"No Country Bureaucratised its way to Excellence": A Content Analysis of Comments on a Petition to Streamline Australian Research Ethics and Governance Processes

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Title: “No country bureaucratised its way to excellence”: a content analysis of comments on a petition to streamline Australian research ethics and governance processes.

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Abstract
We created a petition for a national inquiry into the Australian system of research ethics and governance, to inform the politicians about the problems with the existing system. We analysed the reasons that signatories offered for why signing the petition was important to them. 409 comments (by 805 signatories) focused on five major themes: (1) Views on previous changes to the system of research ethics and governance; (2) Drawbacks of the existing system; (3) Suggested changes to the system; (4) Anticipated impacts of changing the system; and (5) Miscellaneous/other comments. Comments ranged from several words to over 400 words in length, and most often focused on the procedural aspects, and commented on theme 2: Drawbacks of the existing system.

Keywords
Research Ethics; Governance; Site-specific approval; Research Ethics Committees; Low-risk research; Exemption; Health research; Medical research; Proportionate review
"No country bureaucratised its way to excellence": a content analysis of comments on a petition to streamline Australian research ethics and governance processes.

Introduction

Health and medical research aims to improve human health by increasing our understanding of harms and disease, both in terms of their aetiology and prevention. It includes a broad range of activities, from basic pre-clinical research aiming to discover new disease mechanisms and therapeutic targets, through to field and population testing of established practices. Nearly all proposed health and medical research involving human participants is reviewed prior to its commencement, to ensure that the research proposals are compliant with the relevant laws and regulations, and to protect the safety and well-being of the participants (Abbott & Grady, 2011). This involves an assessment to ensure that participants are protected from excessive burdens or risks from participating in research, and that the benefits of the research outweigh the harms (either real or potential) (Brandenburg, Thorning, & Ruthenberg; A. M. Scott et al., 2021).

It is important to differentiate between the procedural aspects of the research review process – such as the application processes – from the principles that underpin the research review process (for example, the principles of beneficence or justice), and the ethical issues encountered whilst conducting research (for example, maintaining participant privacy). Our focus is on the procedural aspects of the process. In Australia, there are two key processes for securing the necessary approvals to conduct research projects that involve human participants. Firstly, researchers must apply to gain approval from a registered Human Research Ethics Committee (HREC). These applications must describe the research team members’ qualifications and provide information regarding: the burden and potential risks to participants, consent processes, and how research data will be analysed, stored, and reported. The number and detail of questions involved in HREC applications depend on the level of perceived risk to participants, with fewer questions required of projects that qualify as “low or negligible risk”. The HREC evaluates the proposed research for compliance with applicable Australian laws, and with the National Statement on Ethical Conduct in Human Research which describes the ethical considerations relevant for the appropriate conduct of research, and the responsibilities of researchers, institutions and review bodies (National Health and Medical Research Council (NHMRC), 2018).

Once the project has been approved by a HREC, researchers must, secondly, submit a Site-Specific Assessment (SSA, also referred to as a governance application) if any aspect of the research will be conducted at a public health facility. Research governance applications must describe the project’s...
site-specific resource requirements, demonstrate site-specific and overall feasibility such as available financial support, and provide evidence that all other legal and regulatory requirements have been met. If any project is to be conducted at multiple public health facilities such as different hospitals, separate SSA applications must be submitted at each study site (De Smit et al., 2016; Duplancic, Crough, & Bell, 2019).

Australian researchers have published numerous accounts of experiences with the human research ethics and governance application processes, describing those processes as: “unwieldy” (Greville, Haynes, Kagie, & Thompson, 2019), “fragmented, complex and lengthy” (Vajdic et al., 2012), “complex and convoluted” (Duszynski et al., 2019), “costly” (A. Barnett et al., 2016; Duplancic et al., 2019; Foot et al., 2018), “onerous and time-consuming” (Clay-Williams, Taylor, & Braithwaite, 2018) and even “unethical” (McGiffin, Kure, Hayward, & Fraser, 2019). Key problems identified include: duplication of effort (Rush et al., 2018), with the same ethical questions being considered by multiple groups (A. Barnett et al., 2016); inconsistencies between jurisdictions (Duszynski et al., 2019); delays in conducting research due to slow or overly bureaucratic approval processes (Guillemin, Gillam, Rosenthal, & Bolitho, 2012; Rush et al., 2018; A. M. Scott et al., 2021); and overreach, as low or negligible risk research applications can experience a disproportionate level of scrutiny (Rush et al., 2018; Anna Mae Scott, Kolstoe, Ploem, Hammatt, & Glasziou, 2020).

Several initiatives have attempted to improve the human research ethics review system, such as the 2013 National Mutual Acceptance Scheme for clinical trials, and new online systems for submitting approvals. However, some of the accounts cited above specifically criticise these new systems (Duplancic et al., 2019; Vajdic et al., 2012), emphasising the burdens imposed by multiple research governance applications. Problems are typically more frequent and severe for national studies that operate across multiple sites and must additionally navigate multiple state-based systems (A. Barnett et al., 2016; Duszynski et al., 2019).

