Ethics, Health Research and Clinical Trials

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National Ethics Advisory Committee Secretariat

Background

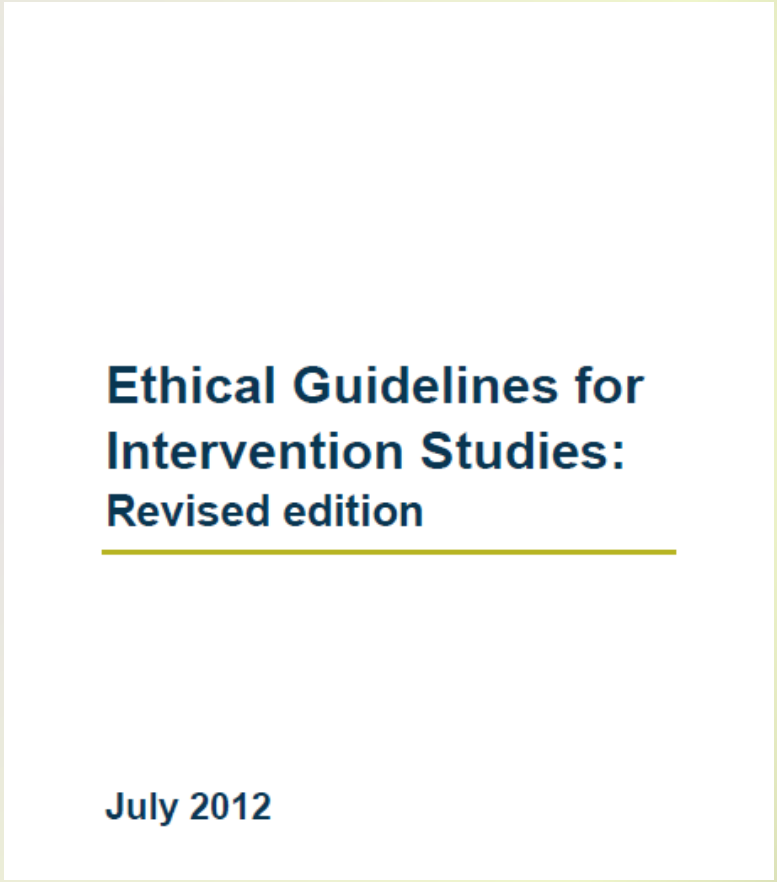
- Employed by the Ministry of Health
- Part of the Ethics team, who sit in Quality Assurance and Safety group.
- Directorate is the Health System Improvement and Innovation directorate is responsible for ensuring strategic leadership and support for the Ministry and wider health sector to deliver ongoing improvements in service quality and outcomes.
- This includes leadership of research and evidence, quality assurance and improvement, data analytics and support for innovation in the sector.
- The Ethics team provides the Secretariat support to the National Ethics Advisory Committee, as well as:

  - the four Health and Disability Ethics Committees,
  - Ethics Committee for Assisted Reproductive Technology and
  - Advisory Committee for Assisted Reproductive Technology

National Ethics Advisory Committee

Established in 2001 the National Ethics Advisory Committee (NEAC) is an:

- Independent advisor to the Minister of Health
- NEAC's statutory functions include:
  - advising the Minister on ethical issues on any health and disability matters
  - **determining nationally consistent ethical standards across the health sector.**

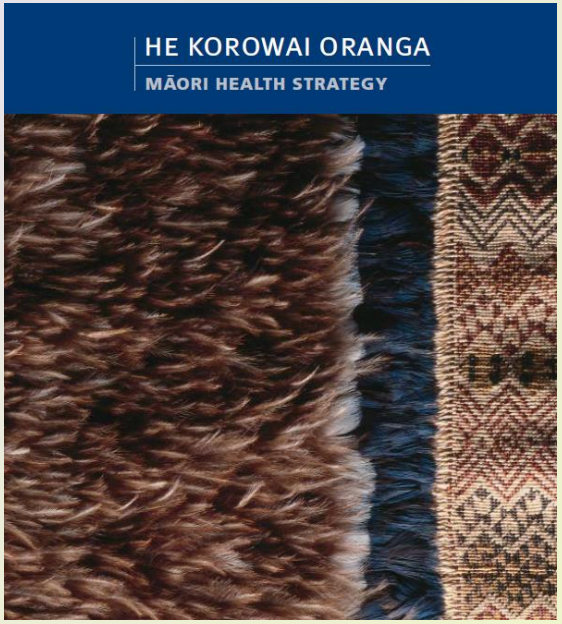


Ethics Working Group

- Review the existing draft Ethical Standards for Health and Disability Research developed by the National Ethics Advisory Committee (NEAC)
- Complete the first draft
- Ensure that Māori ethical perspectives underpin all parts of the Standards
- Take into account the broader policy environment
- Ensuring that the draft is aligned to and informed by national and international developments in ethics

