The University of Melbourne acknowledges the Traditional Owners of the unceded land on which we work, learn and live: the Wurundjeri Woi-wurrung and Bunurong peoples (Burnley, Fishermans Bend, Parkville, Southbank and Werribee campuses), the Yorta Yorta Nation (Dookie and Shepparton campuses), and the Dja Dja Wurrung people (Creswick campus).

The University also acknowledges and is grateful to the Traditional Owners, Elders and Knowledge Holders of all Indigenous nations and clans who have been instrumental in our reconciliation journey.

We recognise the unique place held by Aboriginal and Torres Strait Islander peoples as the original owners and custodians of the lands and waterways across the Australian continent, with histories of continuous connection dating back more than 60,000 years. We also acknowledge their enduring cultural practices of caring for Country.

We pay respect to Elders past, present and future, and acknowledge the importance of Indigenous knowledge in the Academy. As a community of researchers, teachers, professional staff and students we are privileged to work and learn every day with Indigenous colleagues and partners.

Consent waiver: supporting or undermining trustworthy health data governance?

Mark J Taylor, PhD
Professor of Health Law and Regulation, Melbourne Law School

HREC National Conference 2024

10:35-10:55 (AEST)

Home › About us › News and updates ›

The view from the Confidentiality Advisory Group: outgoing chair blogs

Last updated on 26 Oct 2017

After five years as chair (and several more as a member before that), Dr Mark Taylor is stepping down from the Confidentiality Advisory Group.

As Dr Taylor leaves to take on a new role at Melbourne Law School in Australia, he describes how the group gave him a fresh insight into discussions of how the privacy of patients sits alongside the public interest.

The Confidentiality Advisory Group

CAG provides independent expert advice on the appropriate use of confidential patient information. The law recognises that there is important medical research and essential NHS activity beyond individual direct care that requires the use of identifiable patient and service user information, but where it is not always practical to obtain consent. CAG's role includes considering applications for access to confidential patient information, while protecting and promoting the interests of patients and the public. The group also a statutory role to advise NHS Digital on dissemination issues.

"I've always been academically interested in privacy, understanding the relationship between the state and private individuals, and looking at the question of the extent to which the state can legitimately interfere in the privacy of private individuals alongside its responsibilities to protect individual privacy.

"But patient information rights wasn't an area I'd thought to look into, until a colleague spotted an advert in the paper for people to join the Patient Information Advisory Group, and told me I should get involved. That group would go on to become the Ethics and Confidentiality Committee and ultimately CAG."

"My interest has always been in the idea of the public interest and its conceptual connection with an individual's privacy right. What I quickly

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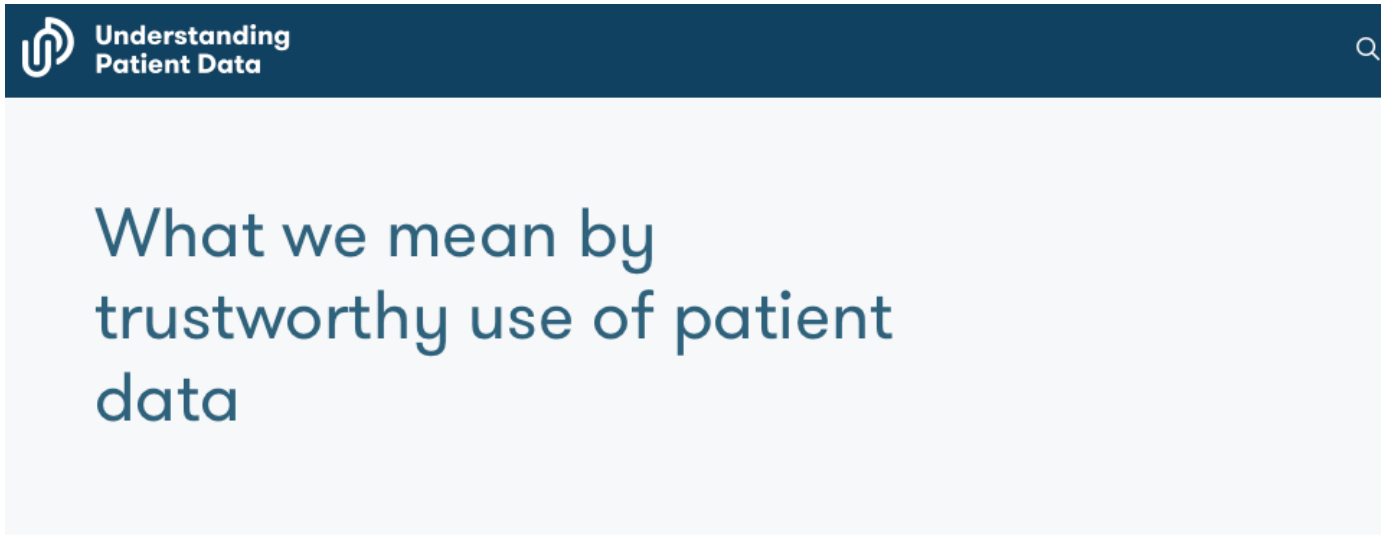
The Confidentiality Advisory Group (CAG) England and Wales

