Privacy on Purpose

Privacy Week 2025
12 - 16 May

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Privacy Commissioner
Te Mana Mātāpono Matatapu

Waipapa Taumata Rau
University of Auckland

Navigating the Health Information Privacy Code 2020 in the Context of Research Ethics Applications

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12 May 2025

Aim of Webinar

This webinar explores and demystifies the role of research ethics committees and their relationship to access to data under the Health Information Privacy Code 2020.

The interaction between research ethics committees and obligations under the Health Information Privacy Code 2020 will be explained to help researchers navigate their dual responsibilities that span ethical and legal obligations.

This webinar will highlight, through the use of some real-world examples, the red flags and pitfalls applicants make in their research ethics submissions.

The webinar will support and uplift understanding of the ethics committee process and show respect for patient data in keeping with ethical obligations

“Information has power. In the case of an individual, their personal information is their whakapapa – past and present. It tells a story about where they have come from and where they are going. It is their story; it is their information to give and to share” – Inquiry Leads Pania Gray and Michael Heron KC


Te Kawa Mataaho
Public Service Commission

Inquiry into how government agencies protected personal information provided for the 2023 Census and COVID 19 vaccination purposes

On behalf of Te Kawa Mataaho | Public Service Commission

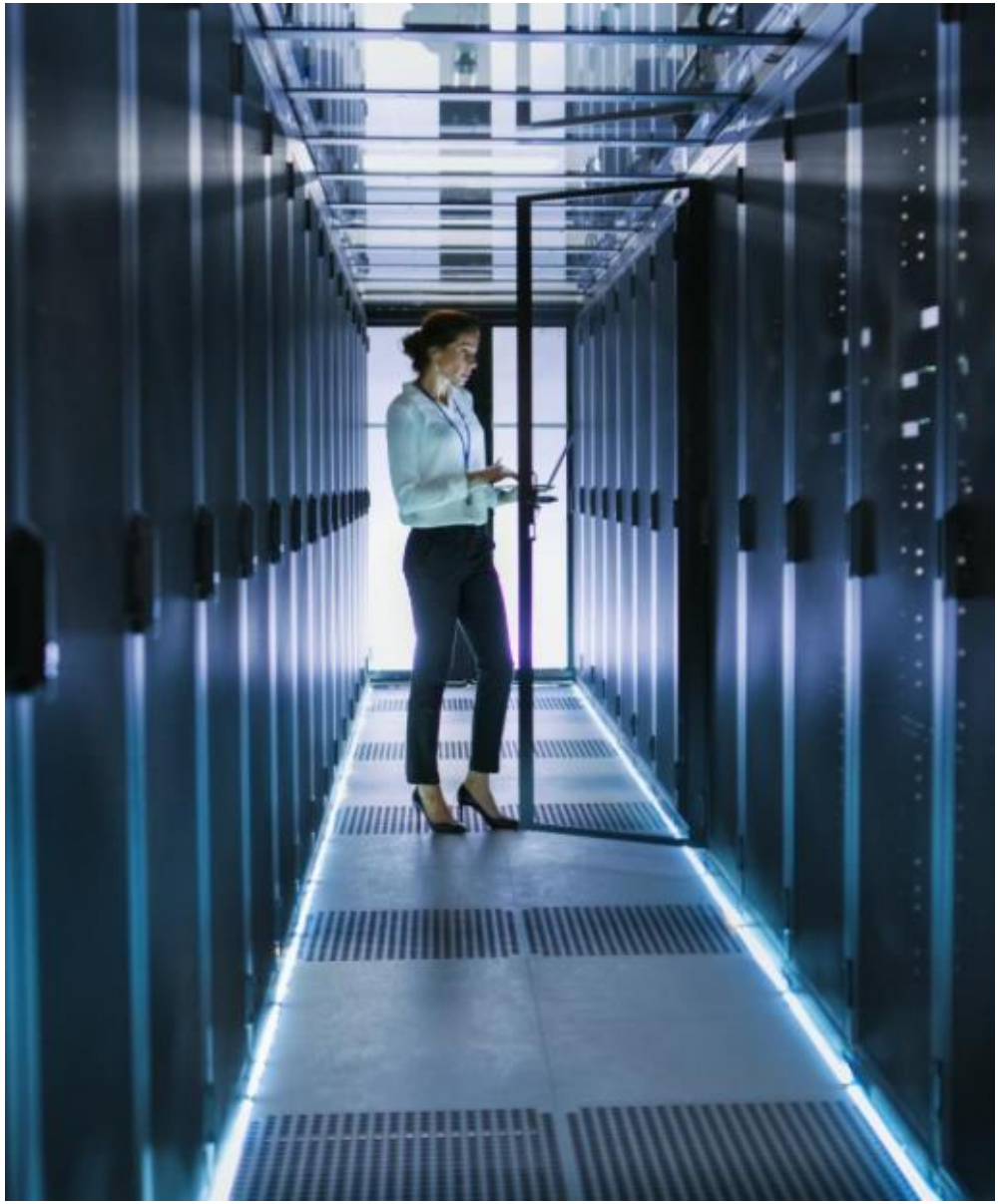
INQUIRY LEADS

Pania Gray and Michael Heron KC

5 DECEMBER 2024

Why discuss this now?

- Shift in research focus away from clinician / practitioner dealing with a finite group of patients or patient files to studies that use large datasets made up of existing health data
- Rise in computer power and increased focus on large datasets | big data analytics to solve issues at the intersection of health, wellbeing, and social issues
- Large number of databanks and ‘unofficial’ collections of data gathered previously with informal data sharing arrangements where there is little or no data governance structure (note many from persons with dual roles - clinician / researcher)
- Application of Māori Research Ethics principles such as Te Ara Tika principles and consideration of indigenous collective views of the right to privacy