We created a petition to give the Australian health and medical researchers the opportunity to articulate the problems they have experienced while navigating human research ethics and research governance application processes (see Appendix 1). Although petitions are not a commonly used tool by researchers, we adopted this approach in order to show that the burdens imposed by current human research ethics and research governance application processes are not confined those researchers who have described their experiences within the published literature (A. Barnett et al., 2016; Clay-Williams et al., 2018; Duplancic et al., 2019; Duszynski et al., 2019; Foot et al., 2018;
Greville et al., 2019; McGiffin et al., 2019; Rush et al., 2018; Anna Mae Scott et al., 2020; Vajdic et al., 2012), but instead, are widely experienced by Australian health and medical researchers. Our goal was to communicate broad experiences to attract the attention of federal politicians with the ability to enact the reforms needed. Our petition asked for a national inquiry into human research ethics and research governance, because both politicians and the public need to be fully informed of the complexity and extent of the problems experienced by the Australian health and medical research sector. Signatories were able to sign their name, and provide a statement in a textbox, in response to a prompt “Why is this important to you?” We analyse here the comments that the signatories provided in response to the prompt.

Method

Protocol
As we had not intended to analyse the petition comments prior to commencing the petition, we did not pre-specify a protocol. Due to the large number of the comments received, as well as the breadth and depth of the issues raised, we subsequently chose to analyse and share their content.

Methods for conducting the analysis were agreed to prior to conducting the analysis.

Ethics
As the data source for this analysis is publicly available
https://www.thepetitionsite.com/981/617/971/we-need-a-national-inquiry-to-streamlineimprove-research-ethics-and-governance-in-australia/), and the project involves the use of existing data, it is considered exempt under section 5.1.22 of the National Statement on Ethical Conduct in Human Research(National Health and Medical Research Council (NHMRC), 2018) – thus we did not seek human research ethics approval.

Dataset
The petition, “We need a national inquiry to streamline/improve research ethics and governance in Australia” was posted on 19 June 2019 and remains available to be signed. The petition was advertised on Twitter (@aidybarnett, @JAByrneSci) and LinkedIn (June 2019 and October 2019), as well as informally, via word of mouth and at research presentations.

The petition could be signed with identifying information (name, location) provided, or anonymously. Each signatory had the option to leave a comment clarifying why the issue is important to them, by filling in an optional text box “Why is this important to you?” (see Appendix
1). The dataset consists of the comments posted on the petition between 19 June and 9 October 2019.

**Approach**
We used the content analysis approach, which examines written content by breaking it up into smaller fragments, in order to determine and describe patterns in the content, and the frequency of their occurrence (Elo & Kyngäs, 2008; Vaismoradi, Turunen, & Bondas, 2013). It is considered an appropriate method for analysis of text data, and has been applied to analyses of comments provided as part of surveys (Iversen, Bjertnæs, & Skudal, 2014) and comments provided on petitions and causes from social media platforms (Carroll & Freeman, 2016; Obermair, Dodd, Bonner, Jansen, & McCaffery, 2018; Sumner, McQueen, Scott, & Sumner, 2014). The perspective adopted here is that of health researchers who have initiated the petition, however, to mitigate the potential for bias in interpretation, the comments were read and coded by two coders independently, one of whom (EAB) was not involved in the petition (see below).

**Procedure**
The petition comments were exported into an Excel spreadsheet (9 October 2019). The Excel spreadsheet included the following information: reference number assigned to signatory, the date the petition was signed, name and location of the signatory (if provided), and comment (if any).

Information on the signatory and date of signature were removed prior to the commencement of coding. For coding purposes, the only information retained in the Excel spreadsheet was the reference number of the signatory and the comment (if any). Although the text-box prompt stated “Why is this important to you?” respondents were free to provide any comment they wished, and we analysed all comments supplied. As the petition was aimed at influencing Australian politicians, only comments from Australian signatories (as identified by the entry in the ‘country’ column in the spreadsheets exported from the petition website) were analysed; we excluded 12 comments from international signatories. All comments from Australian signatories (signed and anonymous) were included in the analysis.

**Coding framework**
The coding framework was generated in two stages: first, identification of the major themes, and second, the identification of sub-themes within each major theme.
One author (AMS) read (without coding) a convenience sample of the first 60 comments in the Excel spreadsheet, and generated a preliminary set of major themes addressed by these comments. A ‘major theme’ was the main idea that could be assigned to a comment – for example, “suggested changes to the system of research ethics and governance,” or “drawbacks of the current system.” Two authors (AMS, EAB) then independently coded the first 60 comments to the preliminary major themes, keeping notes on issues arising whilst coding (e.g., comments not fitting into the major themes, problems interpreting the scope of the major theme, etc.). Two authors (AMS, EAB) then met to modify and finalise the major themes, and subsequently coded all comments to the five major themes. Completed coding was compared, and discrepancies in coding were resolved by discussion and consensus.

The process for generating sub-themes within each of the five major themes was identical, except for theme 1 (views on previous changes to the system); for theme 1, all (n=16) comments or their fragments were used to generate the preliminary set of sub-themes, as there were fewer than 60 in this theme.

