INTERNAL MEDICINE JOURNAL

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doi:10.1111/imj.15773

ETHICS IN MEDICINE

How to streamline the low and negligible research ethics and governance review process from 80 to 10 days: submission to decision

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Key words
research ethics, low-risk research, negligible-risk research, research governance.

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Received 9 December 2021; accepted 19 February 2022.

Abstract

Most clinicians find research ethics and governance difficult and time consuming. This study aimed to develop a better local review process for low-risk research. We used real-time processing, leveraged local expertise and streamlined paperwork. As a result, turnaround times decreased from more than 80 days to 10 days, creating an efficient review process for low-risk projects.

Introduction

One of the foundations of evidence-based medicine is clinical research, as it plays an essential role in providing the best quality care to patients.[1] As such, clinical research needs to be supported and facilitated to develop.[2] When conducting research within an Australian public health institution it must comply with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct.[3] In addition, all public health institutions require an approval process called a research governance review in accordance with the appropriate level of ethical review.[4] These processes ensure that only high quality, ethical and endorsed research is conducted. However, there is growing evidence that current processes are too risk-averse[5] and, at times, stymie clinical research.[6–8] This is a major concern given within Australia there is an under-resourcing of research within the clinical setting.[2] Within our local health district (LHD), most of the research is undertaken by clinicians within their own time.

Compounding these issues is the definition of what constitutes low-risk research. This can be a source of contention and inconsistency. A recent survey assessed the level of agreement between ethics committees and found there was a significant level of variation.[9] Not only are there variations in how ethics committees define risk, but also variations in how research governance requirements are interpreted and applied.[10–12]

Therefore, it is no surprise that researchers experience significant levels of discontent and frustration when dealing with the ethics and governance processes. This has led to a recent 'call to arms' by a group of Australian researchers who are demanding change.[13]

Locally, we were experiencing significant delays, on average more than 80 days between submissions to approval for low and negligible risk (LNR) research. To address these concerns, a review of local LNR review processes was undertaken to identify issues and develop long-term solutions.

The aim of this article is to outline how a LHD in New South Wales (NSW), Australia, created a LNR committee that was efficient and agile.

Abbreviations: HREC, Human Research Ethics Committee; LHD, local health district; LNR, low and negligible risk; NHMRC, National Health and Medical Research Council; NSW, New South Wales; OHMR, Office for Health and Medical Research

Funding: None.
Conflict of interest: None.

Methods

The process is described below following Kotter's eight stages of change framework.[14]

Create a sense of urgency around a single big opportunity

In January 2020, a change in research leadership provided the opportunity to reassess the assessment and management of LNR projects in the clinical space. The concept and initial preparatory work for a local LNR had been attempted twice in the previous 6 years. Both attempts were under two different research leadership teams (2014 and 2016) and both 'failed-to-launch' due to a variety of factors. The reasons for these failures included: inability to convince the Chief Executive that the proposed LNR process was fully compliant with the NHMRC statement and the previous research leadership unwillingness to manage the resistance encountered from the research support staff. A new effort to energise both the LHD executive and researcher clinicians was embarked on, driven by a comprehensive engagement with the breadth of regulation in the ethics landscape.

Build and maintain a guiding coalition

Discussions were held with relevant stakeholders including: the NSW Office for Health and Medical Research (OHMR); the NHMRC Office for Ethics and Governance; the Chair and administration team of the Joint Human Research Ethics Committee (HREC); the Chief Executive of the LHD; local clinical researchers; and research governance and support office staff.

Formulate a strategic vision and develop change initiatives designed to capitalise on the big opportunity

A business case was provided to the Chief Executive that outlined the process and most importantly how this service was cost neutral. Cost neutrality was achieved through a realignment of existing resources into this new service.

Communicate the vision and the strategy to create buy-in and attract a growing volunteer army

The work was largely done by a group of staff whose role was to review a LNR application. They were volunteers from the clinical workforce, many of whom had voiced frustrations at the level of paperwork and time involved in the previous system. Prior to the implementation of our local LNR process we relied on the local conjoint university and LHD HREC. This committee faced challenges to attract and retain clinicians on their committee. In the case of the local LNR committee the volunteers were expected to be fully conversant with the NHMRC statement and the workload was capped at only 3–4 submissions per year for each volunteer. This was achieved by managing a larger pool of volunteers from the LHD and spreading the workload amongst them. All reviews were managed electronically and administered by the research support unit.

Accelerate movement towards the vision and the opportunity by ensuring that the network removes barriers

Some understandable resistance was met to the change in routine. The arguments were based on the following premises: 'we have tried this before and it has failed'; and 'it will be too much work for the research support office'. The research leadership worked through each of the issues with the staff and provided evidence for reasons why previous attempts had failed, as well as a commitment the workload would not increase but instead be reprioritised.

Celebrate visible, significant short-term wins

An anonymous online survey was designed and sent to local clinical researchers to determine their level of satisfaction with the LNR review process before (early-2020) and after (mid-2020 to late 2021) setting up our local LNR review committee. Results were analysed and distributed broadly via the local website, newsletter and monthly district-wide research committee.