What is Trustworthy Governance?

THE UNIVERSITY OF MELBOURNE

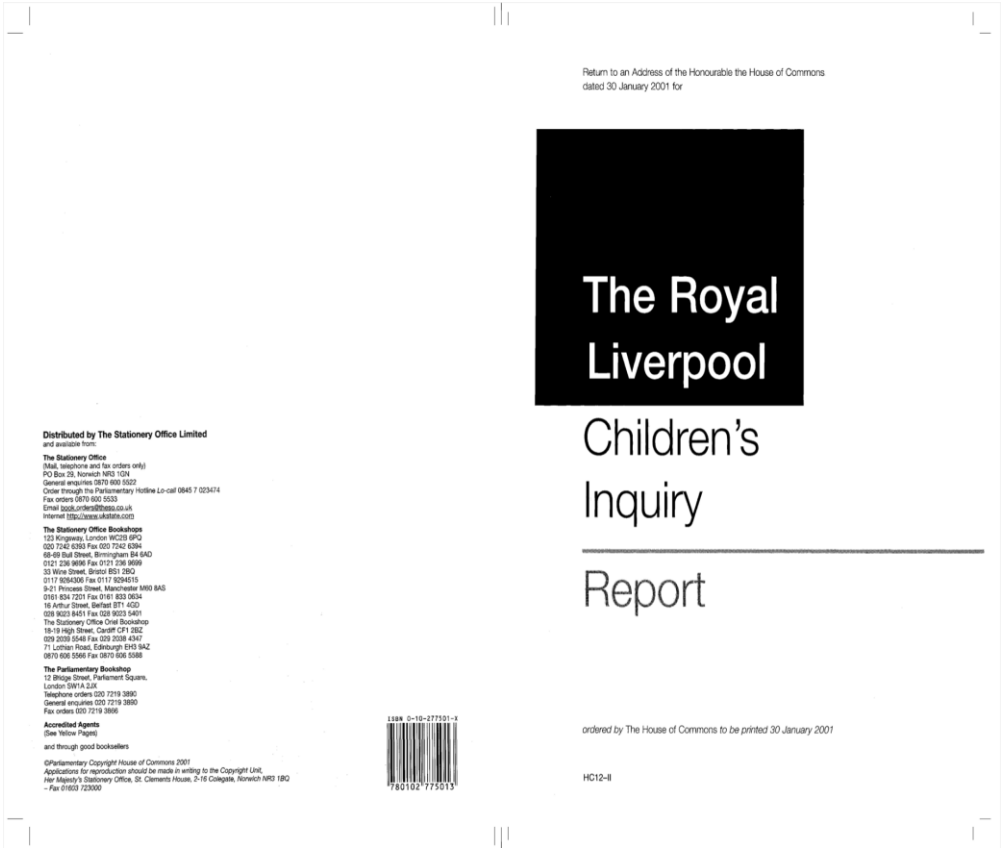
> We need to think much less about trust… and much more about being trustworthy, and how you give people adequate, useful and simple evidence that you're trustworthy.

Onora O'Neill, What we don't understand about trust, TEDx



1. Motivation
2. Competence
3. Transparency
4. Governance
5. Accountability
6. Public Participation

Redfern Report



Why was an inquiry into the use of children's organs launched?

Three children's hospitals had been harvesting hearts, lungs, brains and other organs from (170) dead babies without adequate parental consent.

