Ethics and site-specific governance approvals for multi-centre, inter-sector health care research

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Despite the introduction of multi-centre ethics approval processes, our experience with obtaining ethics and governance approvals for a pragmatic, stepped wedge, cluster randomised trial illustrates the persistence of long timelines and inconsistencies. The REMAIN HOME trial is investigating whether integrating a pharmacist into 14 general practices reduces unplanned hospital re-admissions of patients who were recruited during admission to any of 11 participating hospitals.[1] As

Processes and timelines of applying for ethics and governance approvals for the REMAIN HOME trial

Process	Type of application	Sites for approval	Documents (other than project documents*) required	Authorisation† required (excluding research team)	Communication with ethics officer/RGO to clarify process‡	Submission to approval (days)
Ethics approval	Multi-centre hospital review	9	Submissions: 6 hard copies, one e-copy (NEAF, cover letter, researcher CVs); resubmissions (3): 6 hard copies, one e-copy (modified documents, responses to comments)	Head of department at principal investigator employment site	8 emails; 2 meetings to clarify research design; 3 resubmissions	78
	Expedited review (university)	NA	One e-copy (all ethics-approved documents)	None	6 emails	106§
	Full review (private hospital 1)	2	3 hard copies, one e-copy (application form, cover letter, researcher CVs, prior ethics approvals, support letter from department)	Director of supporting department at hospital	5 emails; 1 resubmission	51
	Low risk review (private hospital 2)	1	One e-copy (low risk application form, cover letter, researcher CVs)	None	6 emails	40
Governance	SSA (LHN 1, H1–H4)	4	One hard, one e-copy per hospital (SSA, cover letter, site-specific PICF, ethics approval, all ethics-approved documents)	7 for each SSA (finance, site contact, heads of supporting departments, executive director of hospital, RGO, district CEO)	H1: none; H2: 18 emails, 1 resubmission; H3, H4: 9 emails (same RGO), 2 resubmissions (one at each hospital)	H1: 5; H2–H4: 44
	SSA (LHN 2, H5–H8)	4	One hard, one e-copy per hospital¶ (SSA, cover letter, site-specific PICF, ethics approval, all ethics-approved documents, contract)	9 (heads of supporting departments, executive director at each hospital, finance manager, RGO, district CEO)	40 emails	20 (H5–H7); 35 (H8)
	SSA (LHN 2, H9)	1	One e-copy (SSA, cover letter, site-specific PICF, ethics approval, all ethics-approved documents, contract)	5 (site contact, head of supporting department, executive director of hospital, RGO, hospital CEO)	17 emails, 1 resubmission	Ongoing**
	University services agreements (14 general practices)	14	One e-copy	2 (university director of research partnerships, director at each general practice)	One email, 14 meetings (one at each general practice)	Ongoing††
Legal review	CRA (LHN 1, H1–H4)	4	One e-copy per hospital (hospital network-specific standard CRAs)	2 (university director of research partnerships, executive director at each hospital)	NA (organised by research office at university)	
	CRA (LHN 2, H5–H9)	5				
Overall	*9 application formats*	*20*	*32 hard copies, 33 electronic copies*	*84 authorisations (signatures)*	*110 emails, 16 meetings, 8 resubmissions*	*230*

CEO = chief executive officer; CRA = collaborative research agreement; CV = curriculum vitae; H = hospital; LHN = local health network; NA = not applicable; NEAF = National Ethics Application Form; PICF = patient information and consent form; RGO = research governance officer; SSA = site-specific assessment. * Standard documents required for conduct of project, including protocol, master PICF, data collection forms, study questionnaires and adverse event reporting forms. † Authorisation of each application required consultation with the specified party, who provided a summary of the project and the details of the completed SSA or contract. Authorisation was indicated by a signature of support on the governance application or contract. ‡ Communications for clarification or other specific purpose (eg, instructions were not clear in documentation; requesting contact details for hospital staff to authorise the SSA). § Delay caused by transfer to new system. ¶ Hospital 8 required the SSA be endorsed at monthly clinical council meeting, then approved by executive committee prior to signing contract form. ** SSA not yet approved (21 March 2018). †† All practices have approved the project, but five contracts are yet to be finalised (for procedural reasons); this has not delayed the project starting. ◆

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governance approval applications could not be submitted until after ethics approval was finalised, the overall process from submitting our first ethics approval application to final governance approval took 230 days (24% of the total project timeline) (Box).