Ethical Standards and the HRS

- Strategic priority 2 – New Zealand regulatory landscape
- The ethical standards focus on reducing inequity
- The ethical standards promote health research and clinical trials
- The ethical standards strengthen our clinical trials environment, providing clarity to researchers and ethics committees



NEAC Consulted on a draft

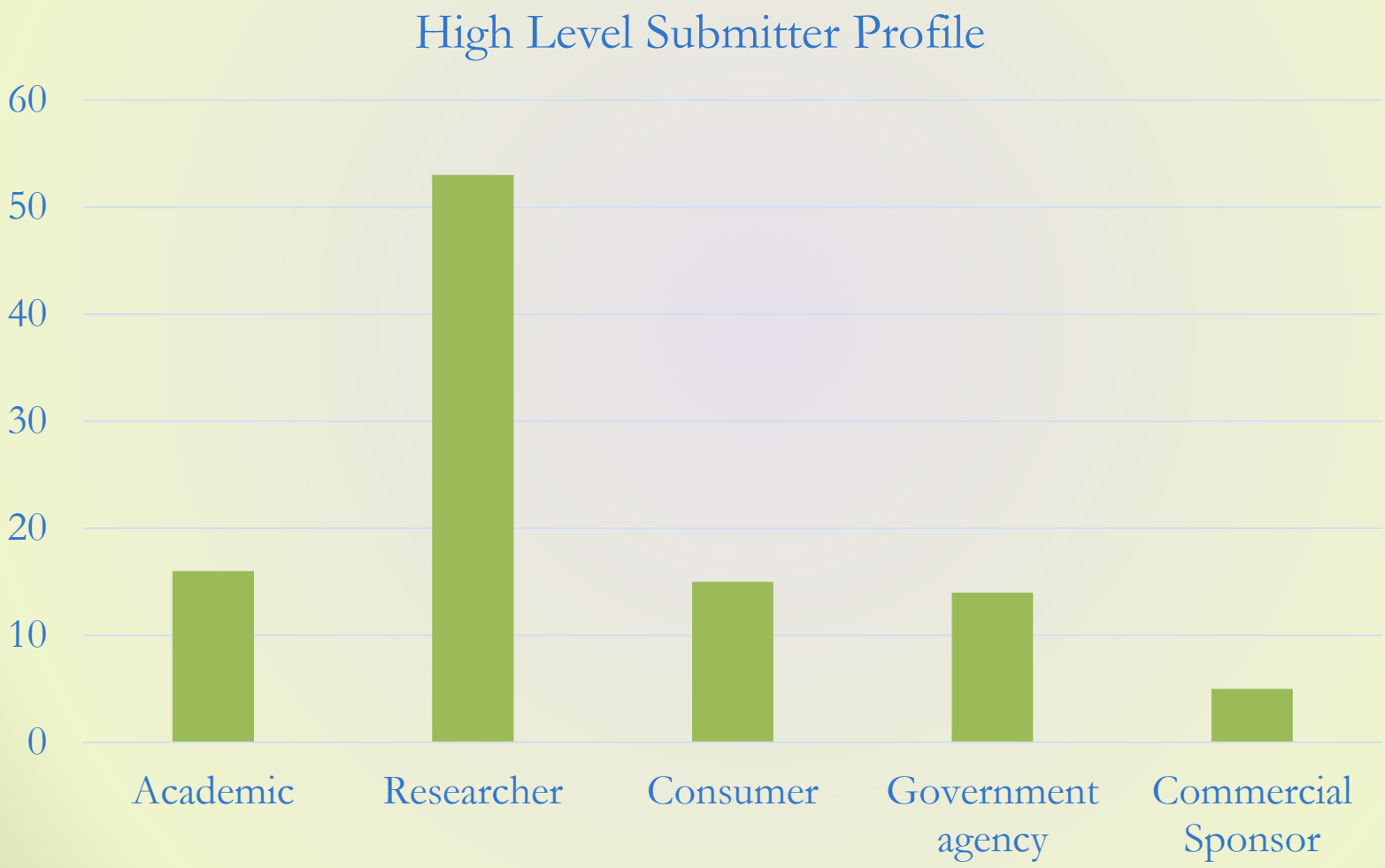
- On 24 July 2018 NEAC called for public submissions on the *Draft National Ethical Standards for Health and Disability Research: Consultation document 2018*.