Analysis
Where a single comment addressed multiple themes or sub-themes, it was broken into fragments, so that each comment fragment addressed only one theme; the process was repeated within each theme for sub-themes if required (e.g., if a comment fragment addressed two different sub-themes within a theme it was further broken down, so that a comment fragment addressed only one sub-theme). The frequency of comments or comment fragments assigned to each major theme and to each sub-theme were assessed using descriptive statistics. Two authors (EAB and AMS) coded all comments to one of the major themes and sub-themes.

Patient and public involvement
Neither patients nor public were directly involved in the conduct or writing of this work.

Reporting guideline
This work is reported following the Standards for Reporting Qualitative Research (SRQR) checklist (O’Brien, Harris, Beckman, Reed, & Cook, 2014).

Results
Summary
Between 23 June 2019 and 9 October 2019 (approximately 3 ½ months), the petition received 805 signatures and 51% (n=409) of respondents also provided comments. Three-quarters of respondents (n=604, 75%) publicly included their name and location; one-quarter responded anonymously. Signatories most commonly came from Brisbane (n=252, 31%), Sydney (n=241, 30%), Melbourne (n=105, 13%) and Perth (n=78, 10%) (see Appendix 2).

Median comment length was 26 words, ranging from short sentences (e.g., “bureaucracy is ruining research”) to 449 words. Many comments raised multiple issues; when comments were broken into comment fragments addressing a single sub-theme each, 1,075 comments or comment fragments addressed one of the 25 sub-themes (Table 1).

Comments or their fragments addressed five major themes (Table 1). The themes are presented in a temporal order – that is, comments on past changes to the Australian system are listed first, under theme 1. These are followed by comments on the issues with the current system in Australia (theme 2), and then by those suggesting changes that could be implemented in the future (theme 3) and the anticipated benefits of implementing changes (theme 4). Comments not falling into any of these categories are presented last (theme 5). (As many full comments had to be sub-divided into comment fragments addressing one sub-theme, we do not present percentages of comments or their fragments falling into each theme). The total number of comments or comment fragments for each of the major themes was as follows:

(1) Views on previous changes to the research ethics and governance system in Australia: n=16 comments or comment fragments
(2) Drawbacks of the current system of research ethics and governance in Australia: n=631 comments or comment fragments
(3) Suggested changes to the system of research ethics and governance in Australia: n=152 comments or comment fragments
(4) Anticipated impacts of changing the system of research ethics and governance in Australia: n=76 comments or comment fragments
(5) Miscellaneous/other comments: n=200 comments or comment fragments (see Table 1)

Major theme 1: Views on previous changes to the system of research ethics and governance system in Australia

Sixteen comments or their fragments addressed Major theme 1: Views on previous changes to the system of research ethics and governance system in Australia. They were coded into one of three
sub-themes: (i) previous changes to the system improved the system, (ii) previous changes to the system worsened the system, and (iii) miscellaneous/other (Table 1).

The comments on previous positive or worsened changes to the system were equally split (n=5 each), with the former focusing on the “recent improvements such as single ethics approval for multicentre trials,” existence of guidelines from the NHMRC, and the view that “ethics paperwork is bad but getting better”.

Changes that worsened the system mentioned: the problems with the Research Ethics Governance Information System (REGIS) system, the existence of multiple application systems (REGIS, Ethical Review Manager (ERM), Online Forms, Research Governance Service (RGS)) across Australia and increases to the processing time of applications associated with the use of these systems.

Comments or comment fragments coded to the ‘miscellaneous/other’ sub-theme included more neutral statements such as “a lot has been done over the last decade.”

**Major theme 2: Drawbacks of the existing system of research ethics and governance system in Australia**

The largest number (n=631) of comments or their fragments left by the petition signatories, pertained to Major Theme 2: Drawbacks of the current system of research ethics and governance in Australia (Table 1). These comments were categorised into one of the following sub-themes: (i) burdensome nature of the system, (ii) system causes delays or inhibits research, (iii) system does not achieve its aims, (iv) inconsistent processes or practices across institutions, (v) current system represents an opportunity cost, (vi) examples or vignettes of the system’s drawback’s affecting research projects, and (vii) miscellaneous/other comments.

Nearly half of the comments addressing this theme (n=309) focused on the burdensome nature of the current system (sub-theme (i)), with comments mentioning time issues (“I work in research and I am well aware of the amount of time (hence, research funding) that is wasted due to complications and delays in research and governance approval process.”) and stress (“This is particularly frustrating when approval to conduct negligible risk studies is needed”). Many (n=103) also pointed out that under the current system of ethics reviews, research is delayed or inhibited altogether, noting that “It’s getting in the way of using the best data and methods available as the time and effort required is prohibitive and sometimes, harmful, to one’s research career”; another commenter stated, “I
speak to many scientists who do not attempt brilliant research ideas they have, because they do not want to have to deal with the ethics committees.”

Commenters also pointed out that the existing system of research ethics and governance fails to accomplish its aims (“Excessive regulation wastes both research and administrative resources without improving research participant safety or ensuing research quality”). Inconsistent processes between institutions were also a concern – with one person asking: “Every application I do is different - why is this???” Examples or vignettes were provided describing the signatories’ experiences within the current system, including the lengthy time to ethics approval and associated costs, needing to return grants as the time to get ethics approval for a trial exceeded the funding time period, and the inability to start research on time (Table 1). Comments or their fragments coded under the ‘miscellaneous/other’ sub-theme implicitly criticised the existing system in Australia, noting, for example, that “no country bureaucratised its way to excellence” or querying “What are the best practice models?”