The ethics approval process began with submission of a National Ethics Application Form (NEAF) to a single public hospital for multi-centre review. One of two private hospitals not participating in the multi-centre review process accepted a low risk application, while the second required a full application using their own forms. An application was also submitted to a university ethics committee; the committee was transitioning to a new system, and this may have delayed approval. Time from submission to approval for these ethics applications ranged between 40 and 106 days. There were 25 emails to clarify the application or submission process, and two meetings and four resubmissions to respond to comments from the ethics committees.

After ethics approval was finalised, six site-specific assessment (SSA) forms were submitted to nine hospitals in two Local Health Networks (LHNs) for governance approval. The two private hospitals did not require governance approval. The need to seek individual site authorisation and differences in site requirements were major obstacles, with time from submission to approval ranging between 5 (by the hospital that approved the NEAF) and 44 days. Approvals of the same SSA by three hospitals in one LHN each took 44 days, with 27 emails for clarifications; they also stipulated that a budget be submitted, despite not providing funding.

In the second LHN, a single multi-centre governance review was undertaken by the lead hospital on behalf of four sites. Information on the hospital website about this form and who to approach at each site was limited. Forty emails between the governance office and the research team were needed to clarify the application process. Despite the ostensibly single approval process, two hospitals insisted on hospital-specific approval protocols. Another hospital in this LHN used a different SSA form, required privacy office approval, and requested changes to the patient information sheet that had to be approved by the ethics committees, causing further delays; as a result, the hospital is yet to enrol patients in the already started trial.

This experience reflects an unnecessarily complex and costly process associated with low risk health services research across organisations within a single Australian state. These challenges are amplified when conducting health services research on a national scale, with one research group reporting delays of two and a half years and $263 750 in costs to receive ethics and governance approvals.[2]

The process of approving research within and across health care sectors requires reform. In line with earlier suggestions,[2] we recommend establishing a single network-level approval process in which investigators submit an application to each LHN with lead governance officers, who would assess the application for appropriateness and completeness on behalf of all hospitals in the network. The conditionally approved application would then be sent to each hospital for rapid review and approval according to a standard template that requires detailed justification should rejection or revision be recommended. Once each hospital has approved the SSA, it would be returned to the lead governance officer for approval. The anticipated turnaround times at each network should be published. An LHN-level governance process would provide consistency of approval processes and enhance efficiency, while ensuring that each hospital retains oversight of research in its remit. Harmonising procedures for approving research across health care sectors is essential given the call for health services researchers to focus on improving transitions in health care and patient outcomes.[3]

In summary, ethics and governance review is vital to ethical and responsible research in health care. Streamlining the governance application process in the hospital sector would minimise the time and resources required by administrative processes, ensure consistency and efficiency of governance across sites, and facilitate multi-centre research.

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1 Foot H, Freeman C, Hemming K, et al. Reducing Medical Admissions into Hospital through Optimising Medicines (REMAIN HOME) Study: protocol for a stepped-wedge, cluster-randomised trial. *BMJ Open* 2017; 18: e015301.

2 Clay-Williams R, Taylor N, Braithwaite J. Potential solutions to improve the governance of multicentre health services research. *Med J Aust* 2018; 208: 152-154. https://www.mja.com.au/journal/2018/208/4/potential-solutions-improve-governance-multicentre-health-services-research

3 Wells L, Dawda P, Knight A. Hospital discharge: a dangerous time for patients. *MJA InSight* 2017; 15 May. https://www.doctorportal.com.au/mjainsight/2017/18/hospital-discharge-a-dangerous-time-for-patients (viewed July 2017). ■