

Country Report from ABN Representatives

***Ethical Challenges of Healthcare
Digitalisation and Emerging
Technologies***

National Health and Medical Research Council

AUSTRALIA

ABN Meeting, 4 September 2023

Outline

1. **Australia's emerging technologies landscape**
2. **Major ethical challenges**
3. **NHMRC/AHEC response:**
 1. **Development of guidance material for human research ethics review committees (HRECs) for research involving emerging technologies**
 2. **Development of information for consumers and community on how emerging technologies are developed, assessed, regulated and integrated into health care and other fields**
4. **Other Ongoing/Upcoming Bioethics Initiatives in Australia**

Australia's Emerging Technologies Landscape

- The development and integration of healthcare digitalization and emerging technologies in Australia resembles the processes in many other technologically advanced countries. It is governed by a web of inter-related federal and state and territory regulations and national ethics guidelines and policies. However, with the exception of the areas of embryo research and genomics, most of the use of and research into these areas is not subject to either national or jurisdictional law.
- While use of 'big data', data linkage and Artificial Intelligence (AI) is well-advanced in medicine and healthcare research in Australia, there are few 'milestones' on which to report. The major new area of activity that can be considered 'emerging technology' is the recent (2023) decision to enable research into mitochondrial donation, making Australia the second country, after the UK, in which this research is officially permitted. Although research in this area will not necessarily lead to making this technology available to Australians, it is understood that this may be the outcome.

Major Ethical Challenges in Australia

S/N	Ethical challenge(s) arising from healthcare digitalisation/emerging technologies
1	Ensuring that Australians adequately understand and are provided with sufficient information about the nature and impact of the developments in healthcare digitalisation and emerging technologies such that they are not subject to undisclosed access to, or use of, information associated with them and are protected against coercion, exploitation or misuse of their information.
2	Balancing the potential, but often very distantly related, benefits of the research into and/or use of emerging technologies with the known and unanticipated risks of this research/use, both on an individual and societal level.
3	Accurately assessing the risks of harm associated with research into and/or use of emerging technologies.
4	Determining to what degree emerging technologies should be subject to guidelines +/- regulations +/- laws and whose responsibility it is to develop and enforce the oversight and governance of these technologies.

Initiatives in Australia to Address the Ethical Challenges

S/N	Initiatives to address the ethical challenges
1	Development of guidance material for human research ethics review committees (HRECs) for research involving emerging technologies
2	Development of information for consumers and communities on how emerging technologies are developed, assessed, regulated and integrated into health care and other fields

Other Ongoing/Upcoming Bioethics Initiatives in Australia

- **Revision of national guidelines:** release of the [National Statement on Ethical Conduct in Human Research 2023](#) to replace the current version (2007, updated 2018), followed by a further update in 2024.
- Major overhaul of guidelines on cell, tissue and organ donation and transplantation
- Major initiative to address the infrastructure and systems for review and conduct of research, focused on clinical trial research, including reform and expansion of the certification/accreditation of ethics committees (HRECs) that review research
- Continuing efforts to respond to the challenges posed by genomics and gene editing research and practice