- NEAC held 5 public meetings with 350 registrations

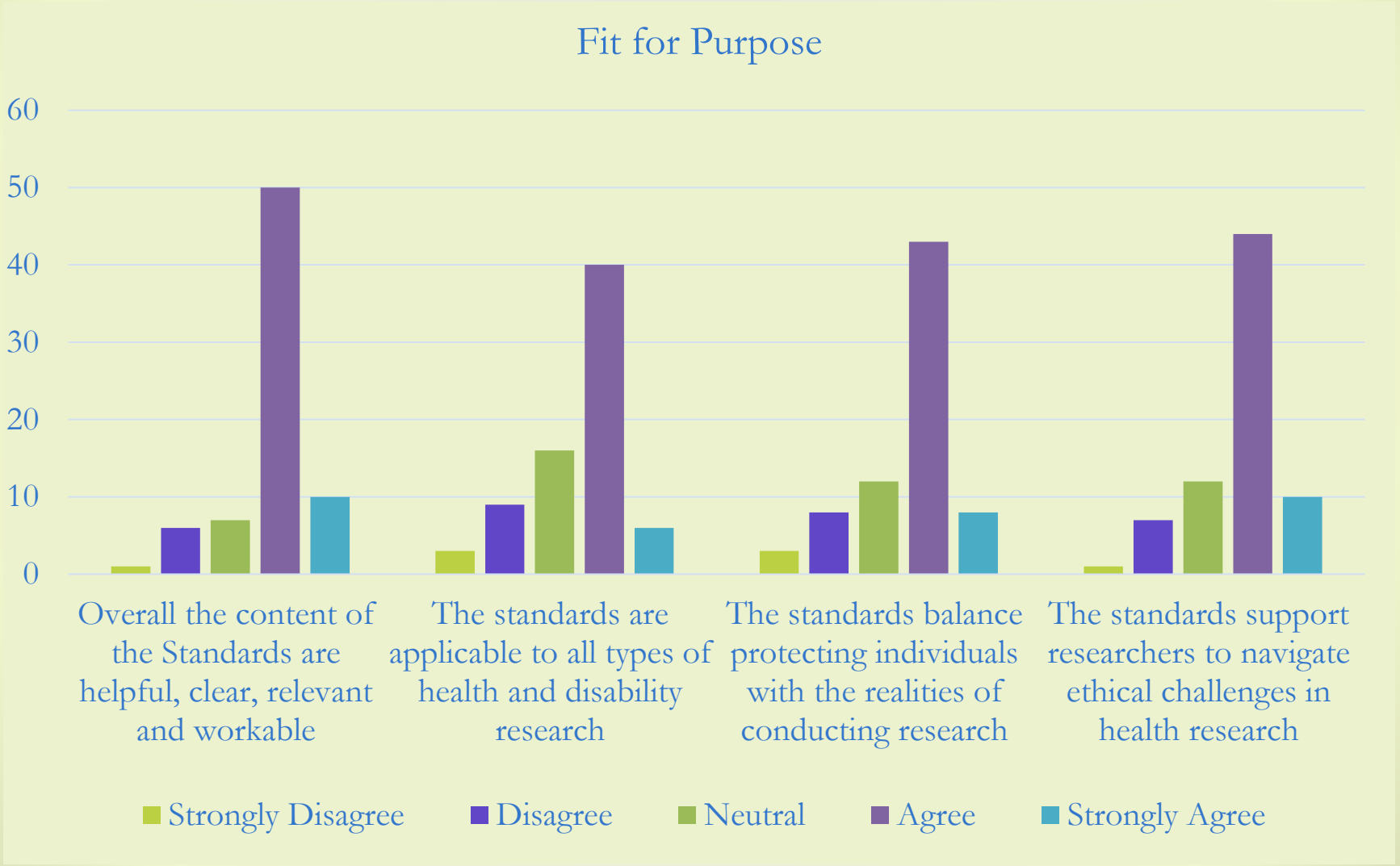
What we consulted on

- Whether the Standards are fit for purpose: are the contents of the Standards helpful, clear, relevant and workable?
- Whether the Standards covers all relevant ethical issues: are there matters missing which on topics where ethical guidance should be provided? Are there any conflicts with other standards, laws or current pieces of work that should be considered?
- General feedback: should any paragraphs be amended? Are there terms that are confusing or could be better defined?
- https://neac.health.govt.nz/
- Full list of submissions
- Summary document