Major theme 3: Suggested changes to the system of research ethics and governance in Australia

In total, 150 comments or their fragments addressed Major Theme 3: Suggested changes to the system of research ethics and governance in Australia. They addressed one of five sub-themes: (i) review/fix of the current system, (ii) implement a single national system in Australia, (ii) make the system more fit for purpose, (iv) reduce waste in the system, (v) miscellaneous / other suggestions for change (Table 1).

Most (n=71) called for a fix or review of the existing system (e.g., “Australia’s ethical review processes need to be overhauled.”) More specific suggestions urged an implementation of a single, national system in Australia – “a united approach to ethics submissions” – or making the system more fit for purpose or risk-proportionate (for example, pointing out that “graduated attention relative to the level of risk would be a significant improvement”) Others suggested that the system become less wasteful (“Let's not waste any more money and time.”).

Major theme 4: Anticipated impacts of changing the system of research ethics and governance in Australia

Seventy-six comments or their fragments were coded as Major Theme 4: Anticipated impacts of changing the system of research ethics and governance in Australia. They were categorised into one
of six sub-themes: (i) enabling research outputs and collaborations, (ii) benefits to the Australian people, (iii) resource savings (e.g., time, money), (iv) reducing waste, (v) enhancing efficiency, and (iv) miscellaneous/other anticipated impacts (Table 1).

Comments or their fragments (n=27) focused on the potential for resource savings from streamlining the system of research ethics and governance in Australia, predominantly from savings of time and money (e.g., “A united approach to ethics submissions would not only save time and manpower but would also make a lot of sense,” “Addressing these issues will save a lot of time and money.”). The potential for increased efficiency and reduced waste in the system from streamlining was also noted, with some commenters mentioning both (e.g., “Enhance efficiency and reduce waste for delivering health research”). Likewise, the potential for enabling research outputs, and benefits to the Australian people, were often addressed simultaneously (e.g., “Streamlining this process will ensure talented researches [sic] spend less time on administrative requirements and more time (and money) on undertaking research and translating this into meaningful outcomes for society.”)

**Major theme 5: Miscellaneous / other comments**

Two hundred comments or their fragments were categorised in Major Theme 5: Miscellaneous/other comments, addressing one of four sub-themes: (i) acknowledgement of the importance of appropriate system of ethics and/or governance; (ii) a statement of support for the petition; (iii) statement of professional or personal role of the signatory; or (iv) other/miscellaneous comments.

Some commenters (n=22) included an explicit statement of support for the petition (e.g., “I think this is a great idea,” “I agree with the arguments presented in this case”), or included a statement acknowledging the importance of a robust system of ethics and governance in research, e.g., “Ethics and governance are important” (n=30).

We did not request that signatories identify themselves, however, one hundred and twenty-five signatories (15% of all signatories) specified their professional or personal role in the text of the comment they left on the petition. Respondents self-identified most commonly as researchers (n=80) or research administrators or managers (n=23); others included higher degree research students (n=9), members of ethics bodies (n=7), and patient or community member (n=6).
Discussion

We synthesised petition-based data to describe the experiences within the current system of ethics and governance processes in Australia. Over approximately four months, we gathered over 800 signatures and over 400 comments from a range of signatories, including research governance personnel, researchers, patients, and the public. Because input in the free-text box with the prompt “Why is this important to you?” was optional, the signatories were not required to provide any identifying information about themselves. Nonetheless, 125 commenters identified their professional role. Unsurprisingly, researchers and research administrators or managers were the most identified roles (in aggregate, 103 of the 125 commenters who identified their role), as these individuals are most likely to deal with these issues in their day-to-day roles.

Positive and negative ‘views on changes to the research ethics and governance system in Australia’ often represented two sides of the same coin and were reflective of existing evidence. For example, whilst the ability to obtain multi-site ethics approval since 2013 was viewed favourably by signatories (Vajdic et al., 2012), comments also indicated that this attempt to streamline has been hindered by the subsequent introduction of different state-based systems (Clay-Williams et al., 2018; Greville et al., 2019), and that gains made since the introduction of the multi-site review have now been replaced with delays and duplication to the governance approval process (A. Barnett et al., 2016; Duplancic et al., 2019; Vajdic et al., 2012).

‘Drawbacks of the current system of research ethics and governance in Australia’ received the largest number of comments, particularly highlighting the time (up to two years was reported in some cases), waste ($130,000 for dedicated roles simply to manage ethics and governance), and stress associated with its burdensome nature. The petition comments are consistent with the findings of other Australian studies reporting challenges in research ethics and governance processes in health and medical research. For example, a study which aimed to link eleven data sources to establish a national dataset for a safety evaluation of vaccines in Australia, required nearly four years from initial requests for data to approval thereof (with an additional year before data transfer occurred); the personnel time cost for obtaining the approvals was estimated at $95,000 (Duszynski et al., 2019). A 3-year, Australia-wide study aiming to assess the relationship between hospital quality management systems, leadership and culture, as related to care delivery and patient outcomes, reported spending over $260,000 on the institutional consent processes in 2015-16 (Clay-Williams et al., 2018). The previously reported barriers associated with these timeframes and costs, include: the need to develop tailored legal agreements between universities and hospitals, the
absence of experienced institutional governance officers, lack of clarity regarding signatories, lack of recognition of ethics approval by private hospitals, and the need for the principal investigators to be employed by the institution (Vajdic et al., 2012); insufficient flexibility for health service research protocols (Clay-Williams et al., 2018; Greville et al., 2019); variance in opinions about levels of risk (Clay-Williams et al., 2018); multiple tiers of approvals (Duszynski et al., 2019); frequent change in regulatory staff, and variability in experience (A. Barnett et al., 2016).