- Risk of re identification amplified by merging multiple datasets and power of new techniques that make most data potentially identifiable



Meet annalise.ai

Harrison.ai and I-MED Radiology, the third largest private network of radiology clinics in the world, partnered in 2020 to create comprehensive radiology AI solutions. The first solution, Annalise Enterprise CXR is one of the world's most comprehensive AI clinical decision-support solutions for chest X-rays and can identify up to 124 findings. Annalise Enterprise CXR was developed and commercialised within 18 months and was followed by the release of another cutting edge comprehensive decision-support AI solution for non-contrast head CT images. Annalise.ai solutions are already available to 50% of radiologists in Australia and clinics in APAC, Europe, UK, Middle-East and the US.

Our radiology solution annalise.ai

FIND OUT MORE

CAREERS

Real world example – use of radiology files to build AI platform

Effects of a comprehensive brain computed tomography deep learning model on radiologist detection accuracy, European Radiology (2024) 34:810–822

Health Information Privacy Code, Research Ethics Committees and the “Research Exception”*

Research Ethics Committees are mentioned in Health Information Privacy Code in four main areas:

- Rule 2 – Source of Health Information
- Rule 10 – Limits on Use of Health Information
- Rule 11 – Limits on Disclosure of Health Information
- Schedule 3 - Secondary use of Newborn Babies’ Blood Samples

*Research exception discussed in Professor Peter Skegg, Faculty of Law, University of Otago. Human Rights Law and Practice, March 1996 (1(4) p 196- 210).

Ethics Committees – Brief oversight

ethics committee means—

(a) the Ethics Committee of the Health Research Council of New Zealand or an **ethics committee approved by that committee**; or

(b) the National Advisory Committee on Health and Disability Support Services Ethics; or

(c) an ethics committee required to operate in accordance with the currently applicable Operational Standard for Ethics Committees promulgated by the Ministry of Health; or

(d) an ethics committee established by, or pursuant to, any enactment

hrc nz
Health Research Council of New Zealand
Te Kaunihera Rangahau Hauora o Aotearoa

Membership – importance of lay members

Research Ethics
Volume 11, Issue 2, June 2015, Pages 82-97

https://doi.org/10.1177/1747016115581723

Article

Lay members of New Zealand research ethics committees: Who and what do they represent?

