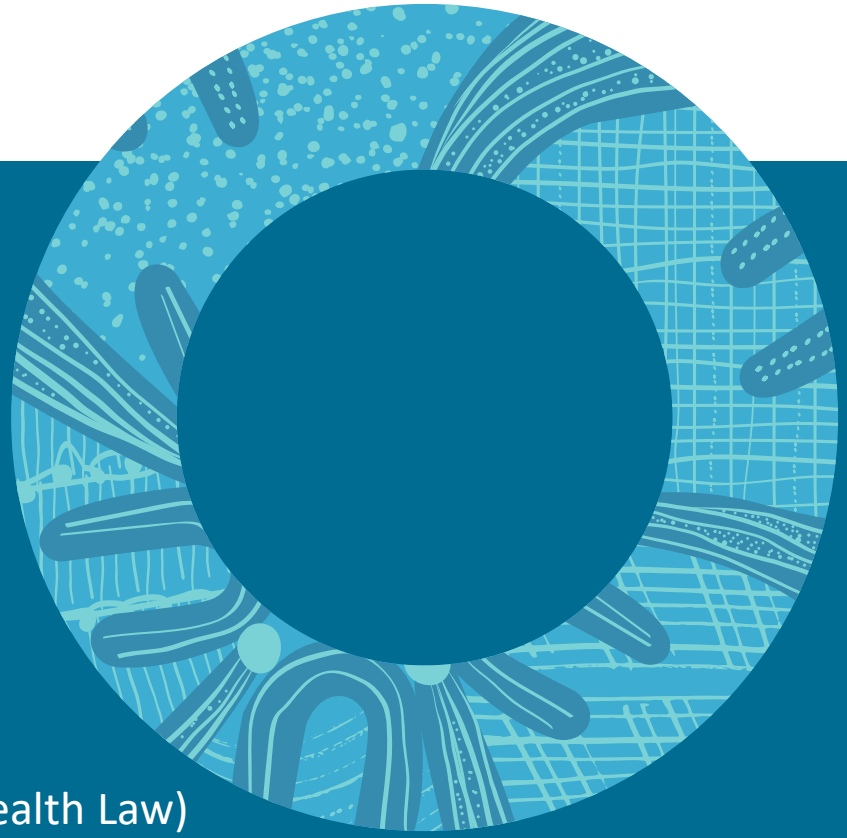
Informed Consent

UNIVERSITY OF CANBERRA



How informed is ‘informed’ when it comes to consent?

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Acknowledgement of Country

I begin by acknowledging the Ngunnawal people as Traditional Custodians of the land on which I make this presentation.

In the spirit of reconciliation I acknowledge the Traditional Custodians of country throughout Australia and their connections to land, sea, and community.

I pay my respects to their Elders past, present, and emerging; and extend that respect to all Aboriginal and Torres Strait Islander peoples.

The Challenge of HREC Membership

Never forget - Human Research Ethics Committees are decision-making bodies.

- Committee decisions are decisions of the Committee – not of individuals.
- If you have a seat at the table – use it.
- Understand the decisions of the Committee.
- Question.
- Question.
- Question.

What is Consent?

Explicit agreement and permission to engage in a specific activity demonstrated clearly through actions, words, or in writing.

Consent must be freely and voluntarily given and mutually understood by all parties involved.

Why Seek Consent?

Ensuring that consent is properly obtained is a legal, ethical, and professional obligation of the researcher before the conduct of human research.

It is considered to be a demonstration of respect for individuals and to demonstrate participation rather than commodification.

The Problem with Consent

Consent is not mere agreement. It is not the signature on a page.

There is tension between the doctrine of informed consent, which '**is intended to protect [individual] patient's decision-making ability and to respect the person's dignity**' and the practicalities of conducting research.

Consent takes time, resources, empathy, mutual understanding … people might say 'no'.

Clinical Trials are a competitive industry.

Researchers have recruitment targets to hit.

Ahmed Elsayyad, 'Informed Consent for Comparative Effectiveness Trials' (2014) 370(20) *New England Journal of Medicine* 1958, 1958.

Lawful Consent

Lawful consent requires each of these elements to be satisfied:

1. The decision is made voluntarily[1]; **and**
2. The person providing the consent must be informed in broad terms about the activity[2]; **and**
3. The person must be provided with any specific information relevant to them as an individual making a decision about participation and any alternatives[3]; **and**
4. The person must have the legal authority and the capacity to make the decision[4].

1. *Beausoleil v Sisters of Charity (1964) 53 DLR (2d) 65 ('Sisters of Charity')*; *Re T (Adult: Refusal of Treatment)* [1992] 4 All ER 649
2. *Chatterton v Gerson* [1981] 1 All ER 257; Ellis v Wallsend District Hospital (1989) 17 NSWLR 553.
3. *Rogers v Whitaker* [1992] HCA 58; Biggs v George [2016] NSWCA 113.
4. *Re C (Adult Refusal of treatment)* [1994] 1 WLR 290; *Re MB (medical treatment)* [1997] 2 FLR 426.

Informed Consent

Accurate and relevant information about the research and alternatives to participation must be provided as part of the consent process:

2. the person providing the consent must be informed in broad terms about the activity; **and**

Chatterton v Gerson [1981] 1 All ER 257;
Ellis v Wallsend District Hospital (1989) 17 NSWLR 553.

Specific Individual Concerns Must be Addressed

This includes adequate knowledge and understanding of the benefits and material risks of the proposed research relevant to the person consenting to participate in the research.

3. the person must be provided with any specific information relevant to them as an individual making a decision about participation and any alternatives;

Rogers v Whitaker [1992] HCA 58.

The information must be understandable

Researchers not only do they have a duty to ensure that patients are adequately advised of the risks of research and alternative options, but they must also convey the information in a manner in which the participant can understand.

3. the person must be provided with any specific information relevant to them as an individual making a decision about participation and any alternatives;

The substance of the information must be mutually understood.

Biggs v George [2016] NSWCA 113

Informed Consent

To be informed, participants need to:

- have enough information about their condition,
- treatment options,
- the benefits and risks relevant to them, and
- alternative options.

It is an opportunity to ask questions and discuss the concerns relevant to their specific circumstances.

Informing participants is about supporting decision-making, and promoting autonomy, and not about discharging minimum legal obligations.

The information must be meaningful to the person making decisions.

https://www.safetyandquality.gov.au/publications-and-resources/resource-library/informed-consent-fact-sheet-clinicians

Minimum Standards for Informed Consent

Broad Terms

Are participants informed – even in broad terms – if they do not understand the information that they have been provided?

If participants do not understand – even in broad terms – how can they ask relevant questions?

Personally Relevant

If the researcher does not understand the circumstances of the participant, how can they ensure that information is provided in a way that is personally relevant to the participant?

If researchers do not meet these MINIMUM standards, ask: **are participants really informed**?

Participation v Commodification

Participation	**Commodification**
Discuss participant circumstances to uncover concerns to be addressed	Tell participants information in general terms
Ask questions to ensure mutual understanding	Provide answers to the questions a generic participant might ask
Adapt communication to context	Reliant on standardised processes
Relational	Transactional

What Questions do you ask?

Thank you

Without an audience, any presentation is pointless.

Thank you for your support and engagement.

BYE

The University of Canberra acknowledges the Ngunnawal people, traditional custodians of the lands where Bruce Campus is situated. We wish to acknowledge and respect their continuing culture and the contribution they make to the life of Canberra and the region. We also acknowledge all other First Nations Peoples on whose lands we gather.