THE UNIVERSITY OF WESTERN AUSTRALIA

FACULTY OF LAW

Consent in the context of assisted reproduction

Brenda McGivern
Deputy Dean of Law, UWA
Member, Reproductive Technology Council

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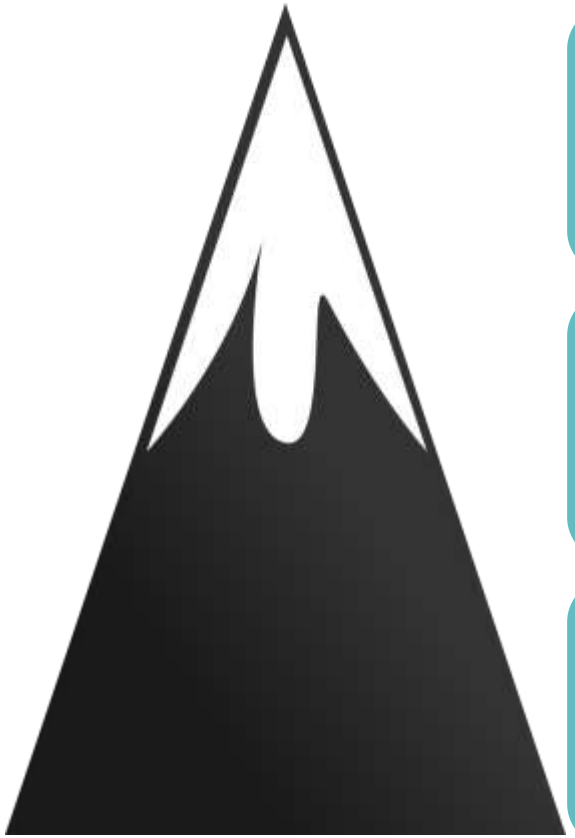
Purpose

The purpose of this presentation is to provide general information about the operation and requirements of consent in the context of assisted reproduction.

It is not intended to be, and must not be relied upon as, legal or regulatory advice.

The Legal Landscape



Statute
(HRT Act; Surrogacy Act)

- Specific application (scope of the Act)
- Prevails over common law
- Gives legislative effect to subsidiary regulations

Common law

- General application
- Applies where consistent with, or in gaps left by, legislation
- The legal ‘safety net’

Professional standards & ethics

- May acquire legal standing by operation of statute or common law

Autonomy: an ethical concept reflected in the law

"[T]he common law respects and preserves the autonomy of adult persons of sound mind with respect to their bodies. By doing so, the common law accepts that a person has rights of control and self-determination in respect of his or her body which other persons must respect. Those rights can only be altered with the consent of the person concerned. Thus, the legal requirement of consent to bodily interference protects the autonomy and dignity of the individual and limits the power of others to interfere with that person's body."

Marion's Case (1992) 175 CLR 218 at 309, McHugh J

Autonomy: an ethical concept reflected in the law

"Fundamentally, the rule is a recognition of individual autonomy that is to be viewed in the wider context of an emerging appreciation of basic human rights and human dignity. There is no reason to diminish the law's insistence, to the greatest extent possible, upon prior, informed agreement to invasive treatment, save for that which is required in an emergency or otherwise out of necessity."

Rosenberg v Percival (2001) 205 CLR 434 at [145], Kirby J

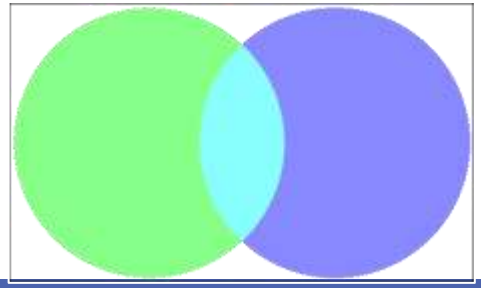
Common Law
Distinguishing Consent from "Informed Consent"

Consent
(battery - criminal & civil liability)

- Operates as a defence to battery (unlawful interference with a person's body)
- Valid consent requires understanding *in broad terms* of the nature of the proposed touching (interference). Must also be competently made and specific.

"Informed Consent"
(negligence – civil liability only)

- Duty to provide information to patients forms part of a broad duty of care (includes warning of 'material risks')
- Failure to provide adequate information may be so gross as to vitiate consent, but does not necessarily do so. A "lesser" failure may still be negligent



Negligence: Duty to inform

- [W]hile evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to "the paramount consideration that a person is entitled to make his own decisions about his life"

  Rogers v Whitaker (1992) 175 CLR 479 at [12]

- While the provision of such written documents is to be commended, as it allows a patient time to reflect on the procedures described and to ask questions on issues left unanswered, such forms are no substitute for dialogue between patient and surgeon. Such dialogue, inherent in informed decision-making, must, to some extent, be "shared" so that it secures consent by a patient to a medical procedure that is truly understood.

  Rosenberg v Percival at [148]

Human Reproductive Technology Act 1991 (HRT Act)

- [Part 4 – Licensing] s33(2) - Every licence granted or exemption issued under this Part is subject to the conditions ... (d) that the requirements of this Act as to the obtaining and recording of effective consents be complied with.
  - s 22 – consents generally: use and storage of gametes / 'embryos'
  - s 23 (1) – when IVF procedures may be carried out
  - s 26 (1) – control of, dealing with, and disposal of 'embryos'
    [s 33 (2), (4) – licensing requirements]
  - s 49 (2e) – divulging or communicating identifying information

  see also
  - HRTA Directions Part 3 (consents); Part 4 (information before consent)
  - Surrogacy Directions, s 11; and
  - RTAC Code of Practice, Critical Criterion 14

HRT Act – ‘effective consent’

- s3 (definitions) - *effective consent* is to be construed in accordance with section 22(8)
- s 22 (8) - For the purposes of this Act a consent to the use or keeping of any human gametes, a human egg undergoing fertilisation or a human embryo shall not be taken to be effective unless –
  - (a) it is given in writing;
  - (b) any condition to which it is subject is met;
  - (c) it has not been withdrawn; and
  - (d) those gametes are, or that egg or embryo is, kept and used in accordance with the consent.
- s 22 (4) The terms of any effective consent may from time to time be varied or the consent withdrawn [unless materials already used in accordance with consent given] ...

RTAC Code of Practice – Critical Criterion 14

- The Organisation must have a process whereby clinicians ensure that consent is obtained from all patients and/or donors (and, where relevant, their spouses or partners) before treatment commences.
- The Organisation must provide patients with information that is accurate, timely and in formats appropriate to the patient.
- The Organisation must provide evidence of implementation and review of policies/procedures:
  - which define the consenting process
  - to ensure that consent is informed, voluntary, competent, specific, documented and remains current.

Note that accreditation is a requirement for being granted / renewed, and is a condition of holding, a licence: HRT Act, ss 29(5), 33(2)

Putting it all together

- Legislative compliance, including compliance with subsidiary regulation
  - HRT Act
  - Directions (HRTA and Surrogacy)
  - RTAC Code of Practice (incorporating NHMRC Ethical Guidelines)
- Legislative requirements do not exclude operation of common law (except where inconsistent)
  - broad obligations, including duty to inform of material risks, continue to operate
- Also think about any additional professional regulatory requirements (AHPRA / Boards)

Consent requirements are key features of almost every arm of regulation (legal and quasi-legal). Although specifics may differ, all of these requirements are broadly consistent, being underpinned by *patient autonomy* and *professional accountability*.

Discussion