Helen Gremillion[1], Martin Tolich[2], and Ralph Bathurst[3]

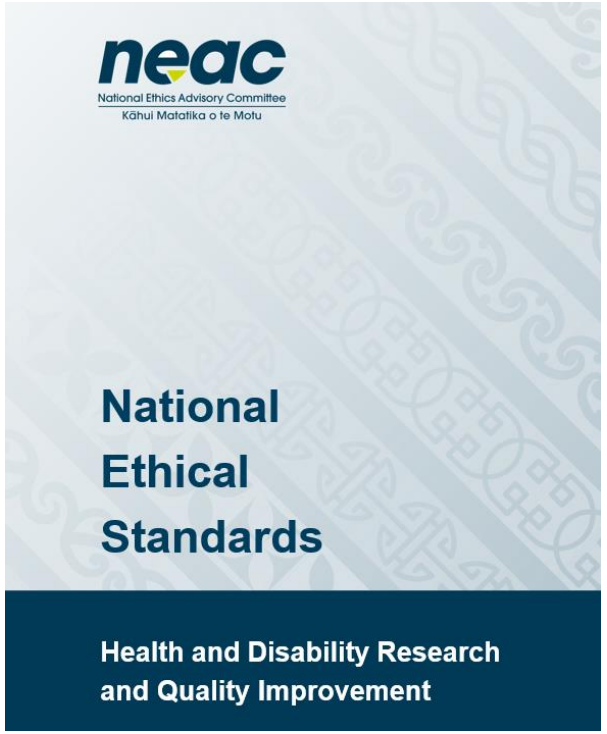
Abstract

Since the 1988 Cartwright Inquiry, lay members of ethics committees have been tasked with ensuring that ordinary New Zealanders are not forgotten in ethical deliberations. Unlike Institutional Review Boards (IRBs, or ethics committees) in North America, where lay members constitute a fraction of ethics committee membership, 50% of most New Zealand ethics committees are comprised of lay members. Lay roles are usually defined in very broad terms, which can vary considerably from committee to committee. This research queries who lay representatives are, what they do, and what if anything they represent. Our findings are based on data collection with 12 participants: eight semi-structured interviews with lay members from diverse types of ethics committees who described their roles, and commentary from four ethics committee chairs, three of these lay members who commented on this article's final draft. Findings indicate that the role of New Zealand lay persons – although distinctively valued – is otherwise similar to the documented role of lay persons within North American ethics committees. Lay members see their role as primarily protecting the research participant and at times offering a corrective to non-lay members' views and the interests of their institutions. However, in spite of their numbers, most lay members do not see themselves as representing any particular constituent groups or institutionally unaffiliated areas of concern. On tertiary education committees especially, there is a good deal of ambiguity in the lay role.

WORLD MEDICAL ASSOCIATION

DECLARATION OF HELSINKI

Medical Research Involving Human Participants



Ethical Standards

Source of health information – Rule 2

Role of Ethics Committee

(1) If a health agency collects health information, the information must be collected from the individual concerned.

(2) It is not necessary for a health agency to comply with subrule (1) if the agency believes, on reasonable grounds,—

[…]

(g) That the information

(i) will not be used in a form in which the individual concerned is identified; or

(ii) will be used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or

(iii) will be used for research purposes (for which approval by an ethics committee, if required, has been given) and will not be published in a form that could reasonably be expected to identify the individual concerned;

Limits on Use of Information – Rule 10

Role of Ethics Committee

(1) A health agency that holds health information that was obtained in connection with one purpose **may not use the information for any other purpose unless** the health agency believes on reasonable grounds

e) that the information—

(i) is to be used in a form in which the individual concerned is not identified; or

(ii) is to be used for statistical purposes and will not be published in a form that could reasonably be expected to identify the individual concerned; or

(iii) is to be used for **research purposes** (for which approval by an **ethics committee**, if required, has been given) and will not be published in a form that could reasonably be expected to **identify** the individual concerned

Limits on Disclosure of Information – Rule 11

Role of Ethics Committee

(1) A health agency that holds health information **must not disclose the information unless** the agency believes, on reasonable grounds,—

(b) that the disclosure is authorised by—

(i) the individual concerned; or

(ii) the individual's representative where the individual is dead or is unable to give their authority under this rule; or

(2) Compliance with subrule (1)(b) is **not necessary if the health agency believes on reasonable grounds**, that it is either not desirable or not practicable to obtain authorisation from the individual concerned **and**—

