviewer experience some challenges or setbacks related to the ethics protocol system (Research Master) or confusion in how to manage the application on the back-end.	*With apologies for the delay in this application being processed - I have amended the proposed amendment date so that the system will allow me to continue to review application. Please review and amend this date to suit adjusted commencement date of study*

Table 2 (continued)

Name of theme coded (with % Frequency)	Definition	Example quote
Risk to participant (5.7%)	Unacceptable physical, psychological, or other risks to participants are identified by HREC members; also risk and crisis management plans may be referenced.	*Tick "involves personal sensitive information and psychological emotional stress". Faith is personal. Emotions can be strongly felt and sometimes distressing. You will need to attach a distress protocol detailing culturally appropriate support resources and actions if a participant became distressed.*
Diversity (1.1%)	Comments that address concerns that research may be exclusionary of someone on the basis of culture, language, or ability.	N/A – parent code
• Cultural sensitivity	Comments around cultural or ethnic considerations.	*Please also consider that given the nature of island communities that ensuring anonymity and confidentiality of participants may also require masking of organisation names and communities/towns etc.*
• Language and accessibility	Ease of reading and language barrier concerns that may prevent a participant from understanding the information or that the HREC finds difficult to understand.	*Please provide clarity regarding how you will communicate the Participant Information Sheet to participants (whose first language is not English), to ensure each participant gives free and voluntary consent to participate in the project.*
Participant compensation (1.0%)	Where a HREC member comments on the financial or material compensation that participants will receive.	*Under the heading 'Payment', please clarify if participants will be paid the $20 Gift Voucher for each phase of the study that they complete (i.e.* [sic]*- if they complete both groups they will receive a $40 gift voucher in total)*
Research team expertise (0.7%)	Questions about the knowledge, skills, and qualifications possessed by the research team.	*Please list your qualifications (e.g. undergrad, hons, masters etc.) as well as your experience. Please also list the qualifications and experience of your supervisor*
Unsure (0.6%)	Comments that are unclear and/or lack context.	*OK as E2.* [later established as referring to the assessed level of risk and whether it needed to be raised to E3]
Scope and scale of project (0.5%)	Comments regarding the scope and scale of projects.	*Please could you clarify for the ethics reviewers if any information generated by this project may be used for another purpose/future research and/or to establish a database/ register for future use? Many thanks*
Risk to researcher (0.5%)	Where physical, psychological, or other risks to the researcher are identified that were not considered or well fleshed out in the application.	*Please reconsider whether there are any risks to the researcher given the researcher will be visiting homes of children both of which are unknown. Please consider whether it is necessary to check in and out of the home visits with a local "safe" person such as the principal of the school. Further, to carry a mobile phone when conducting the school visits.*
Merit and beneficence (0.4%)	Comments on the merit or benefit of a study either broadly or for participants.	*please consider adding here that, although this research may have no direct benefit to individual participants, they will have the opportunity to voice their opinions and contribute to research that may inform future development and debate*

Table 2 (continued)

Name of theme coded (with % Frequency)	Definition	Example quote
Request for clarification (0.4%)	Where HREC members ask the researcher to clarify something. Items are coded here when they are unrelated to the other themes.	*Please expand on your response to this question. Your answer should incorporate some supporting information and references sourced from the key references you have included in the 'Attachments' section of this application.*
Duplicates (0.3%)	Where two identical comments are discovered, one is coded here.	N/A – contains only duplicates
Praise for applicant (0.3%)	Comments that have no requests for changes and instead praise the research application for quality and detail.	*Thank you for providing a well written participant information sheet that covers the aspects of your research project.*
Commercial benefit (0.2%)	Comments on the commercial benefit of research.	*provide details of the commercial benefit including the benefit itself and identify the recipient(s)*
Financial resources (0.2%)	Comments relating to funding or financial backing of a study.	*With reference to the information provided under the 'Project Funding' page, please include a brief statement regarding funding and support sources. National Statement, Ch2.2 (2.2.6).*