Who we heard from



What we heard: high level feedback



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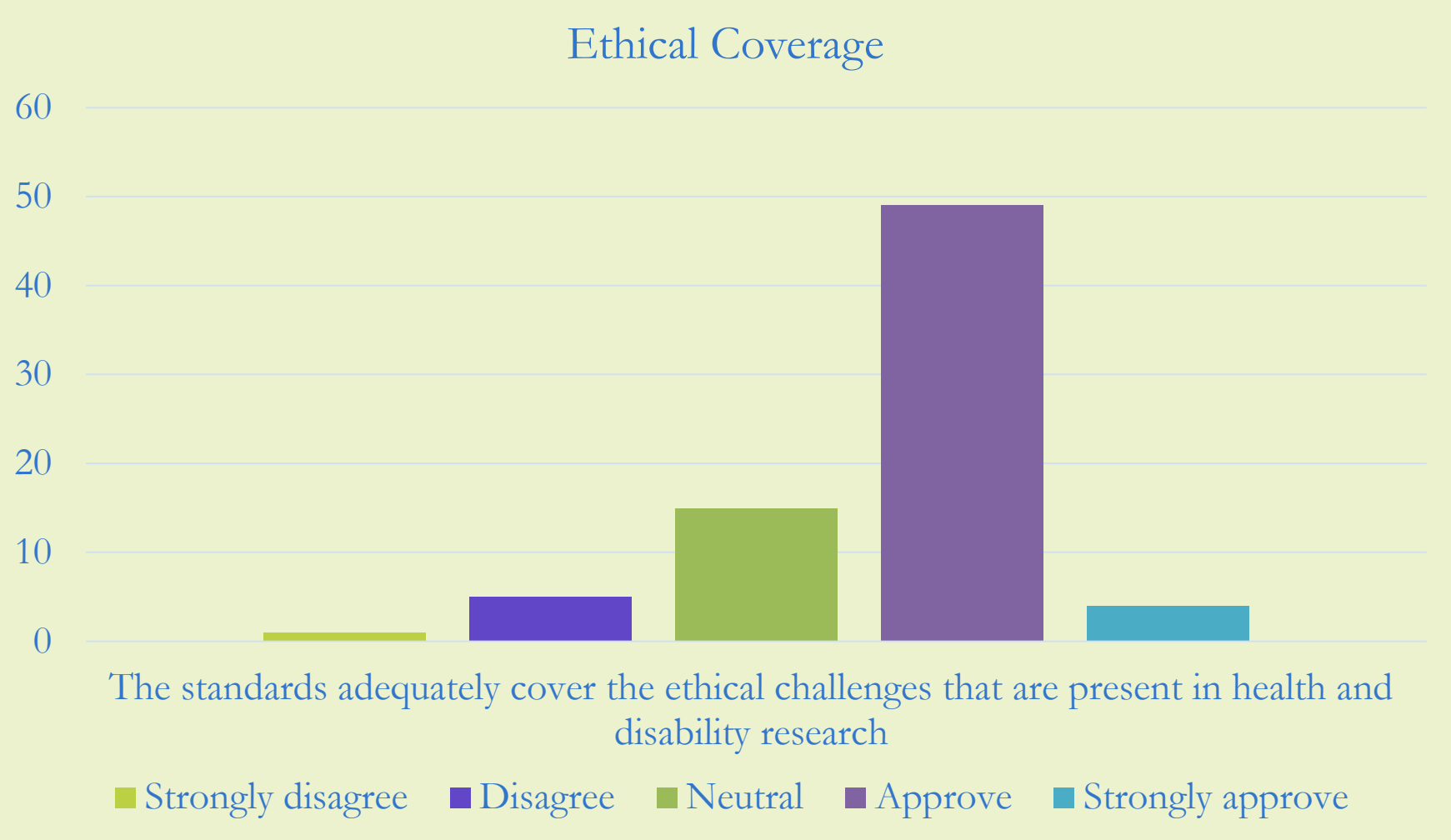