The need to divert research resources to administration has the potential to alienate funding bodies and reduce community support for research (Rush et al., 2018). There is growing concern that many of these requirements may cause researchers to be selective about research sites to work with – or avoid – leading to reduced study quality through bias or time fragmentation (Rush et al., 2018). Our findings also reveal that research ideas are not being pursued due to the anticipation of a prolonged ethics/governance process, and that researchers have had to return grant funding following notification of lengthy approval processes, which are consistent with the findings of a recent survey of the Australian human research ethics committee members and health and medical researchers (A. M. Scott et al., 2021).

Calls for ‘changes to the system of research ethics and governance in Australia’ to resolve some of the identified drawbacks were made through over 150 comments in our petition. Suggestions in the petition comments included a “simpler system” with “graduated attention relative to the level of risk”, and more use of common sense to “prevent waste”. These suggestions align with previous recommendations in a range of published studies, which include: a national system supporting both ethics and site specific governance applications (Clay-Williams et al., 2018; Duplancic et al., 2019; Duszynski et al., 2019); expediting subsequent reviews of previously approved applications (A. Barnett et al., 2016); risk-appropriate legal agreement negotiation time (Duplancic et al., 2019); and the ability for researchers to monitor the progress of their application online (Duszynski et al., 2019); uniform templates for assessing risks, reconsideration of governance requirements around the need for employed site based principal investigators, streamlined procedures for public and private hospitals (Vajdic et al., 2012); and resources and ongoing training for HREC and research governance office (RGO) staff, particularly around the low risk nature of health services research (Greville et al., 2019; Rush et al., 2018).
Our signatories’ comments revealed that they considered the impacts of the changes they suggested to the system of research ethics and governance in Australia. Positive outcomes such as enabling research outputs and collaborations are reflected in previous insights which suggest that changes to the current system would increase the speed of critical research (Greville et al., 2019), and provide more timely access to research outcomes (Clay-Williams et al., 2018). Additional benefits from these changes could also include: reduced workload for ethical review bodies (A. Barnett et al., 2016) (e.g., through removing the need to assess studies already approved, duplicate signatures, document reformatting, and repetitive uploading) (Duplancic et al., 2019), enabling researchers to more accurately account for the ethics/governance timeframes when submitting research proposals, and enabling research funds to be used for the intended research activity as opposed to being swallowed up by the lengthy approval process (A. Barnett et al., 2016). Ensuring the public are informed about reduced delays and timely research is also likely to increase satisfaction about the use of research funds and confidence about the extent of research contribution to improvements in society (A. Barnett et al., 2016; Duszynski et al., 2019).

Many comments acknowledged the challenges in the existing system of ethics and governance in Australia implicitly – that is, by identifying specifical drawbacks of the existing systems, or suggesting specific changes, or anticipating the benefits of those changes. Twenty-two commenters also acknowledged the importance of these changes explicitly, by noting that they agree with the petition or support it. This petition therefore adds to the previous calls to streamline, improve efficiencies, and develop a national system for research ethics and governance. However, any changes to governance practices will require careful planning and taking into consideration complexities such as legislation, and infrastructure that needs to be developed and aligned with health departments under different state jurisdictions in order to ensure the feasibility (Duplancic et al., 2019). Changes to ethics review processes, on the other hand, will need to strike an appropriate balance between protecting participants from undue risks or burdens, and facilitating research to occur. This could involve a firm commitment to implementing different review pathways, depending on the anticipated benefits and harms of the research – including an exemption pathway for negligible risk project, risk proportionate review for lower risk projects and a full review pathway for higher risk ones, as is the case in the United Kingdom, for example (NHS Health Research Authority, 2020, March 2021). Whilst the option to use these types of pathways are currently indicated in Australia’s National Statement (National Health and Medical Research Council (NHMRC), 2018), their use – or disuse – in Australia, currently varies by institution and by HREC (A. M. Scott et al., 2021).
This work has limitations. Because we had not anticipated receiving so many comments to the petition, there was no a priori framework to guide the questions for the qualitative responses. Petitions are also not commonly used as a tool by researchers. However, in the absence of certainty about the best methods to conduct the research on challenges in the area of research ethics and absence of a gold standard for evaluating the review processes (Lynch, Nicholls, Meyer, & Taylor, 2019; Nicholls et al., 2015; Resnik, 2015; Tsan, 2019), this petition allowed the respondents to emphasise the key points of importance to them. Importantly, the petition represents the views of an opportunistic sample who chose to sign our petition and provide comments, which likely over-represents those who have had bad experiences with ethics and governance processes and may not be generalisable to all experiences. Most of the signatories who identified themselves stated that they were researchers, and hence the views also over-represent this group. To identify whether patients and the public share these – or have differing – concerns, will be the subject of subsequent work. It is also possible that the signatories did not differentiate between the issues with the ethical review and with governance practices. Finally, our focus is on issues and challenges encountered in the health and medical research areas. However, several comments expressed the desire that streamlining of these processes in health and medicine could lead to a shift the situation in other fields as well (see Table 1), possibly reflecting ethics review and/or governance challenges in research encountered in the areas of social sciences and humanities in Australia (Wynn, Israel, Thomson, White, & Carey-White, 2014). However, a strength of taking this informal approach is that we have given individuals involved in research and affected by ethics and governance processes a voice. Its importance is underscored by the relatively high number (over half) of signatories voluntarily leaving comments in addition to signing the petition. This adds weight to the need to address the issues identified.