Never let up

Despite some misgivings, the project proceeded. The approach taken by management was to share openly the processes and outcomes, providing any data requested by the NSW OHMR. In addition, an independent review of the new LNR process was commissioned in February 2021. The recommendations included: ensuring an auditable trail of paperwork for all decisions reached, providing staff access to the terms of reference for the LNR committee and including participants' feedback when/if required. All were accepted and actioned. An annual evaluation has been embedded within the operating procedures and the results of this evaluation allow improving the process when required.

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Table 1 Metrics pre and post the implementation of a local low and negligible risk review committee 2019 versus 2020

Measure/Metric	HREC LNR (Jan.–Dec. 2019)	Local LNR (Jan.–Dec. 2020)
Number of LNR processed	19	22
Average time from submission to final decision of ethics and governance (total days)	84.7	9.7
Average time for governance review (total days)	18.8	1.0
Range (total days)	17–284	0–55†

†There have been two outliers. This was due to the over-reliance on one reviewer who also had a heavy clinical workload. This has been improved by increasing the pool of potential reviewers from each of the three professional groups, thereby ensuring a more even workload distribution. HREC, Human Research Ethics Committee; LNR, low and negligible risk.

Institutionalise strategic changes in the culture

We employed a front-end preparation of all applications prior to submission, conducted by a staff member with formal research training, to ensure required standards were met. Research governance questions were included within the one application form to avoid duplication for the researcher. The governance review was completed separately by the Research Governance Officer and at the same time as the ethical review. This change was achieved by instilling a different approach in the governance officer, from policing the project to proactively assisting staff to meet the governance requirements. Staff were able to submit their application at any time via email attaching a completed application form or directly into the management information system (REDCap; Vanderbilt University, Nashville, TN, USA). Templates were developed including a checklist for committee members, head of department support and for complaints/adverse events.

Results

Workforce cost

The initial set-up cost was approximately 520 h. This included 8 weeks of development of internal processes (320 h) and formal training of five staff in a 40-h ethics online course (200 h). Once established, the total administrative cost was approximately 2 h per application excluding the reviewer's time. There were no additional staff employed, instead the research governance staff had their processes reviewed and all redundant tasks such as double and triple handling of information and the use of paper-based information systems were replaced with efficient information management systems. These technical improvements delivered time savings that were redirected into supporting the LNR process.

Process outcomes

Outcomes pre and post implementation of the local LNR process are shown in Table 1.

End-user satisfaction with LNR process

Figure 1 shows the end-user evaluation before and after implementing the local LNR review process. Figure 2 provides an overview of the LNR review pathway.

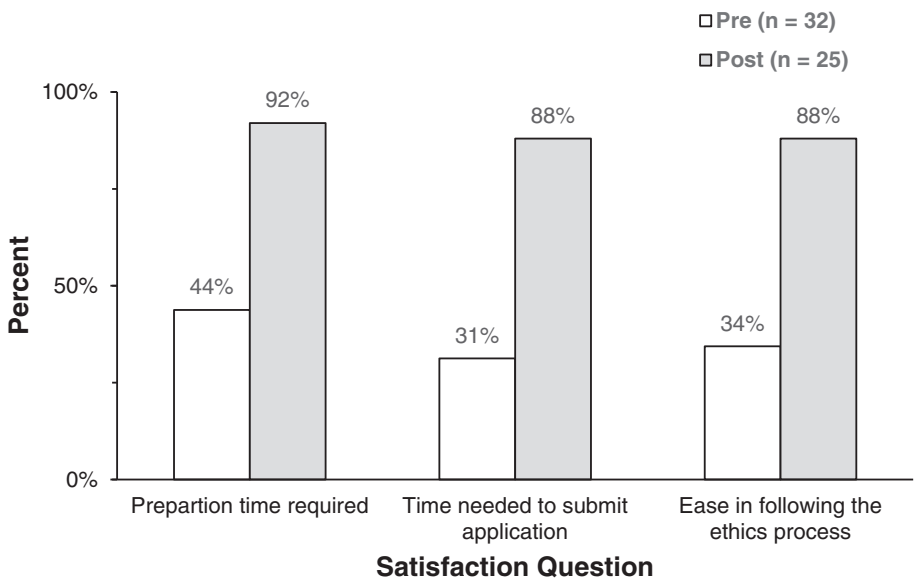

Figure 1 End-user evaluation before and after implementing the local low and negligible risk review process.

