

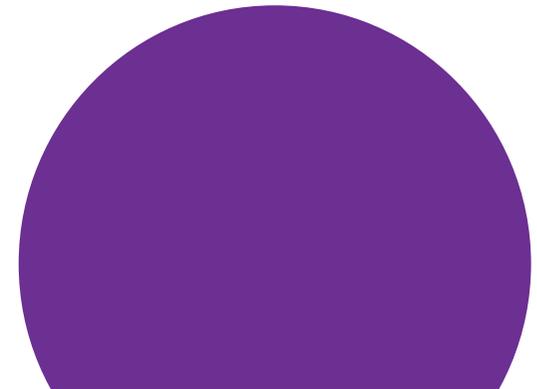
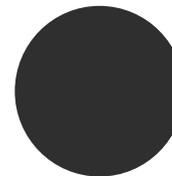


Australian  
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# Data Sharing for Secondary Research in Australia: results from a Shared Ethical Debate exercise

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# The challenge: Inconsistent and opaque HREC decisions

- Human Research Ethics Committee (HREC) decision-making is inherently subjective. There can be justifiable differences of opinion as to whether a research proposal meets ethical requirements.
- While institutions must have **complaint handling** processes, there is no requirement for an HREC **appeals** process.
- HREC decision making is not publicly available (cf NZ HDECs) and freedom of information/right to information requests have been applied inconsistently.

# The Shared Ethical Debate (ShED) Methodology

Trace and Kolstoe *BMC Medical Ethics* (2017) 18:65  
DOI 10.1186/s12910-017-0224-7

BMC Medical Ethics

RESEARCH ARTICLE

Open Access

## Measuring inconsistency in research ethics committee review



Samantha Trace and Simon Erik Kolstoe

- Real applications circulated to approx twenty committees.
- Participating RECs review at next meeting and return minutes.
- Basic content and/or thematic analysis.
- Results circulated to participating committees to inform them of their performance, and used to set training and policy agendas

“

Whilst a certain level of inconsistency might be expected within any process relying upon discourse ethics, the challenge is to measure inconsistency, understand why it occurs, and then determine what level is acceptable.

”





# What Can We Learn from a ShED in Australia?

## Quantification of the ethical review criteria which garnered attention

- Where we are focusing (and not focusing) our attention

## Quantification of the variation in decision-making

- Variation in outcome
- Variation in rationale

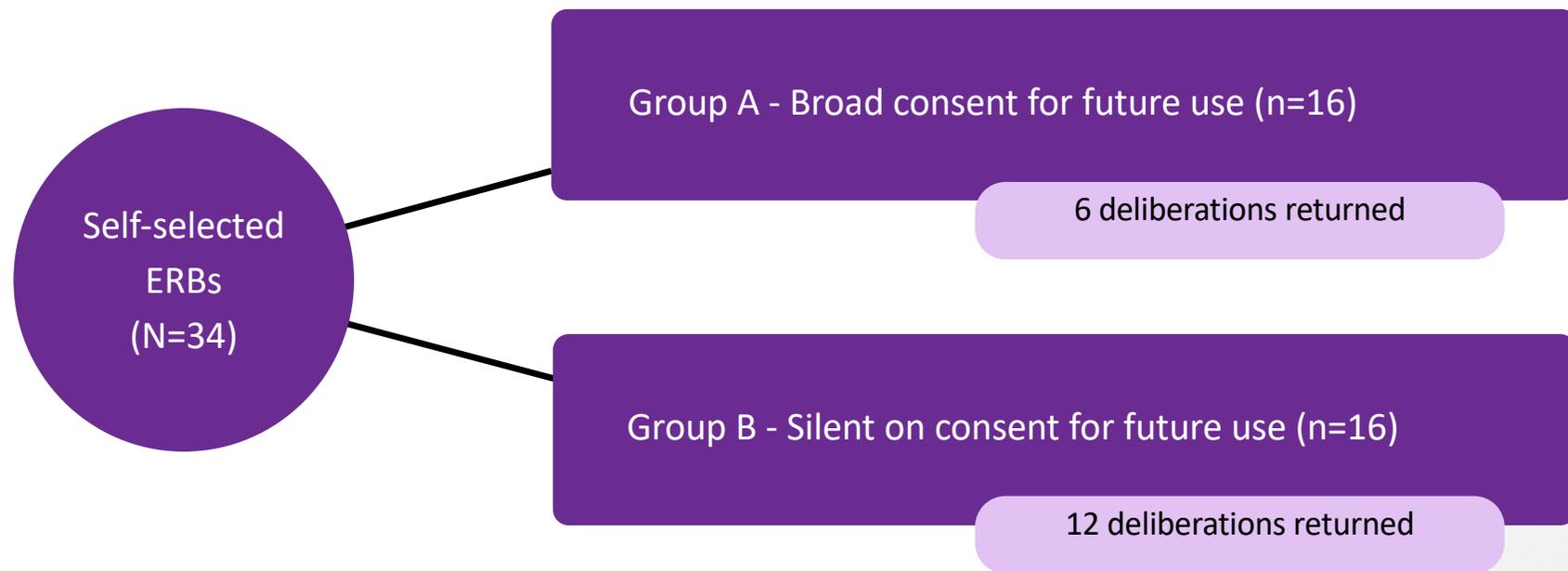
## Any indications of a lack of reasonableness in decision-making