(iii) is to be used for **research purposes** (for which approval by an **ethics committee**, if required, has been given) and will not be published in a form that could reasonably be expected to **identify** the individual concerned; -

Example of “two step” approach in Rule 11(2)(c):

STEP ONE: Health agency

Rule 11(2)

Compliance with subrule (1)(b) is not necessary if the health agency believes **on reasonable grounds**, that it is either

- not desirable or
- not practicable

to obtain authorisation from the individual concerned **and**—

STEP TWO: Ethics Committee

Rule 11(2)(c)-

(c) that the information—

(iii) is to be used for **research purposes** (for which approval by an ethics committee, if required, has been given) and will not be published in a form that could reasonably be expected to identify the individual concerned

The growing problem of re-identification

"In numerous studies, deep learning algorithms have proven their potential for the analysis of histopathology images, for example, for revealing the subtypes of tumors or the primary origin of metastases. These models require large datasets for training, which must be anonymized to prevent possible patient identity leaks. This study demonstrates that even **relatively simple deep learning algorithms can re-identify patients in large histopathology datasets with substantial accuracy.** In addition, we compared a comprehensive set of state-of the-art whole slide image classifiers and feature extractors for the given task."

Re-identification from histopathology images, Jonathan Ganz et al Medical Image Analysis Vol 99, Jan 2025

NEAC Standards (2019)- Guidance on ‘Identifiable’

Identifiable data

Data from which it can reasonably be assumed that it is possible to identify a specific individual involved in the study

Direct identifiers

- NHI
- Name
- Street address
- Phone number
- Online identity (e.g., email, twitter name)
- Identification numbers (e.g., community services card, driver's licence).

Indirect identifiers

- Date of birth
- Identification of relatives
- Identification of employers
- Clinical notes
- Any other direct or indirect identifiers that carry significant risk of re-identification.

NEAC: There are two levels of non-identifiable data: de-identified data and anonymised data

De-identified data

- The fields listed under the definition of identifiable data are excluded, and
- Fields that might be used for deliberate re-identification are included, such as:
  - encrypted NHI or study codes
  - year of birth or age in years at a given date
  - event dates
  - gender
  - ethnicity (Level 2 as defined by Statistics New Zealand)
  - mesh block or suburb
  - deprivation index

Anonymised data

A minimal operational standard of anonymity should:

- Exclude fields listed under the definition of identifiable or de-identified data, and
- Obfuscate data to minimise re-identification risk, including but not limited to the following measures:
  - disclosure of the bare minimum data set for purpose
  - use of 5–10-year bands rather than dates
  - aggregation of ethnicity data (level 1 as defined by Statistics New Zealand)
  - blurring of geographic data (by area unit or city)
  - exclusion of low-frequency characteristics useful for re-identification (e.g., rare medical conditions)
  - strong consideration of more technical assessments or approaches such as k-anonymity ≥5, federated learning, differential privacy.

Research purposes c.f. statistical purposes-

Rule 2, Rule 10, Rule 11 -
- All contain exception for research purposes with approval by an **ethics committee**

Note: Identifiable data can be used for '**statistical purposes**' *without the need for ethics committee approval*

*Proviso: I*t "will not be published in a form that could reasonably be expected to identify the individual concerned"

Rule 2(g) (ii), Rule 10(e)(ii), Rule 11 (c) (ii)

Eligibility Screening – access to patient files – NEAC Guidelines

Rule 7.5.a

Researchers may review clinical notes and previously completed standard-of-care diagnostic tests prior to obtaining consent **for the purposes of eligibility screening** (eg, a diagnostic biopsy or CT scan in the case of lymphoma).

What does ethics committee ‘if required’ mean -

Publication does not mean an activity is classified as research

Publication does not make it a more than minimal risk activity

Publication does not alone trigger specific requirement for ethics committee review

National Ethics Advisory Committee. 2019. *National Ethical Standards for Health and Disability Research and Quality Improvemen*t. Wellington: Ministry of Health.

Quality improvement or research ?