“Birmingham and Liverpool hospitals had also given thymus glands, removed during heart surgery from live children, to a pharmaceutical company for research in return for financial donations.”

“Alder Hey hospital also stored 1,500 foetuses that were miscarried, stillborn or aborted without consent. “

https://www.theguardian.com/society/alderhey/story/0,,450736,00.html

How does CAG seek to earn public trust?

What does CAG do?

Thematic analysis was conducted on a corpus of Section 251 feedback reports from the NHS Health Research Authority Confidentiality Advisory Group.

Four themes emerged from the feedback. These were:

(a) Patient and Public Involvement,

(b) Establishing Rationale,

(c) Data maintenance and contingency, and the need to gain

(d) Further Permissions from external authorities prior to full approval.

International Journal of Population Data Science (2020) 5:1:34

International Journal of Population Data Science

Journal Website: www.ijpds.org

Guidance for researchers wanting to link NHS data using non-consent approaches: a thematic analysis of feedback from the Health Research Authority Confidentiality Advisory Group

Lauren Cross[1*], Lauren Emma Carson[1], Amelia Jewell[2], Margaret Heslin[3], David Osborn[4], Johnny Downs[1], and Robert Stewart[1]

Submission History
Submitted: 08/06/2020
Accepted: 30/07/2020
Published: 02/10/2020

[1]Department of Psychological Medicine, King's College London, Strand, London WC2R 2LS, UK
[2]South London and Maudsley NHS Foundation Trust, National Institute for Health Research (NIHR), Maudsley Biomedical Research Centre, Denmark Hill, London, SE5 8AF, UK
[3]Department of Health Services & Population Research, King's College London, Strand, London WC2R 2LS, UK
[4]Division of Psychiatry, University College London, Maple House, 149 Tottenham Court Rd, Bloomsbury, London W1T 7BN, UK

Abstract

Introduction
The use of linked data and non-consent methodologies is a rapidly growing area of health research due to the increasing detail, availability and scope of routinely collected electronic health records data. However, gaining the necessary legal and governance approvals to undertake data linkage is a complex process in England.

Objectives
We reflect on our own experience of establishing lawful basis for data linkage through Section 251 approval, with the intention to build a knowledgebase of practical advice for future applicants.

Methods
Thematic analysis was conducted on a corpus of Section 251 feedback reports from the NHS Health Research Authority Confidentiality Advisory Group.

Results
Four themes emerged from the feedback. These were: (a) Patient and Public Involvement, (b) Establishing Rationale, (c) Data maintenance and contingency, and the need to gain (d) Further Permissions from external authorities prior to full approval.

Conclusions
Securing Section 251 approval poses ethical, practical and governance challenges. However, through a comprehensive, planned approach Section 251 approval is possible, enabling researchers to unlock the potential of linked data for the purposes of health research.

Keywords
data linkage; section 251; thematic analysis; non-consent approaches

What does CAG do?

The emphasis here was on an approach to PPI that was beyond tokenistic, forming an integral part of the research schedule and strategy.

In particular, there appeared to be two phases of the research cycle in which PPI is viewed as of importance.

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What does CAG do?

First, during the initial stages (prior to linkage) the CAG expected methodological consideration from service users:

“feedback from the planned activity would also need to be reported to understand the views of this cohort in relation to the proposal”

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What does CAG do?

Second, the CAG required the development of information materials […] **informing patients and the public about how their data is being used**, and importantly the opportunity and **tools to o**bject (opt-out)”

Such information needs to be released with enough time ahead of the linkage to allow a “specific time period for meaningful opt-out”

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What does it mean to regulate in the public interest?

THE UNIVERSITY OF MELBOURNE

Regulatory principles underpinning legitimate (Public Interest) Decision making?

