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The Role of Ethics Committees under the Health Information Privacy Code 2020

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Aim of presentation

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

It identifies the ‘two step’ process embedded in the Health Information Privacy Code 2020 with reference to rules 2, 10, and 11.

I discuss a real-world example to highlight the complexity of decision making, the process for deidentification, and identify some ‘red flags’ for ethics committees when assessing ethics applications

Final observations to 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?

Change in research design	Data from multiple sources	Complexity in deidentification determination |Māori Data Sovereignty
Shift in research focus away from clinician / practitioner dealing with a finite group of patients or patient files to studies using large datasets made up of existing health data	Increased interest in commercialisation of research results or end product, as we see increase in public / private partnerships – eg mHealth Apps, medical devices, AI platforms	Application of Māori Research Ethics principles such as Te Ara Tika principles and consideration of indigenous collective views of the right to privacy
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)	Risk of re identification amplified by merging multiple datasets and power of new techniques that make most data potentially identifiable

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

Meet annalise.ai

- The founders launched Harrison.ai in 2018 and partnered with I-MED to create comprehensive AI supported radiology platform
- The first AI offering from this partnership was Annalise Enterprise
- Developed and commercialized within 18 months
- Available to 50% of radiologists in Australia and clinics in Europe, UK, Middle-East and the US.
- A study published in European Radiology set out the results of the trials
    - A subset of the data from (168,326 unique patients), was used for training.
    - No informed consent from participants whose data was used was provided but multiple review boards at different levels provided waiver of consent.

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).

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**—

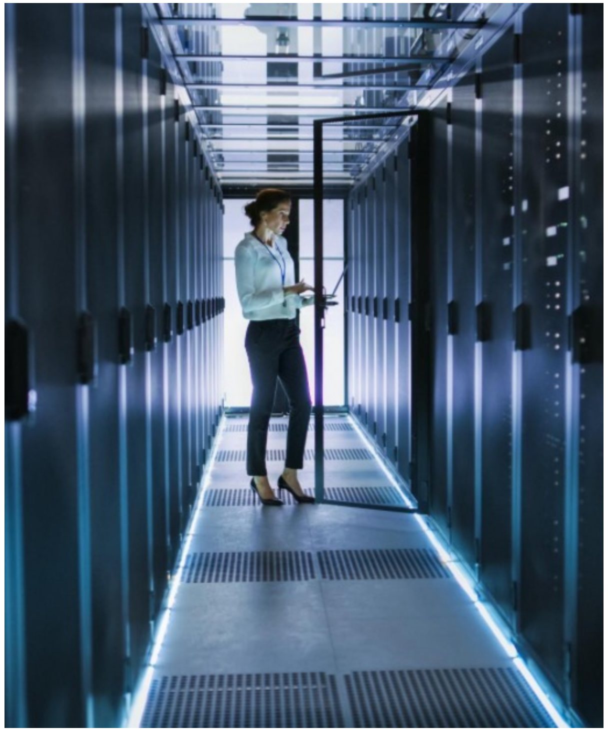
STEP TWO: Ethics Committee

Rule 11(2)(c)-

(c) that the information—

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

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)

Two issues for ethics committees: deidentification and reidentification

Deidentification:

See NEAC guidance on “identifiable” data

Direct identifiers (NHI, name, address, phone number etc)

Indirect identifiers (Date of birth, identification of relatives, employers, clinical notes, other)

Two levels of <u>non-identifiable data</u>:

- Deidentified
- Anonymised

Reidentification

“For the purposes of these Standards, data should be stored, utilised, and disposed of on the assumption that it is potentially re-identifiable.” NEAC (12.3)

Australian Government
Office of the Australian Information Commissioner

> “Whether a person is ‘reasonably identifiable’ is an **objective test** that has practical regard to the context in which the issue arises. Even though it may be technically possible to identify an individual from information, if doing so is so impractical that there is almost no likelihood of it occurring, the information would not generally be regarded as ‘personal information’. An individual may not be reasonably identifiable if the steps required to do so are excessively time-consuming or costly in all the circumstances.”

Report into preliminary inquiries of I-MED
published 31 July 2025
Report into preliminary inquiries of I-MED | OAIC

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).

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

Areas of further clarification

- Weighing the public interest in research v's individual right to privacy
- Clarity on whether process of deidentification is 'use" Rule 10
- 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
- Clearer boundaries between 'two step' process of organisational approval and ethics committee approval (Rules2, 10, and 11)

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Any Questions?

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