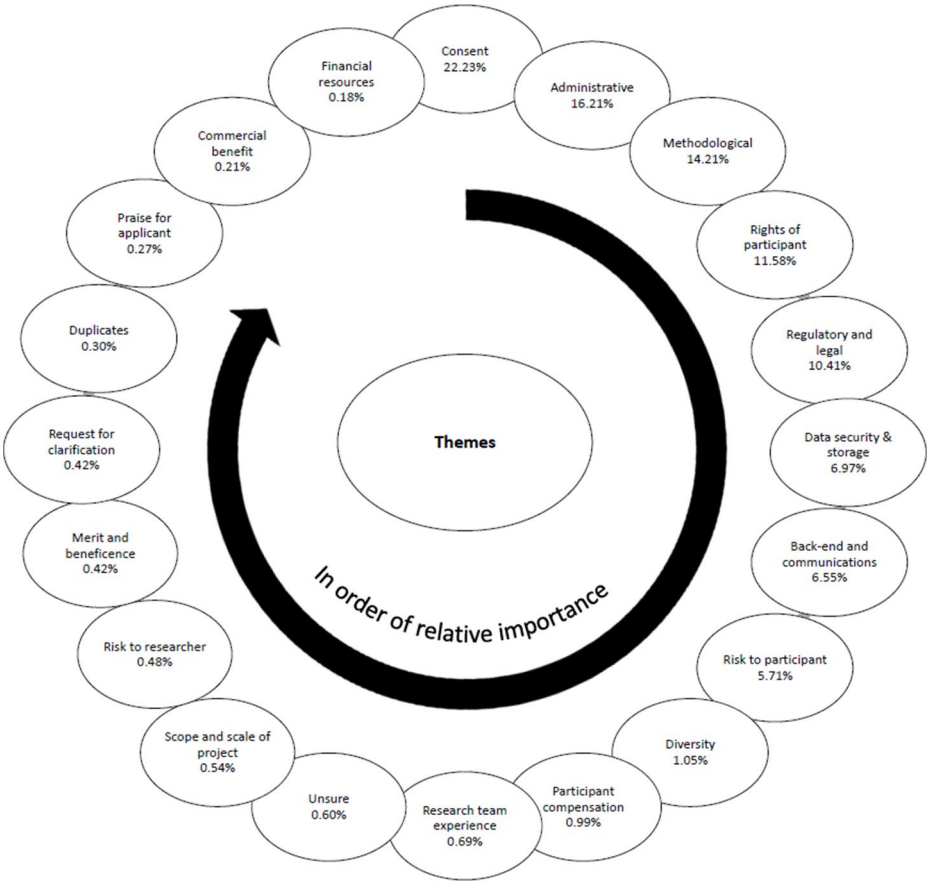

Fig. 2 Results of the reflexive thematic analysis of $N = 2{,}962$ comments made by HREC reviewers, organised by relative frequency (content analysis)

literature inadvertently combining two unique themes into one broader 'Administrative' construct, but that these two themes actually contained a finer selection of sub-themes not otherwise detailed in previous research. For example, our 'Regulatory and Legal' code (which was itself subsumed under typical administrative concerns in previous studies) held a rich selection of unique themes such as the preparation of agreements with key stakeholders, the potential for conflicts of interest, the absence of insurance documentation, and even possible concerns over intellectual property. Each of these different sub-themes brings hitherto unforeseen nuance to the ethical review process, and due to the methodological shortcomings of existing literature the sub-themes have been unexplored to date. However, it is important to see that the top 3 overarching themes are indeed consistent between the review of previous literature and our own dataset, because it reinforces that all HRECs do have a shared experience in their common feedback, suggesting that our findings may be generalisable to HRECs abroad.

Important Differences from Previous Empirical Findings

There are some key differences between the literature review of previous studies and our own dataset, and we have highlighted three important elements: (1) the researchers themselves (risk to researchers in our findings, vs. critique of researcher expertise in existing literature); (2) commercial benefits and complaints processes; and (3) anonymity.

Risk to Researchers vs. the Research Team's Expertise

First, the theme 'Risk to Researchers' did not arise in previous studies, whereas in our data we discovered that REAs were indeed concerned about the welfare of researchers during data collection and in the context of both physical and psychological safety. This may again be due to the strength of our methodology, because it is unlikely that protecting the researcher is the first thought that springs to mind for a HREC member being interviewed about the review process. In contrast, the existing literature had a strong representation of concerns around a lack of expertise in the applicant's research team, but we found a lower prevalence of these comments in our dataset. This finding is also paralleled by the higher prevalence in previous literature of interviewees critiquing the merit or beneficence. This could be due many reasons including past methodological issues wherein interviewees disproportionately recall criticism, or it simply being of less concern at our institution.