- Operating outside remit
- Not objectively assessing the proposal against relevant laws or guidelines
- Not incorporating appropriate expertise

# ShED Australia

- **Scenario** (credit to Jonathan Williams and Kylie Hunter, NHMRC CTC)
  - Request for data to undertake a hypothetical meta-analysis to establish quality of life (QOL) of parents of very preterm infants in Australia.
  - Seeking participant-level data from a 2018 trial comparing oxygen levels to support very preterm infants. Included parental QOL survey at 6 and 12 months.
  - QOL data includes health outcomes, social and familial wellbeing, financial status and psychological wellbeing.
- Approved by the expedited review panel of the Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee (HREC)
- All HRECs registered with the NHMRC and with accessible contact information were invited to participate (n=188).
- Participating ERBs received a \$100 gift card honorarium in recognition of their contribution.

# Data collection



# Participating ERBs

ERB Characteristics		n (%) ERBs
<b>Location</b>	NSW	6 (33%)
	VIC	3 (17%)
	SA	3 (17%)
	QLD	2 (11%)
	WA	2 (11%)
	ACT/NT/TAS	2 (11%)
	<i>Total</i>	<i>18 (100%)</i>
<b>Institution type</b>	Health	9 (50%)
	Higher Education	5 (28%)
	Government	2 (11%)
	Private/NGO	2 (11%)
	<i>Total</i>	<i>18 (100%)</i>
<b>Participation in the National Mutual Acceptance (NMA) Scheme</b>	Yes	7 (39%)
	No	7 (39%)
	Not sure	1 (6%)
	Information not available*	3 (16%)
	<i>Total</i>	<i>18 (100%)</i>
<b>How often does your ERB assess applications involving the secondary use of data?</b>	Never	0 (0%)
	Every few meetings	6 (33%)
	Most meetings	3 (17%)
	Every meeting	6 (33%)
	Information not available*	3 (17%)
	<i>Total</i>	<i>18 (100%)</i>

# Results: A huge spread of reviews

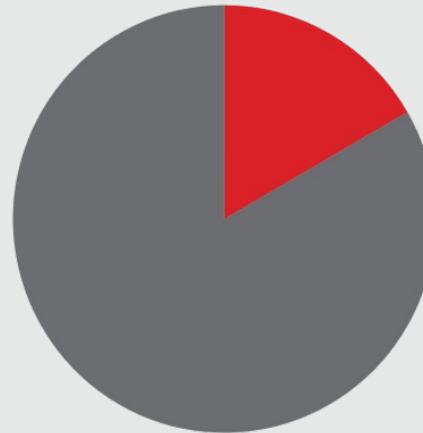
## Consent for 'related' research (n=6)

● Approve ● Reject  
● Request changes



## Silent on data sharing (n=12)

● Reject ● Request changes



# Disparate Views on the Ethics of Data Sharing

“The use of existing data reduces the need for new studies and burden to a population at a very stressful time in their life (having a very preterm infant). Therefore, the research has been designed to minimise the risks of harm or discomfort to participants (NS 1.7).”

“We don’t approve groups looking at data outside of department – data to people unrelated to original treatment”



# Was the Data 'Deidentified'?

"How will the data be de-identified? Only removing direct identifiers (names, addresses and contact information) may be insufficient to render the data non-identifiable."

"The Privacy Act does not apply as the data is deidentified"

"The collected data is so detailed as to personal information, demographics, birth details and medical information about hospital stay and other information about wellbeing of the family after the birth, financial status etc as to present a clear risk that the participant and their baby might be personally identifiable from the relatively small population of very preterm births in Australia."

# Is a Waiver of the Requirement for Consent Warranted?

"There are no valid reasons provided for a consent waiver."

"The waiver in this particular case seems well justified against the NS S2.3.10."

"Original PICF form has clear statement that once contacted after x point you will have no further input in this study therefore a waiver of consent could be seen as contradictory to the original PICF ."

# Recommendations

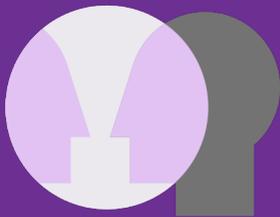
- **Targeted resources and activities for researchers and HRECs to facilitate thorough and informed review processes**
- **For researchers:**
  - Guidance on the information required in applications.
  - Examples of what may satisfy criteria for waivers of the requirement for consent.
  - Education and resources on deidentification.
- **For HRECs:**
  - Education on the ethics of secondary data sharing research, including ethical trade-offs.
  - Resources on role and remit of HRECs when considering requests to access data.
  - Resources on the privacy risks associated with participant-level data.
  - Guidance on the provision of responses to applicants, including tone, link to NS criteria, and specificity.
  - Opportunities for consensus-building on key criteria of the National Statement.

Further details and full report: <https://ctiq.com.au/current-projects/clinical-research-data-sharing-frameworks/>

# What Activities Can a ShED Promote?

**How were we similar or different from others?**

Self-reflection within ethics review bodies



**Can we agree on a shared interpretation or approach?**

Consensus building among ethics review bodies



**On what questions do we most need guidance?**

Targeted engagement with consumers



# Acknowledgements

## Project Team



And our incredible CT:IQ and ARDC Advisory Committee

<https://ctiq.com.au/current-projects/clinical-research-data-sharing-frameworks/>