Public Interest, Health Research and Data Protection Law: Establishing a Legitimate Trade-Off between Individual Control and Research Access to Health Data

Author & abstract | Download | Related works & more | Corrections

Author

Listed:

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  (Melbourne Law School, University of Melbourne, Parkville VIC 3010, Australia)

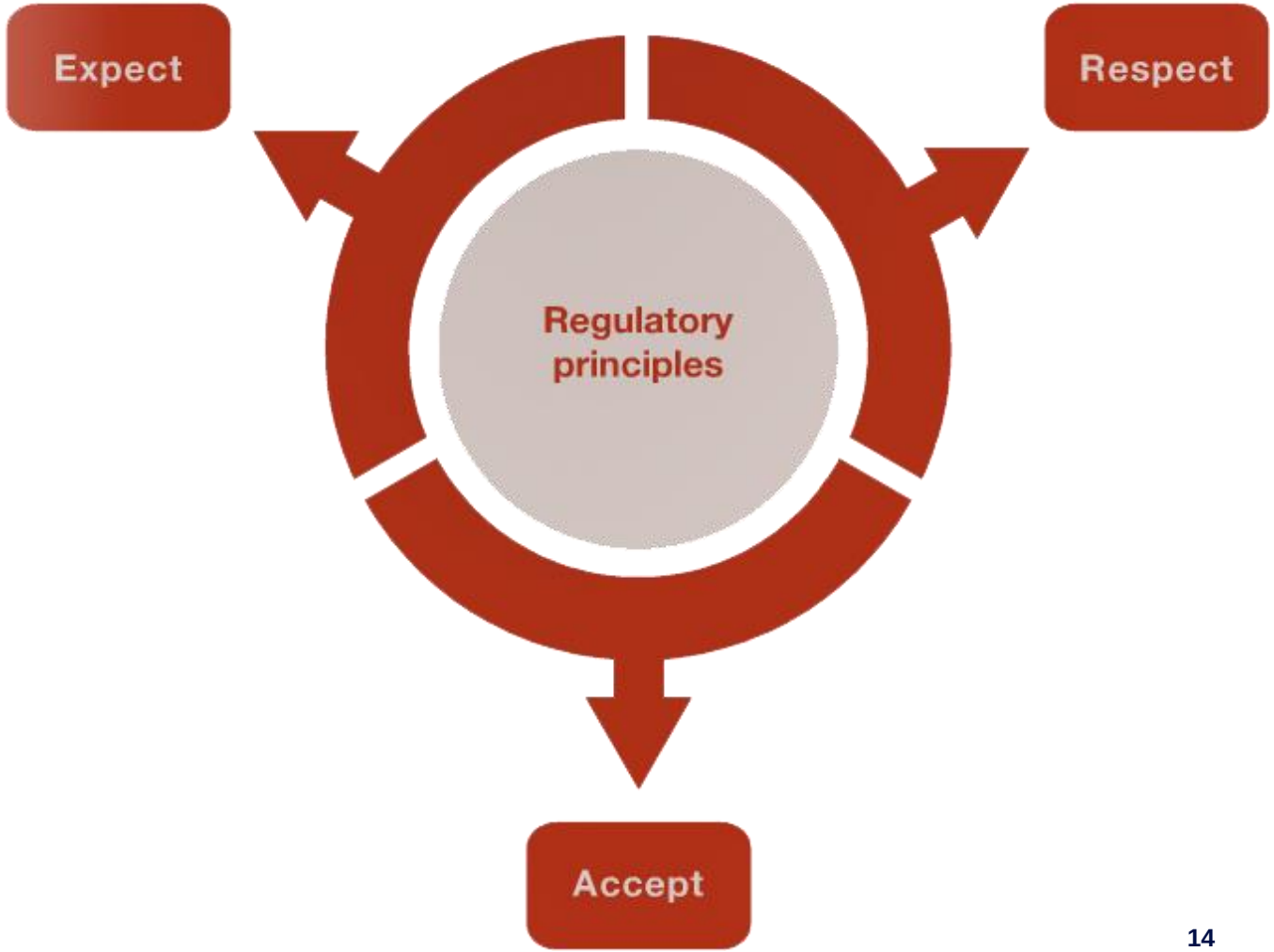
Registered:

Abstract

The United Kingdom's Data Protection Act 2018 introduces a new public interest test applicable to the research processing of personal health data. The need for interpretation and application of this new safeguard creates a further opportunity to craft a health data governance landscape deserving of public trust and confidence. At the minimum, to constitute a positive contribution, the new test must be capable of distinguishing between instances of health research that are in the public interest, from those that are not, in a meaningful, predictable and reproducible manner. In this article, we derive from the literature on theories of public interest a concept of public interest capable of supporting such a test. Its application can defend the position under data protection law that allows a legal route through to processing personal health data for research purposes that does not require individual consent. However, its adoption would also entail that the public interest test in the 2018 Act could only be met if all practicable steps are taken to maximise preservation of individual control over the use of personal health data for research purposes. This would require that consent is sought where practicable and objection respected in almost all circumstances. Importantly, we suggest that an advantage of relying upon this concept of the public interest, to ground the test introduced by the 2018 Act, is that it may work to promote the social legitimacy of data protection legislation and the research processing that it authorises without individual consent (and occasionally in the face of explicit objection).