Use available resources and if not sure ask for help

Table 1.2 – Differentiating research from quality improvement

Human participant research	Quality improvement activities
•	• Activities which aim to improve healthcare by assessing current situation and systematically implementing/testing evidence -based knowledge within a local organisation.
Goal **Quantitative research** • Acceptance or rejection of a hypothesis in relation to treatment, cause, risk or diagnosis of a health problem. Small differences may represent a significant finding. **Qualitative research** • Description and interpretation of something in its natural setting. May address how treatments and relationships are experienced.	• Ensure healthcare delivered by organisations are effective, safe, and equitable through the applications of improvement science methodology.
Setting • May be conducted within a healthcare setting or primary research setting.	• May be conducted within a health and care or community setting
Methods **Quantitative research** • Emphasis on prespecified aims, clearly protocolised methods, high precision measures, careful bias control, sample size calculations and statistical analysis. • May involve random allocation and blinding to intervention. • Attempts to remove/minimise contextual influences.	• Uses established, structured quality improvement methodologies to evaluate baseline performance, implement change and retest for sustained improvement. • Approaches include diagnosing and understanding the issue, followed by testing an intervention (usually a known intervention) to ascertain if it results in an improvement in the local context prior to full implementation. Small samples are often adequate.

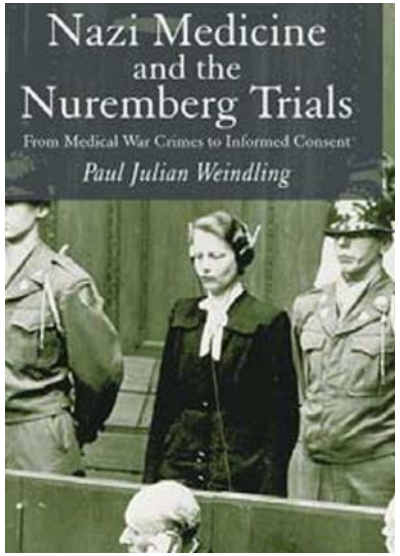
[14] This is consistent with the guidance provided in the International Committee of Medical Journal Editors' *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* (2018, section 2.A).

Demystifying the Ethics Ecosystem in Aotearoa –

- Examining how ethics decisions are made

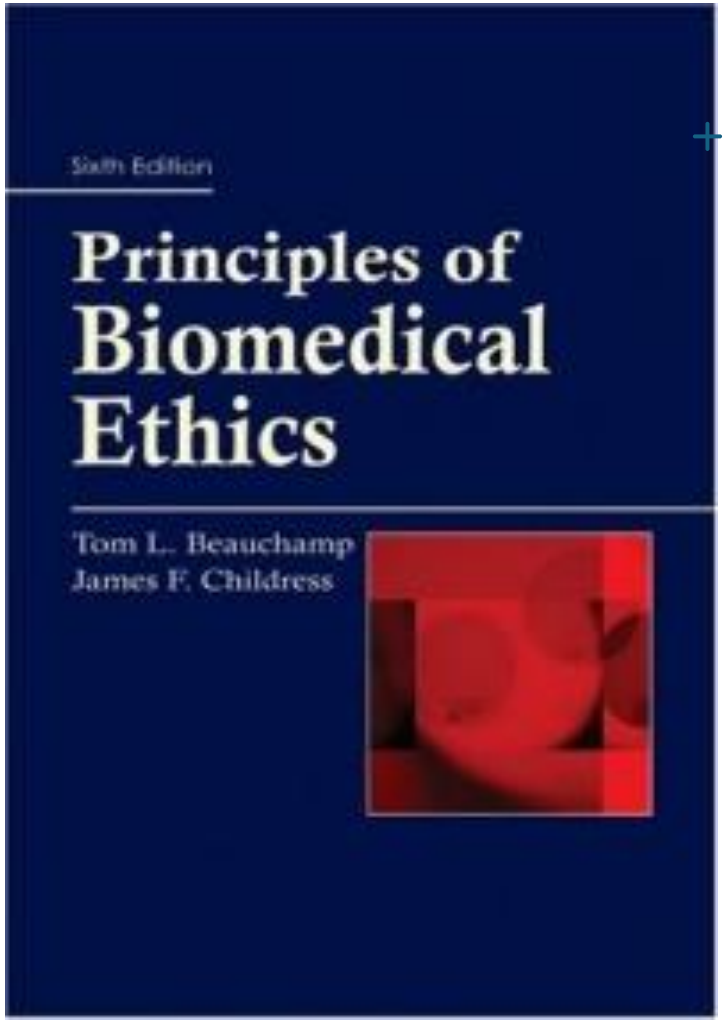
Why did research ethics develop?