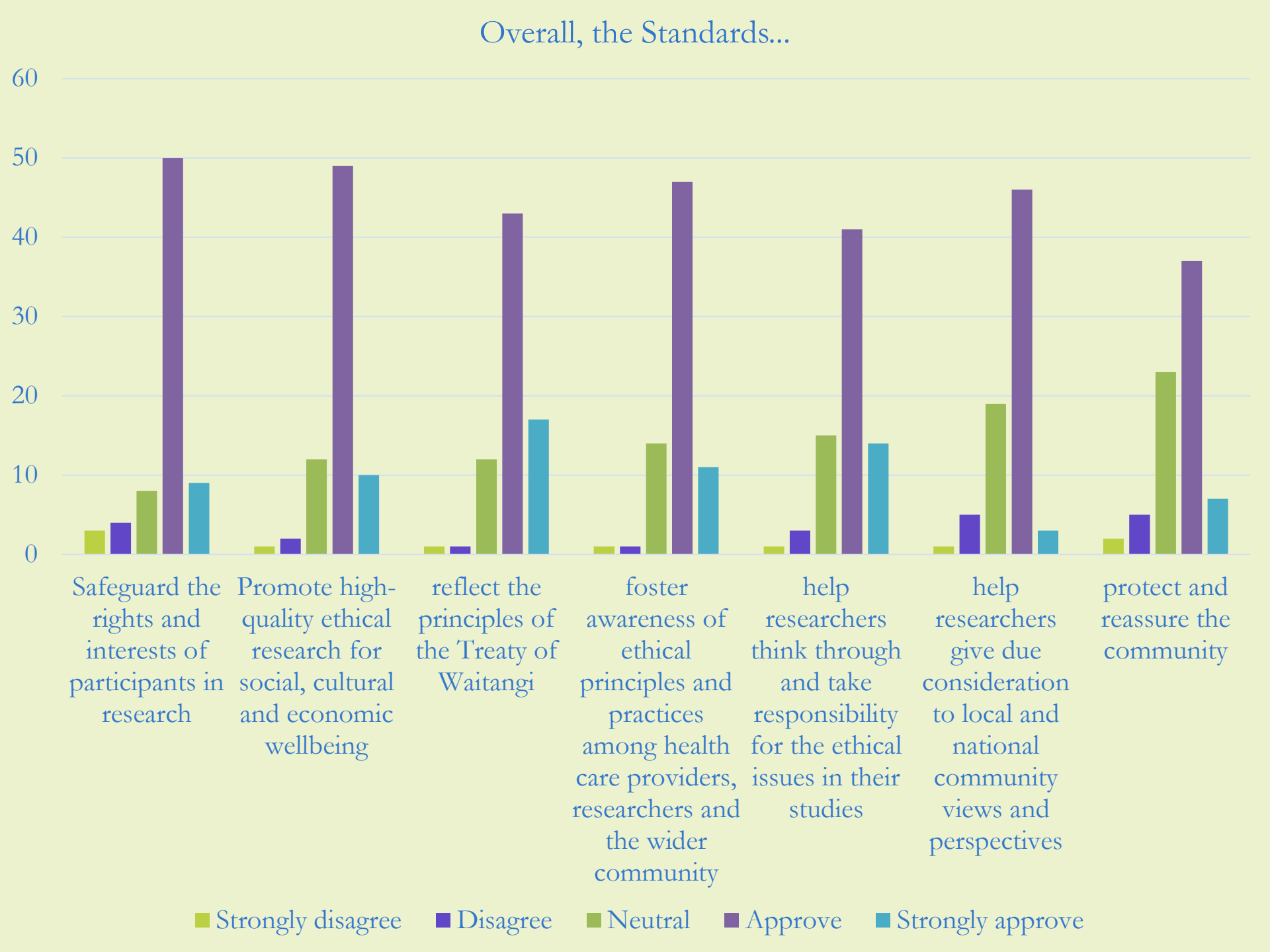
Overall, the Standards...
60
50
40
30
20
10
0
Safeguard the rights and interests of participants in research
Promote high-quality ethical research for social, cultural and economic wellbeing
reflect the principles of the Treaty of Waitangi
foster awareness of ethical principles and practices among health care providers, researchers and the wider community
help researchers think through and take responsibility for the ethical issues in their studies
help researchers give due consideration to local and national community views and perspectives
protect and reassure the community
Strongly disagree
Disagree
Neutral
Approve
Strongly approve

