

Enhancing Research Ethics and Governance Processes : Monash Partners Academic Health Science Centre Experience

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on behalf of the Ethics and Governance Working Group and Clinical Research Advisory Committee

BACKGROUND:

Since 2005, Australian jurisdictions and federal initiatives, have sought to reform and streamline ethical review and avoid unnecessary duplication of review for multicentre studies. Two key drivers of this were:

- Certification of HRECs by the NHMRC for benchmarking of processes and building trust between institutions.
- Separation of ethical review from "Research Governance" processes.

Currently 43 HRECs of more than 200 are NHMRC certified. Of these 34 are part of the National Mutual Acceptance (NMA) scheme established by the State Public Health systems, to approve multisite ethics applications.

Monash Partners Academic Health Science Centre (MP) is an NHMRC accredited Advanced Health Research Translation Centre (AHRTC) accredited to integrate research, education and healthcare to deliver "better health through research". The Ethics committees of the lead agencies, Alfred Health and Monash Health, are both NMA and NHMRC certified, Cabrini and Eastern Health are only NHMRC certified and Epworth and Peninsula Health had HRECs that were not certified.

THE PROBLEM:

The NMA scheme created a 2 tier system with non accredited HRECs unable to provide ethics reviews for multisite projects. Ethics processes were not streamlined and were duplicative and inefficient and prior efforts to collaboratively improve this had not succeeded.

OBJECTIVES:

Toward addressing these problems we aimed to co-design, implement and evaluate streamlined ethical review through building trust, relationships and processes across member organisation HREC activities.

METHOD:

MP created a platform dedicated to addressing these gaps and provided EFT to strengthen partnership and drive progress. We established two partnership wide working groups that bring together key stakeholders to co-design approaches integrated with the processes, systems and experience of each health service:

- a multi-disciplinary, clinical research advisory committee and,
- an ethics and governance working group.

A phased approach included workforce development with the development and implementation of a TransCelerate accredited clinical research training program, provided at scale and at no individual charge, and integrated as a requirement of ethics submissions. This was followed by a change management process to streamline ethics and research governance approval processes across partner organisations.

Ethics and Governance Working Group: Alison Hutchinson (Monash Health), Andrew Carey (Baker Institute), Angela Henjak (Alfred Health), Anne Spence (Cabrini), David Taylor (Eastern Health), Deborah Dell (Monash Health), Janet Russell (Baker Institute), Lee-Anne Clavarino (Peninsula Health), Souheir Houssami (Monash University), Victoria McMorrin (Epworth)
Clinical Research Advisory Committee: Emma Baker (Cabrini), Ian Davis (Eastern Health), John Zalberg (Monash University), Jonathan Shaw (Baker Institute), Paul Myles (Alfred Health), Velandai Srikanth (Peninsula Health), William Sievert (Monash Health), Yahya Shehabi (Monash Health), Nikolajs Zeps (Epworth)

OUTCOMES:

Over 2000 staff have been trained across our partner organisations.

A shared Ethics Review Model was co-designed including:

- Legal sign off by health services partners and the University for mutual acceptance of ethical review
- Centralised ethics review with Epworth Healthcare closing its HREC in December 2018 and Cabrini scheduled to do so in 2019
- Plans are underway to increase the frequency of HREC meetings to improve review times
- An agreement to progress optimisation and integration of the Victorian State Government ERM IT infrastructure for an end to end electronic governance approval workflow
- Adoption of a standardised Participant Information & Consent Form

CONCLUSION:

Through working closely together, MP member organisations have significantly advanced integrated ethics and governance across the partnership.

Most importantly, integration of HRECs across the partnership has allowed closure of two smaller HRECS, without adverse outcomes. Benefits include cost savings for Epworth and Cabrini and expansion of available ethics review expertise in the larger committees. Workload increases for the two lead HRECs is offset by increased revenue from an agreed business model to support staff increases

A functional IT infrastructure is now critical to take the streamlining activities to the next stage and is being optimised in collaboration with State Government. The NHMRC accredited AHRTCs offer an ideal collaborative vehicle for system level change in research, ethics and governance.

Next Steps:

- Workforce development programs are expanding
- Epworth and Cabrini have significantly changed their governance processes to ensure compliance, in the absence of their own HRECs
- Together, MP members have been reviewing the likely requirements of the ACSQHC Research Governance Framework
- A Victorian Translational Research Alliance has been formed across MACH, Monash Partners and State Government, linked to a Hospital Research Directors and Research Managers Forum to address state barriers to research governance and ethics
- Data sharing, governance and efficiency challenges are being explored to consider an NMA approach with data sharing principles now well advanced and feasibility testing of the ERM IT system for governance of data projects
- The NHMRC accredited AHRTCs have developed a National Systems Level Initiative and national committee to share and advance the facilitation of clinical research.