- There is a long history of abuse of participants in research trials
  - From 1932- 1972 experiments were conducted by the U.S. Department of Health on 400 African American men without their consent (Tuskegee Syphilis Study)
  - In Nazi Germany brutal experiments were conducted by Nazi scientists on concentration camp prisoners leading to war crime prosecutions called the “Nuremberg Trails” – from which we get the Nuremberg code
  - In New Zealand, Doctor Herbert Green conducted experiments at National Woman's Hospital on women with cervical cancer without their consent, resulting in patient deaths from delayed treatment



Principles of Research Ethics

Autonomy – Respect for persons	• Respect for persons, capacity for self-determination (informed and voluntary consent)
Beneficence	• Acting in the public good and promoting the good of other people (assessment of risks and benefits)
Non-maleficence	• Consider the harm that the research project might cause (minimising harm)
Justice	• Treating others equitably and distributing burdens and benefits fairly (selection of participants)



Principles Unique to Aotearoa

Te Ara Tika Principles incorporated into the National Ethics Advisory Committee Guidelines in 2019

Whakapapa Relationships – trust, respect, integrity between researchers and participants

Mana Upholds mana of each participant. Each individual has the right to determine their own destiny upon their own authority

Tika What is right and what is good for every situation

Manaakitanga Caring for others, nurturing relationships being careful in the way we treat each other

This paper has identified a number of privacy issues for Māori arising from the status quo. A key concern is that the Privacy Act 2020 does not explicitly provide for the protection of privacy from te ao Māori perspectives. More specifically, it:

- has an exclusive focus on personal information and personal privacy, thus excluding group/collective information and privacy
- does not explicitly recognise tikanga Māori or Māori concepts of privacy, and
- does not have a Tiriti clause.

Part 4: FUTURE DIRECTIONS

Privacy is both a fundamental human right and a gateway right that reinforces other rights such as the right to non-discrimination and freedom of expression. Big data technologies and practices pose challenges and risks to individual and collective privacy, particularly for marginalised and over-surveilled groups. While data privacy research, standards and laws focus on the protection of individual data, personal data protection is part of a much wider set of data privacy considerations and Indigenous data rights.

Māori Data Sovereignty and Privacy

Tikanga in Technology Discussion Paper

March 2023

Te Ngira
Institute for
Population Research
THE UNIVERSITY OF WAIKATO

National Ethics Advisory Committee standards 2019 p99

Table 8.2 – Potential harms for research participants

Category	Potential harms
Physical harm	• Injury, illness, pain, permanent disability, death
Psychological harm	• Feelings of worthlessness, distress, guilt, anger or fear (e.g. through disclosing sensitive or embarrassing information or learning about a genetic possibility of developing a disease)
Disrespect or harm to dignity	• Devaluation of personal worth, including being humiliated, manipulated or in other ways treated disrespectfully or unjustly
Social or cultural harm	• Damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; social stigmatisation; findings of a previously unknown paternity status; loss of trust; harm to wairua or mana
Privacy harm	• Identification or disclosure of private information
Economic harm	• Direct or indirect cost, I.e. cost for treatment for physical or mental harm caused by participation in the trial, particularly where the trial is not covered by ACC, and loss of earning potential from physical or mental harm caused by participation in the trial.
Legal harm	• Discovery of criminal conduct or prosecution for it
Data harms	• Surveillance, inferential harm or social harm such as stigmatisation

Waiver of consent – examining the NEAC threshold

- ❑ Gaining consent to use previously collected identifiable data should always be the **default starting point**

- ❑ If you ask for a waiver of consent you must justify to the ethics committee that you meet the threshold in Rule 7.47 of the NEAC Standards

The Ethics Committee will consider the following:

- ✓ Potential benefits (to individuals or wider public)
- ✓ Nature and degree of likely harms (to individuals and / or the public)
- ✓ The scientific, practical, or ethical reasons why consent cannot be obtained
- ✓ A review of what data governance plans are in place
- ✓ To what extend consultation has taken place by the research team with cultural or other groups and whether these groups support the secondary use
- ✓ If there is any known reasons why the participant (or group) **would not support** the data being used in this way

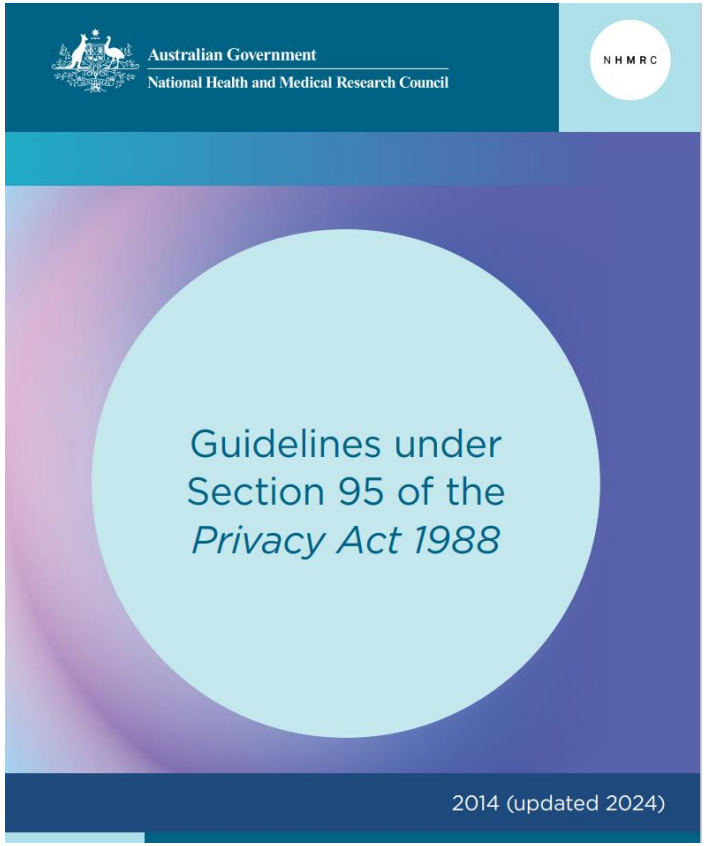
Tips and Red Flags to Avoid

- Reach out to ethics committee support staff in your organisation early to assess the need for ethics approval
- Facts matter! Small distinctions can tip a project from audit, to quality improvement and on to research
- Carefully consider if your project is going to use identifiable health information
- Consider the potential for data to be identifiable through improvements in computational techniques, use of AI, and merging of datasets
- Consider the statistical purposes exception in Health Information Privacy Code
- Consider the research exception and the need for approval by an ethics committee
- If applying to an ethics committee make sure you can identify what datasets you want to use and can provide organisational permissions
- If asking for a 'waiver of consent' use the list in Rule 7.47 of the NEAC Standards to guide your answers
- Consider any conflicts of interest or dual roles you may have, or members of your team may have, and state these for the committee

- Conflicts of interest not disclosed or mitigated
- Commercialism not disclosed
- Lack of data management plan to show how data will be transferred from an organisation(s) to the research team and at what stage the data will be deidentified
- Researcher with ‘dual roles’ who does not separate out clinical role from research project
- Applications that ask for wide range of data without justifying this in terms of research design
- Applications that seek to create an AI platform without being able to answer questions around AI – new pre-screening questions are being introduced
- Lack of engagement with Te Ara Tika principles and failure to address issues of Māori Data Sovereignty

Red Flags to Avoid

Areas of further clarification



- Weighing the public interest in research v's individual right to privacy
- Further consideration of what the term "not be published in a form that could reasonably be expected to identify the individual concerned" means
- How to weigh issues of justice when health data from public health agencies is accessed for commercial gain and benefits may not be evenly distributed
- If ethics committees are asked for a waiver of consent, further understanding of how this balancing is arrived at, and if there is consistency across all ethics committees
- Clarification for researchers on the division between 'statistical purposes' and the 'research exception' in the Health Information Privacy Code

Thank you.

Questions?

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