Commercial Benefit and Complaints Processes

In contrast, our dataset revealed more frequent comments around the commercial benefit, scope and scale of applications. This may be due to the background of the institution; as an ATN University there is legacy of the application of knowledge and translation of theory into practice. It is also interesting to note the higher frequency of comments on diversity in our dataset, such as references to cultural sensitivity, language, and accessibility. Further, there was a high representation of comments asking researchers to include a complaints process; just like accessibility, this issue resonates with a failure to uphold participant rights and fairness to all. Whilst it is possible that these themes are the result of idiosyncrasies in institutional systems (the present study does not directly compare how each institution's protocols are structured), it is important to recognize the potential that current literature with its methodological shortcomings may fail to recognize or inadvertently downplay the importance of some of these key common omissions in low-risk ethics applications.

Anonymity

In the literature review we saw the topic of anonymity buried amidst other related constructs, represented in the 'Participant Data Security' theme. However, in our analysis of all comments we found the topic of anonymity to be a prominent theme in and of itself. Anonymity encompassed comments that: sought clarification on identifiability; suggestions for information sheets and consent forms; or, proper communication on the nuances of anonymity to research participants (e.g., requesting that researchers include an agreement to maintain anonymity amongst participants of a focus group). Many applications failed to consider these elements so 'Anonymity' became a highly-coded sub-theme of the 'Rights of

Participants'. Researchers often treated data as entirely anonymous in their applications, but the ethics reviewers did not agree and asked for the response to be amended. There seem to be researcher misconceptions around the modalities of anonymity in research, which makes for an important area of ethics education. For example, tertiary educators could discuss how different methodologies can impact on anonymity, how data can be reidentified through voice recordings, and how pseudonyms or codes that are applied to the data can be stored separately (the difference between anonymity and confidentiality).

How These Findings May Inform Better Supports for Applicants

The aforementioned is just one example of how new supports could be informed by the gaps in existing literature that we have identified. Conversely, the fact that previously established themes are also present in our thematic analysis (without adhering to preconceived categories or checklists) also underlines the importance of recurring topics, such as consent. For example, by exploring continued dialogue over the course of each protocol review we noticed that many of the issues in the highly prevalent 'Consent' theme stemmed specifically from problems with consent forms and participant information sheets (from formatting through to terminology for seeking explicit consent), suggesting that applicants might benefit from better templates, clearer directions, or a 'common omissions in your consent form' FAQ. This type of broad-strokes approach presents a low-investment first step toward addressing commonplace issues and increasing the standard of applications prior to the reviewer stage. For example, we noticed that it was common for researchers to not understand the implications of using online survey platforms and how they relate to secure servers ('Data security and storage' theme), and clearly communicating this on participant information sheets ('Administrative' and 'Consent'). Likewise, it was common for researchers to either neglect to obtain approval from an industry partner or another division of the university ('Regulatory and legal'), or for them to have obtained it but not attached it to the application ('Administrative'). Last, inconsistency presented an issue for reviewers because they presented additional hurdles ('Request for clarification' theme), and time could be saved on both ends of a protocol by relaying to applicants that repeating themselves is perfectly acceptable. Where the information is relevant to multiple questions, then using consistent language, terminology and phrasing reduces the likelihood of misinterpretations. In sum, our data provided the unique opportunity to deeply explore data rich communications in the research ethics space across the lifespan of an application and understand the common themes that arise over the course of review.

Theoretical Implications

We have identified major methodological shortcomings that have limited the scope of thematic analysis in previous research of ethics review processes. One previous study did attempt a similar approach to ours; Bergstraesser et al. (2020) assessed HREC feedback from a single ethics committee. However, their sample was derived from a paediatric clinical research facility in Switzerland, with a narrow scope limited only to research on children in a medical setting. Further, they did not explain the theoretical paradigm or ethics discipline from which they approached their data. It was important for us to apply the methodological strengths of Bergstraesser et al. (2020) to a sample that was more generalisable to

the broader research contexts and use an applied ethics perspective. Although research with children is presented with teleological ethical challenges in that it is hard to accurately evaluate the risks to participants who cannot consent for themselves, it is often just as important to understand ethics research in adults because their agency is already presumed. Deontological ethical principles may provide a false sense of researcher security when conducting research 'correctly' by providing clear opportunities for informed consent, inadvertently overlooking rights of adults (in comparison with children in a clinical setting). This is an important demonstration of both the value of ethical pluralism that we adopted in our study, as well as the strength of applied ethics in seeking the best solution by evaluating each discrete scenario in the context of real-world risks.