Suggested Citation

Mark J. Taylor & Tess Whitton, 2020. "**Public Interest, Health Research and Data Protection Law: Establishing a Legitimate Trade-Off between Individual Control and Research Access to Health Data**," Laws, MDPI, vol. 9(1), pages 1-23, February.



Public Interest and Trustworthiness

"The decision-making process must be able to offer a **reasonable justification**, for the vulnerabilities implied by decisions on (non)interference with medical confidentiality, **to the people affected** by those decisions.

"If a reasonable justification cannot be offered, then the decision-making process is not trustworthy."

2

PUBLIC INTEREST AND TRUSTWORTHINESS

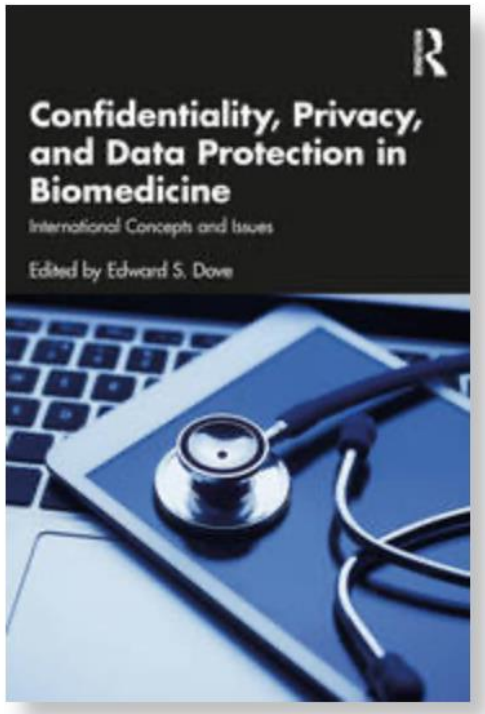
Connecting the concepts through reasonable justification for (non)interference with medical confidentiality

Mark Taylor

Introduction

In the trial of the Duchess of Kingston for bigamy, reported in 1776, the surgeon to the Duchess initially refused to answer questions about what he may, as surgeon to one or both, have heard of the Duchess' marriage to Lord Bristol. Lord Mansfield, cross-examining Mr Caesar Hawkins, conceded that "if a surgeon was voluntarily to reveal these secrets, to be sure he would be guilty of a breach of honour, and of great indiscretion".[1] However, he continued, "but, to give that information in a court of justice, which by the law of the land he is bound to do, will never be imputed to him as any indiscretion whatever".[2] The value and significance of medical confidentiality has long been recognized but the law has never recognized a health professional's duty to preserve confidentiality to be absolute.

The limits of confidentiality are no longer determined by questions of "professional honour" nor understanding what would be imputed by others to be an indiscretion. Now, more typically (though not exclusively),[3] the extent of the duty and its limits are characterized around the world by reference to the concept of the public interest. The concept of public interest has been employed as both a justification for upholding confidentiality and a justification for overriding it. I will argue here that there may be merit in reconnecting with the values expressed in 18th-century England: not to the idea of professional honour, but to the idea that there are normative expectations held reasonably by patients and publics more generally of health professionals (and others such as academic researchers in whom they confide health information) that may help to enliven a modern understanding of the concept of public interest. An advantage of doing so is that it may (re)connect the



DOI: 10.4324/9781003394518-4

Summary

Earning public trust = consistent competence in:

- delivering **safe and secure** uses of data;
- respecting individual **choice and control**; and
- demonstrating **value and benefit** (individual and collective)

Provide reasonable justification for any consent waiver, meeting triple text of **expect, accept, respect**.