We aimed to obtain 300 signatures on the petition prior to presenting it to the federal Minister for Industry, Science and Technology (also a local representative to the Parliament for one of the authors). The meeting with the Minister’s Electoral Officer was held on 13 September 2019, to discuss the petition and seek advice and presentation and processes for submitting the petition to the Minister. We were advised to prepare a two-page Executive Brief, and relevant attachments. On 25 October, we submitted the following: a two-page Executive Brief, Attachment 1: List of petition signatures; Attachment 2: Sampling of comments received on the petition; Attachment 3: Economic modelling of the costs of the current system in Australia and estimated savings from change to a simplified model; Attachment 4: A brief history of changes to the ethics/governance system in Australia; and Attachment 5: A summary of a survey of Australian researchers’ and HRECs’
experiences. All of these attachments are publicly available on the Open Science Framework (Adrian Barnett, Byrne, Scott, & Taylor, 2020). On 12 November, the Minister’s office sent representations on our behalf to the Minister for Health, who subsequently declined our request to establish a National Inquiry to streamline research ethics and governance in Australia (Adrian Barnett et al., 2020). We plan to continue to lobby government on this issue and to use research to provide further evidence of the issues faced by Australian researchers.

Best practices

In light of the issues raised by the comments left on the petition, we propose that the following areas are prioritised for initiating changes to human research ethics and governance across Australia. First, a national system (e.g., a single body) be established, which would support both ethics and site-specific governance applications. This body should establish standardised processes and criteria for exempt and low risk research, as well as timelines for both ethics review and governance applications. Second, duplicated ethics reviews for multi-site projects should be transitioned out, or alternately replaced by a process of a full committee ethics review (for the main study site) and expedited reviews (other sites). Third, resources and training should be provided to ethics review and governance staff, particularly around the research that is negligible or low risk. Finally, and in conjunction with that, implementing standard templates for assessing risks could also help to mitigate the review time. These actions could help to improve the Australian human research ethics and site-specific governance review processes, to the benefit of the researchers, funders, HRECs, and the patients and the public whom the research ultimately aims to benefit.

Research Agenda

Because issues around research ethics review processes and governance of research most immediately impact researchers and research managers, it is unsurprising that among individuals who identified their professional role, those were the most commonly identified roles. However, to the best of our knowledge, little research on the patients’, carers’ and the public’s perspectives of health and medical research ethics and governance review processes has been conducted in Australia or elsewhere, although members of these groups have been recognised as valuable voices in ensuring that these issues are addressed in the future (Evans, Thornton, Chalmers, & Glasziou, 2011). A notable exception to this, is the study by Morse and colleagues, which explored Australian consumer and carer perspectives on research ethics procedures in the area of mental health (Morse, Forbes, Jones, Gulliver, & Banfield, 2019). Relatively few petition signatories, among those who self-
identified, stated that they were patients or the public (n=6). The issues they identified, included excess wait to participate in a trial, and ability for Australian patients to participate in international trials (Table 1). However, a research agenda prioritising engagement with the patients and the public on this topic could reveal additional issues of concerns to those groups, which have not yet been considered.

Educational implications
A key aim of our work was for the voices of researchers to be heard by Australian government policy makers, and they are a key audience for this work. Published evidence indicates that the frustrations expressed by Australian health and medical researchers are also echoed in other fields, and in other countries. Therefore, any policy makers working on research ethics and governance policy could benefit from reading this work and considering the perspective of researchers, especially as the costs and difficulties experienced by researchers are hidden, with no formal mechanisms for feedback and no audits of costs.

It is also currently not clear to what extent the patients and the public are aware of these issues, and how they impact them – as both the intended beneficiaries of the research (via, e.g., access to new treatments), and payers for the research (as taxpayers). Therefore, educational initiatives aimed at increased awareness of these issues – e.g., in the form of ‘town-halls’ or community juries or James Lind Alliance-style priority setting partnerships – may offer viable pathways to address this issue.

Acknowledgements
We would like to thank all of the individuals who signed the petition, and very generously shared with us their insights, views and personal stories of experiences with research ethics and governance, as well as the peer reviewers for the Journal, for their very helpful suggestions.

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This is the peer reviewed version of the following article:
Authors biographical sketches

**Anna Mae Scott** is an epidemiologist with a background in philosophy. Her research interests focus on waste in research, and methodological development in systematic reviews.