The theoretical contributions of Bergstraesser et al. (2020) are also distinct from ours; for example, they discovered issues with age-adapted patient information and informed consent. Whereas we unearthed themes that diverged from their clinical paediatric setting, which underlines the importance of analysing proposals that involve more diverse settings to afford a strong cross-section of the most common types of research. Another important theoretical distinction was the way in which we approached coding and analysis; Bergstraesser et al. (2020) extracted comments that were already categorized by theme as determined by the reviewers themselves prior to the study. Conversely, for our applied ethics study we conducted reflexive thematic analysis adopting a stance of ethical pluralism which afforded us a clearer perspective to remain open to potential new themes. In essence, unlike Bergstraesser et al. (2020) we had no a priori judgment on which themes to seek and instead allowed the coded passages to speak for themselves, and in the process elucidating new and previously undiscovered themes to arise, prior to quantifying them in subsequent content analysis. Therefore, we propose that our findings fill gaps in existing literature and offer a more generalisable evaluation of the typical researcher-reviewer experience.

Practical Implications

Our findings help identify the common challenges experienced in HREC review and can be used to better inform tailored supports to researchers, and by extension reduce reviewer and HREC system workload burdens. As an important primary intervention, these themes could guide postgraduate students and reduce some of the negative experiences that were reported by Brindley et al. (2020), to ensure that emerging researchers experience less trepidation towards ethics and are by extension more likely to actively engage in meaningful research rather than avoid it. Our findings are particularly relevant for international researchers who are even more time-limited in terms of visas, scholarships, or contracts/residencies. In an Australian context, our findings might better support researchers from different countries to navigate the Australian ethics approval processes; as discussed by Davis et al. (2022), ethics approval practices differ across the globe, and some countries even have no formal processes in place. Likewise, researchers conducting studies abroad may be working with diverse populations, and our findings specifically call attention to the need for accessibility to be considered at every stage of a project (including language barriers as well as cultural sensitivity). Most importantly we demystify the ethics approval process is an effort to change attitudes, shifting perception away from 'difficult processes' and reducing the barriers to actively engage in meaningful research.

Strengths, Weaknesses and Limitations

A major strength of our study is the significant detail provided by our chosen sampling and methodology. By accessing the full spectrum of thousands of comments made by all HREC members over the course of a full year it allowed us the opportunity to better understand the nature of all possible feedback themes, not just those that rely on retrospective recall of interviewees. This helped to provide a more accurate and detailed picture of common pitfalls to applicants that already arose in the literature review, as well as discover areas that have yet remained uninvestigated. Both our literature review and data analysis corroborated the top 3 themes in feedback, suggesting that certain aspects of the ethics review process are universally common considerations (namely issues of consent, methodological and administrative concerns) in applications at our institution. However, whether these might be generalisable in other countries and contexts remains to be seen.

Although we clarify that the scope of this study covered all applications in the E2 ('low-risk') category, it is important to note that themes extracted from the literature review were drawn from studies that may also contain protocols deemed higher risk. By focussing our scope we also limited the generalisability of our findings because the exclusion of E3s fences out the highest risk projects that need to be handled at milestone committee meetings including community members; applications which often face the highest hurdles due to dealing with highly invasive, sensitive, or issues of significance to First Nations peoples. However, E2 applications are arguably the most important cohort to study because they form the vast majority of all applications and are more likely to benefit from support resources. 'Low-risk' projects are a good target for intervention because researchers can address issues pre-emptively which has flow on effects for streamlining and reducing reviewer workload, whereas higher-risk protocols must always go to full committee sittings regardless (in our institution certain check-boxes flag a protocol for mandatory E3 review, such as work with or about Aboriginal and Torres Strait Islanders, or seeking to recruit participants who cannot consent for themselves such as children or people with cognitive impairment). Therefore, whilst omitting high-risk applications may be considered a limitation, in reality the negligible and low-risk applications have the most to gain from the results of this study.