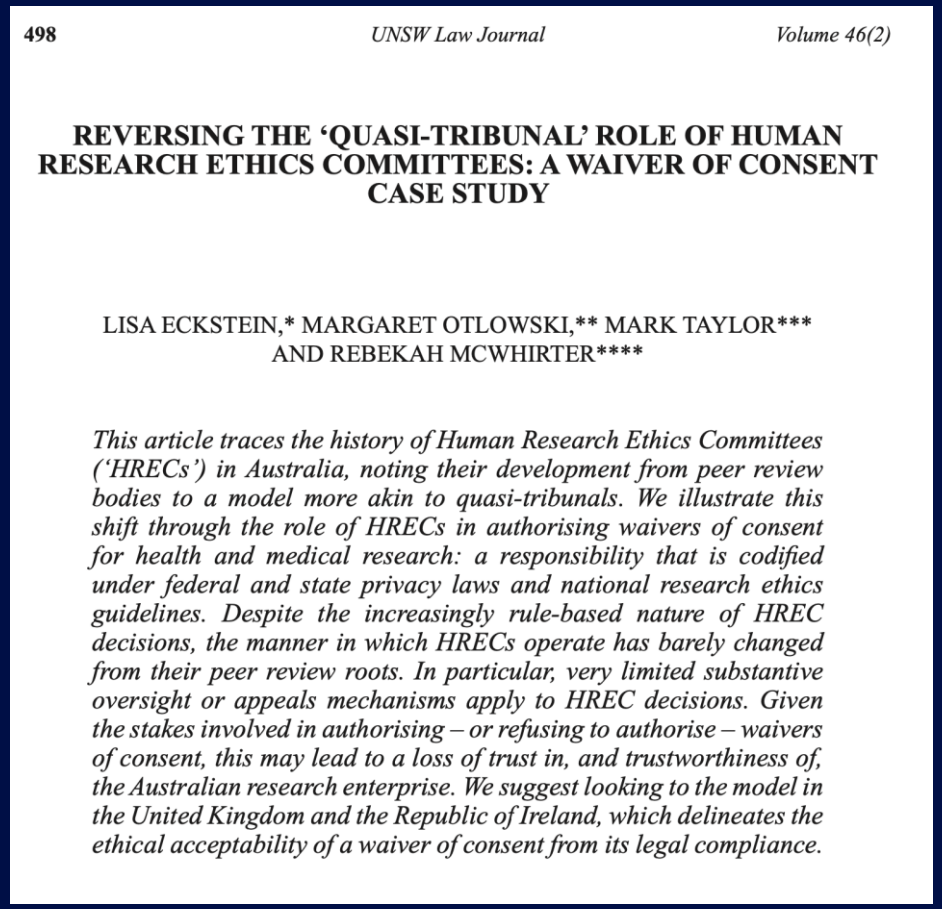
This means:

a. We do NOT rely exclusively upon consent or anonymisation. But we do promote necessary **transparency** *and* **enable opt out** in all but the most exceptional circumstances.

b. Minimally operate with a conception of fairness that permits only justified interference, justifying any consent waiver with reference to **values and interests that data subject holds** (avoid instrumentalization)

c. Provide **adequate**, **useful**, and **simple evidence** that we are doing this through meaningful **PPI**

Further reading for those interested



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REVERSING THE 'QUASI-TRIBUNAL' ROLE OF HUMAN RESEARCH ETHICS COMMITTEES: A WAIVER OF CONSENT CASE STUDY

LISA ECKSTEIN,* MARGARET OTLOWSKI,** MARK TAYLOR*** AND REBEKAH MCWHIRTER****

This article traces the history of Human Research Ethics Committees ('HRECs') in Australia, noting their development from peer review bodies to a model more akin to quasi-tribunals. We illustrate this shift through the role of HRECs in authorising waivers of consent for health and medical research: a responsibility that is codified under federal and state privacy laws and national research ethics guidelines. Despite the increasingly rule-based nature of HREC decisions, the manner in which HRECs operate has barely changed from their peer review roots. In particular, very limited substantive oversight or appeals mechanisms apply to HREC decisions. Given the stakes involved in authorising – or refusing to authorise – waivers of consent, this may lead to a loss of trust in, and trustworthiness of, the Australian research enterprise. We suggest looking to the model in the United Kingdom and the Republic of Ireland, which delineates the ethical acceptability of a waiver of consent from its legal compliance.

Lisa Eckstein, Margaret Otlowski, Mark Taylor and Rebekah McWhirter

'Reversing the 'Quasi-tribunal' Role of Human Research Ethics Committees: A Waiver of Consent Case Study

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Thank you

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