**E. Ann Bryant** is a MSc candidate with an animal science and psychology background. Her current research interest is patient and public involvement in developing clinical practice guidelines.

**Jennifer A. Byrne** is a molecular biologist and cancer researcher who studies human health biobanking and publication integrity.

**Natalie Taylor** is a Health Psychologist and Implementation Scientist with expertise in health systems and health behaviours research. Her program of research focuses on using implementation research methods to design and study approaches for optimising the translation of innovations and interventions into the healthcare system.

**Adrian Barnett** is a statistician working in health and medical research. He is interested in improving statistical practice and reducing waste in research.

Authors' contributions

All authors (AMS, EAB, JAB, NT, AGB) contributed to conception and design of the project. AMS and EAB coded the comments. All authors (AMS, EAB, JAB, NT, AGB) contributed to writing and critical revisions of drafts of the manuscript. All authors have approved the final version of the submitted article.

Declaration of conflict of interest and funding:

AMS, EAB, JAB, NT: none to declare. AGB: supported by an NHMRC Fellowship (APP1117784). This work received no specific grant from any funding agency in the public, commercial, or not-for profit sectors. Funder of AGB’s fellowship (NHMRC Fellowship APP1117784) was not involved in the design, conduct, writeup of this study, or the decision to publish.

Reporting guideline

The Standards for Reporting Qualitative Research (SRQR) checklist is appended to this submission and referenced in the manuscript.

List of Abbreviations

**HREC**: Human Research Ethics Committee

**ERM**: Ethical Review Manager

**REGIS**: Research Ethics Governance Information System

**RGO**: Research governance office

**RGS**: Research Governance Service

**SSA**: Site-specific approval
References


Brandenburg, C., Thorning, S., & Ruthenberg, C. What are the most common reasons for return of ethics submissions? An audit of an Australian health service ethics committee. *Research Ethics, 0*(0), 1747016121999935. doi:10.1177/1747016121999935


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Scott, A. M., Chalmers, I., Barnett, A., Stephens, A., Kolstoe, S. E., Clark, J., & Glasziou, P. (2021). ‘The ethics approval took 20 months on a trial which was meant to help terminally ill cancer patients. In the end we had to send the funding back’: a survey of views on human research ethics reviews. J Med Ethics. doi:10.1136/medethics-2020-106785


This is the peer reviewed version of the following article:

Table 1: Sample comments addressing the major themes and sub-themes.

<table>
<thead>
<tr>
<th>Sub-themes</th>
<th>Example quotes from the petition</th>
<th>N comments or comment fragments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major theme 1: Views on previous changes to the system of research ethics and governance</strong></td>
<td></td>
<td>16</td>
</tr>
<tr>
<td>(i) Previous changes to the system improved the system</td>
<td>“With the ethics National Mutual Acceptance, at least the ethics process only requires submission of 1 set of forms in 1 system to 1 committee…”</td>
<td>5</td>
</tr>
<tr>
<td>(ii) Previous changes to the system worsened the system</td>
<td>“It has become increasingly difficult over the years, with bandaid remedies that cause more problems.”</td>
<td>5</td>
</tr>
<tr>
<td>(iii) Miscellaneous/other comments in Major Theme 1</td>
<td>“a lot has been done over the last decade”</td>
<td>6</td>
</tr>
<tr>
<td><strong>Major theme 2: Drawbacks of the existing system of research ethics and governance</strong></td>
<td></td>
<td>631</td>
</tr>
<tr>
<td>(i) Burdensome nature of the system</td>
<td>“The overly bureaucratic and defensive nature of research ethics and governance processes in Australia…” “The overburden of bureaucracy in research…”</td>
<td>309</td>
</tr>
<tr>
<td>(ii) System causes delays to or inhibits research</td>
<td>“The process is… an impediment to research being conducted at a larger scale.” “Our research is hampered.”</td>
<td>103</td>
</tr>
<tr>
<td>(iii) System does not achieve its aims</td>
<td>“current system incentivises misrepresentation of the research and therefore compromises the integrity of the process.” “does little to achieve its stated goal”</td>
<td>58</td>
</tr>
<tr>
<td>(iv) Inconsistent processes or practices across institutions</td>
<td>“…the main barrier we have hit is the amount of differences in processes and forms for each state and territory in Australia” “systems and processes are disparate and incredibly laborious.”</td>
<td>86</td>
</tr>
<tr>
<td>(v) Current system represents an opportunity cost</td>
<td>“Time spent on paperwork represents time not spent on actual research.” “This time could be spent changing lives!” “We can't compete with the world with such regulations in place”</td>
<td>42</td>
</tr>
<tr>
<td>(vi) Examples or vignettes of the system’s drawbacks affecting research projects</td>
<td>“We spent more than one year on the ethics application for a multi-location 3-year NHMRC project. It is a low-risk project, using hospital admissions and ED [emergency department] presentations data.” “We run trials in SA [South Australia] and have in fact had to give grant money back as it took over two years to get approval for a trial in which time the funding time period had lapsed.” “As a 6 time survivor of cancer, research and research trials are critical for my survival. I had to wait around 6 weeks for ethics approval to start on a trial for which I was eligible. This is unacceptable.” “I am involved in research and the recent study I am working on took 1.5 years to get approved by ethics and governance for a low risk clinical trial having a large impact on the research funding.” “Our department usually has about 16 active trials at a time &amp; now has now a dedicated nurse just to manage ethics and governance requirements. This is at a cost of $130,000/year.”</td>
<td>30</td>
</tr>
<tr>
<td>(vii) Miscellaneous/other comments in Major Theme 2</td>
<td>“The ethical issue lies with NOT evaluating treatments, not vice-versa.” “No country bureaucratized its way to excellence.”</td>
<td>3</td>
</tr>
<tr>
<td><strong>Major theme 3: Suggested changes to the system of research ethics and governance</strong></td>
<td></td>
<td>152</td>
</tr>
<tr>
<td>(i) Review/fix the current system</td>
<td>“Ethical clearance processes and policies in Australia are absolute rubbish and in desperate need of reform.” “Australia’s ethical review processes need to be overhauled.”</td>
<td>71</td>
</tr>
<tr>
<td>(ii) Implement a single national system in Australia</td>
<td>“A national system would streamline and encourage collaborative research across sites and states…” “A single national system and a single source of research conduct guidelines is needed.”</td>
<td>34</td>
</tr>
</tbody>
</table>