What we heard: Major Themes

- **Inclusion, representation and fairness of advancement of knowledge**
- **Safeguards, wider ethics landscape and impact of the Standards**
- **Accessibility, complexity and functionality of the Standards**
- **Balancing protections with facilitating knowledge advancement**
- **Knowledge advancement; gaps in ethical guidance**

Inclusion, representation and fairness of advancement of knowledge

- An overarching theme was advancement of knowledge, and how fairness, inclusion, and representation among different patient groups and types of participants were considered in the Standards.
- Recognition of importance of Research with Māori
- Disability perspectives
- LGBIQ+ perspectives
- Participants who could not provide their own consent
- Health improvement research involving cluster control randomisation (consent waiver research)

What we are doing

- Review of introductions to consistently link back to partnership of principles
- Review document to be more consistent in embedding of Māori bioethics (Te Ara Tika)
- Full review of document with Disability perspectives working group (7 May), potentially a disability research chapter
- Changes incorporated to be more inclusive of LGBIQ+ perspectives
- NEAC are working with other agencies (HRC EC, HDC) to follow up the legal issues in relation to non-consensual research (both cluster design and clinical trials with adults who lack capacity to consent)

Safeguards, wider ethics landscape and impact of the Standards

- ACC exclusions for commercially sponsored clinical trials
- Requests for guidance on ethics review processes in New Zealand
- Related to this request was feedback about Māori consultation, locality review, and information for researchers on how to meet these requirements
- A further consideration was the scope of the standards

What we are doing

- NEAC will review their advice on ACC taking into account feedback from the public consultation.
- NEAC takes the view that the Ethics Standards should not be overly prescriptive, but acknowledged that more information can be provided on the New Zealand ethics landscape.
- Maori consultation guidance was being considered, however there is existing guidance on this already in other documents and publications.

What we are doing

- Scope – will remain broad, consistent with local and international developments – but tempered by using a risk based model.

- NEAC's view is that the guiding principles are applicable to researchers **whether or not ethics** review is required, and the interpretation of those principles should be commensurate to risk.

- A section on ethics review in New Zealand is to be drafted, to link with the new categories of risk.

Accessibility, complexity and functionality of the Standards

- Structure and functionality

NEAC observed that one of the most common themes related to structure and functionality of the document.

- Ethics and the law

NEAC read with interest the feedback about the interplay with the law and ethics, in particular with areas of right 7(4), cluster control trials, and community intervention studies.

What we are doing

- NEAC have discussed and agreed upon a plan to restructure the document that should address the concerns raised in the feedback
- NEAC have a clear quick access table of contents
- NEAC have added a glossary
- Instead of stating what is legal in New Zealand, the Standards will provide relevant references or links (for instance, to the "legal requirements" section) and state that legal advice should be sought where appropriate.

Example of old vs new structure

Old	New
1.1 Introduction	Introduction
Standards	Subheading
1.2 XXX	1.1 Standard
1.3 XXX	1.1.a Commentary
1.4 XXX	1.2 Standard
Commentary	1.2.a Commentary
1.5	
1.6	Subheading

New full contents of topics

Balancing protections with facilitating knowledge advancement

- Balance as a theme was observed throughout the document, in terms of balancing principles, balancing information, and balancing protections.

- In relation to this was a wider challenge, how can the standards better explain proportionality?

- How can these competing interests be balanced?

Knowledge advancement; gaps in ethical guidance

- IDI data and health research using the IDI.
- Emerging technologies such as CRISPR, algorithms / machine learning, and artificial intelligence.
- Post disaster research, emergency research, and pandemic research.
- Disability research
- Knowledge generation activities (that may not be research)

What we are doing

- NEAC and the HQSC are holding a working day on audit and related activities (11 April)
- NEAC are working with the HRC Ethics Committee to ensure a consistent national ethics approach
- NEAC has convened a number of working groups to develop guidance on AI, gene editing, disability.

Next steps:

- NEAC are meeting on 30 April to review the next draft
- Aim is to launch the Standards late July with a month lead in period before they are active

Operationalisation

Ministry of Health is currently

- Exploring **training** options for researchers and ethics committee members – including a roadshow following publication of the new Standards and online training modules
- Updating all HDEC templates in line with new guidance
- Exploring IT options for updating infrastructure to support ethics committees, secretariat and researchers. This would replace Online Forms – and new application processes.

- Planning, reviewing and organising updating of:
  - HDEC Standard Operating Procedures
  - Terms of Reference
  - Templates, guides
  - Application forms
  - Scope of review

He waka eke noa

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