In some instances, comments regarding participant information sheets and consent forms have limited generalisability because applicants often use templates provided by the organisation; issues in the 'Administrative' theme may reflect more of an issue with our templates rather than a deficit in general researcher knowledge or understanding. It is also worth mentioning that our decision to analyse pre-2019 data was designed to intentionally focus on the themes that arise from research ethics as a whole, rather than be skewed by the high proportion of COVID-related discussion in 2020 through 2022. However we do have to acknowledge that as a result of COVID there may be potential long-lasting changes to HREC processes related to infectious diseases that aren't captured.

On the topic of institution-specific processes, it is important to note that this study was conducted using data from a single university with a single HREC, limiting the broader generalisability of our findings. Likewise, comments were made by the same $N=16$ HREC staff, so themes may be a reflection of their personal attitudes (e.g., see Handal et al. (2021). To counter this we did attempt to cover a diversity of opinion because the sample was made up of academics from diverse areas such as allied health; architecture; business and marketing; education; human performance; law; psychology; sociology; and STEM. However, we

did not attempt to ascertain the nature of personal attitudes to better understand *why* certain feedback was provided, which is a potential line of inquiry for future research.

Future Directions

Areas that our study was unable to address include the paucity of research into the experiences of postgraduate students, because the existing literature relies on only small, self-selected samples (e.g., see Brindley et al., 2020; Davis et al., 2022). Our methodology could be replicated but with a focus on postgraduate student applications to help better design bespoke supports to set up inexperienced but an emerging next generation of researchers. On that note, our study identifies information on which to base supports for applicants, but we didn't set out to *develop* said supports. Future research could evaluate the effectiveness of an 'ethics FAQ/guide' that is based on the themes we have extracted. For example, a case study with a cohort of applicants who are preparing their ethics proposals and then statistically determine whether their applications are approved quicker (and with less HREC system workload required) than a control group. Last, we propose expanding or replicating our approach to evaluate whether research applications processes across institutions experience the same themes and truly evaluate whether these findings are globally generalisable.

Conclusion

Ethics applications processes can be made more efficient by improving researcher understanding of the principles underpinning them. Key areas impacting low-risk applications include the appropriateness of research design and methods in relation to answering research questions, participant rights to confidentiality of data, informed consent and risk management, as well as ensuring applications are complete, accurate and properly describe the planned research process (including a complaints process). Strategies to develop researcher knowledge of human research ethics processes can include; (1) ongoing linked access to the National Statement on Ethical Conduct of Human Research (2018); (2) institutional requirements for researchers to complete online research integrity and ethical research courses; (3) training and resourcing Research Ethics Advisors to provide timely, individualized advice to researchers; (4) reviewing explanatory and template resources for accuracy and accessibility; and (5) reviewing the online application protocol to support researcher comprehension of the category and meaning of input required. A further indication is the need for institutional promotion of a culture of valuing ethical research and research integrity to counter discourses positioning human research ethics review as an unjust imposition, or barrier to conducting research. This can be achieved by recognising and rewarding innovation in research ethics, and reducing perceived barriers by demystifying the ethics application process. Our study identifies the key areas on which applications fall short, and we propose that developing new supports for applicants on these themes will see an overall higher quality of ethics protocols. This would serve to reduce applicant stress prior to and during the process, reduce HREC review workload and burden on the system, speed up timely completion of projects, and most importantly reduce the perception that ethics approval is a barrier in order to encourage undertaking meaningful and important research, no matter how challenging the topic.

Author Contributions SSM: Conceptualisation; Methodology; Investigation; Supervision; Writing; Project Administration. SNM: Formal Analysis; Visualisation; Software; Writing. BG: Validation; Writing. EM: Resources; Writing.

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Data Availability The dataset is composed of comments that were made on individual HREC applications, addressed to each researcher. Whilst we have permission to access these for the purposes of qualitative analysis, due to their sensitive nature a copy of these data cannot be stored in a publicly available data repository.

Declarations

Ethical Approval Approval was received from the *University of South Australia Human Research Ethics Committee* (Protocol #202708) on 29th Oct 2019.

Consent All HREC staff who commented on ethics applications in the listed period provided written consent for their comments to be extracted from the database, de-identified, and provided to the research team for analysis.

Competing Interests The authors declare they have no competing interests relevant to this article.

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