This is the peer reviewed version of the following article:
### Major Theme 3: Make the system more fit for purpose

| (i) Make the system more fit for purpose | "Graduated attention relative to the level of risk would be a significant improvement."
| | "I'm sure the process could be simpler and still protect participants."
| (ii) Reduce waste in the system | "we need to find sensible and meaningful ways to prevent/reduce wasteful activity..."
| (iii) Miscellaneous/other comments in Major Theme 3 | "This should extend beyond health and medical research to explore ethics and governance for all research in Australia."
| | "What are the best practice models?" |

### Major Theme 4: Anticipated impacts of changing the system of research ethics and governance

| (i) Enabling research outputs and collaborations | "Clinical trials would start earlier and more data could be collected if ethics was streamlined."
| | "allow Australian brain tumour patients to participate in large scale international trials in a timely manner." 
| (ii) Benefits to the Australian people | "making the process of conducting research more efficient benefits us all."
| | "Better approval systems would mean more efficient and better quality outcomes for patients." 
| (iii) Resource (e.g., time, money) savings | "Addressing these issues will save a lot of time and money"
| | "Less time on the process of ethical approval and research governance means more time for actually DOING the research!"
| (iv) Reducing waste | "This seems an important way to reduce paperwork for academics"
| (v) Enhancing efficiency | "streamline any process that can make research more efficient"
| | "If Australia is to be competitive on the international research stage, ethics processes have to be streamlined."

### Major Theme 5: Miscellaneous / other comments

| (i) Acknowledgement of the importance of appropriate system of ethics and/or governance | "Ethics & governance are absolutely critical to the proper conduct of research." 
| | "Ethics oversight and approval is essential to research..." 
| (ii) Statement of support for the petition | "The argument is well stated in the petition information." 
| | "I agree with the arguments presented in this case."
| (iii) Statement of professional or personal role | "As a research administration officer, I'm dealing with this issue constantly..."
| | "as a cancer researcher..."
| | "I am a cancer survivor and consumer advisor involved in clinical trials." 
| (iv) Miscellaneous/other comments in Major Theme 5 | "The only way to improve care is via research"
| | "The rest of the world is laughing at us"
Appendix 1 – Copy of the petition


Text:

We need a national inquiry to streamline/improve research ethics and governance in Australia

By: Adrian Barnett
recipient: Australian House of Representatives

 Millions of dollars worth of Australian health and medical researchers' time is being wasted on: submitting the same forms to multiple review committees; or submitting forms for negligible risk research that should not need formal oversight. These unnecessary applications waste huge amounts of time and money, and are impeding health and medical research in Australia.

Previous fixes to the system have been inadequate as many site-specific processes remain in place. Excessive paperwork slows collaborative research projects and clinical trials, and in some cases may even prevent research from taking place.

This is the peer reviewed version of the following article:
We want a national inquiry to examine the entire system of ethics and governance approvals.

Many other countries have far simpler approval systems. The fragmented Australian system is hampering our ability to conduct research by tying up researchers in wasteful knots of unnecessary paperwork.

We want national systems with standardised forms that are used by every state and territory health department.

Recent studies by Australian researchers on the time wasted by unnecessary approvals are available here, here or here.

Can you help us send a message to federal government by signing and sharing this petition?

Adrian Barnett, Queensland University of Technology
Jennifer Byrne, University of Sydney
Amanda Rush, University of Sydney
Anna Scott, Bond University
Natalie Taylor, University of Sydney

This is the peer reviewed version of the following article:
Appendix 2 – Locations of the petition signatories from Australia

<table>
<thead>
<tr>
<th>Location</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brisbane</td>
<td>252</td>
</tr>
<tr>
<td>Sydney</td>
<td>241</td>
</tr>
<tr>
<td>Melbourne</td>
<td>105</td>
</tr>
<tr>
<td>Perth</td>
<td>78</td>
</tr>
<tr>
<td>Adelaide</td>
<td>66</td>
</tr>
</tbody>
</table>