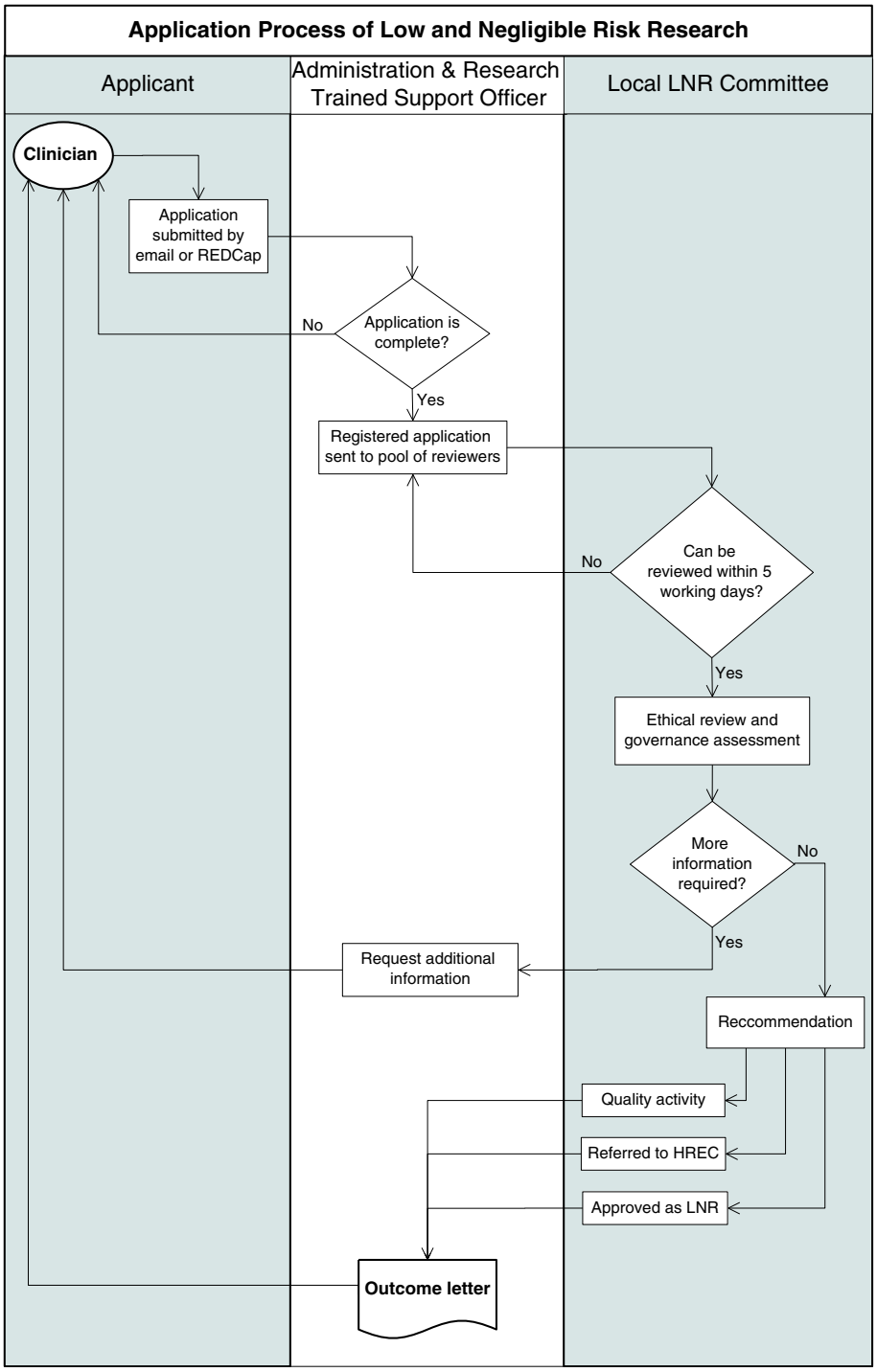

Figure 2 Application process of low and negligible risk (LNR) research.

Discussion

From the feedback received from clinicians and the reduction in time taken, we believe the local LNR process has been improved. We continue to review and refine all aspects of the process by utilising regular feedback from end-users. We have also maintained comprehensive records that provide an auditable trail of decisions, ensuring there is evidence of compliance with the NHMRC National Statement. Of the eight steps involved in establishing the local LNR, the two most critical were:

gaining the support of the Chief Executive; and the determination of the research team to deliver a more efficient model. The realignment of research support office processes was initially labour intensive, but once the process was developed it only required a relatively small amount of administrative support and has been integrated into the everyday work duties of the research support team.

This LNR model is a streamlined process that includes utilising staff with a thorough understanding and contemporary working knowledge of the clinical context, combining ethics and governance review in one form, using real-time processing of applications, employing a front-end review of all applications prior to submission, and balancing the level of ethics and governance review with the risk of the research. The corollary success was the upskilling of local health service staff in research ethics and governance (i.e. empowering staff to decrease their reliance on the interpretation of these processes by non-research trained support staff).

The NHMRC Statement allows for institutions to establish non-HREC review for any research defined as low risk. Despite this, most public institutions do not use a non-HREC review process for low-risk research, instead they utilise a subcommittee of their lead HREC. Based on data provided by the OHMR, we purport that although this approach might be convenient, developing a local institutional review committee might provide a better service to end-users.

Conclusion

Much of the literature, both locally and internationally, has focussed on the challenges encountered with the current ethical and governance review structures.[15–19] This report is the first to outline a practical solution that has been very well received by clinicians and has produced an almost 10-fold improvement in the turnaround times of LNR applications. We hope this experience proves useful to other health districts who might be looking for a more efficient and agile LNR review process. The advantage to this home-grown solution is that it leverages existing resources by realigning work processes and utilising interested clinical staff. It is a business model with in-built sustainability, an efficient and agile LNR process.

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