MEMORANDUM RE INFORMED CONSENT

Re:	The Concept of Informed Consent in Australia
Date:	11 October 2021

Summary

This memorandum explores the concept of informed consent and aims to give a detailed overview of its historical development and current standing in Australian law.

The concept, overall, is not clearly or consistently defined in statute. In the case law, it is usually invoked as a corollary to other primary issues, usually in cases concerning guardianship, medical negligence and battery.

In saying that, regulation and policy refers to the concept as if it *is* enshrined in law; giving weight to its importance as a tenet of medicine.

International instruments, although instructive, have not been appropriately enshrined into Australian law.

This memo discusses:

1. The origins and development of informed consent in Australian law;
2. The current characterisation of informed consent in Australian law including;
    a. Statute;
    b. Common law; and
    c. Policy and regulation
3. Constitutional Arguments for Informed Consent;
4. How Informed Consent appears in International Instruments; and
5. The tangential Concept of Bodily Integrity.

Pleadings

Consent requirements are pleaded at paragraphs 24-31 of the draft SOC, alleging invalidity due to the failure to permit informed and voluntary consent.

The origins and development of Informed consent in Australian Law

Origins and Development of the Concept in Australia

The use and definition of "informed consent" as a legal concept has occurred over time through the common law, mostly in the context of claims for medical negligence.

The term "informed consent" first arose in North America in 1957[1] where it was introduced as a means of shifting practitioner emphasis away from medical paternalism towards a "duty" to respect the autonomy of patients.

The Australian and English courts were initially uninfluenced by this decision or concept, instead favouring the more conservative *Bolam* test,[2] (summarily; that a doctor who reaches the standard

[1] See *Salgo v Leland Stanford Jr University Board of Trustees* 317 P 2d 170 (1957) (Cal Dist Ct App).
[2] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 852 at 587.

of a responsible body of medical opinion is not negligent, whether or not they informed their patients of any risks).

The first major development in Australia occurred in *Sidaway v Board of Governors of Bethlem Royal Hospital [1985]*,[3] where it was held that "currently accepted practice" would not override or excuse the non-disclosure of a particular risk of serious adverse consequences to the patient, where it is "obvious to the prudent doctor" that such disclosure would be "necessary if the patient were to make a rational or informed choice as to whether to accept or reject the treatment offered". Failure to do so, it was said, may provide grounds for negligence.

The second major development was *Rogers v Whittaker (1992)*.[4] Here, the Court actually rejected the use of the expression "informed consent" as "apt to mislead", instead introducing the term "duty of disclosure". In doing so, the Court reaffirmed that doctors have a duty to disclose and warn patients of "material risk".[5] Furthermore, the basic duty to disclose was deemed to be present even when the patient does not seek information through specific questions. This was emphasised by Gaudron J when she wrote:[6]

> where, for example, no specific inquiry is made, the [doctors'] duty is to provide the information that would reasonably be required by a person in the position of the patient

Gaudron J also pointed out that the duty to disclose or to warn of all material risks was a minimum, not a maximum. She added; "a patient may have special needs or concerns which, if known to the doctor, will indicate that special or additional information is required. In a case of that kind, the information to be provided will depend on the individual patient concerned". Thus, disclosure of information to the patient must now take account of factors associated with the specific needs of the patient, be they wishes, anxieties or beliefs.[7]

The current characterisation of informed consent in Australian Law

Statute

First, it is important to note that there is no statutory enshrinement of informed consent in NSW in a general sense. There are some statutes however which define or use the phrase for their purposes.

For example, the *Guardianship Act 1987 (NSW),*[8] in the context of consent for the carrying out of mental or dental treatment on patients under a guardianship order, implements several checks and balances which might be complied with by the guardian:

> 40 Consents given by persons responsible for patients
>
> (1) Any person may request a person responsible for a patient to whom this Part applies for that person's consent to the carrying out of medical or dental treatment on the patient.
>
> (2) Such a request shall specify—

[3] AC 871 at 893.
[4] 175 CLR 479.
[5] R Ottley, "Duty to Warn" (1993) 7 *Australasian Journal of the Medical Defence Union* 43.
[6] *Rogers v Whittaker (1992)* 175 CLR 479 at 493.
[7] *Rogers v Whittaker (1992)* 175 CLR 479 at 493.
[8] Division 3, s40.

(a) the grounds on which it is alleged that the patient is a patient to whom this Part applies,

(b) the particular condition of the patient that requires treatment,

(c) the alternative courses of treatment that are available in relation to that condition,

(d) the general nature and effect of each of those courses of treatment,

(e) the nature and degree of the significant risks (if any) associated with each of those courses of treatment, and

(f) the reasons for which it is proposed that any particular course of treatment should be carried out.

(3) In considering such an application, the person responsible for the patient shall have regard to—

(a) the views (if any) of the patient,

(b) the matters referred to in subsection (2), and

(c) the objects of this Part.

The above criteria seem to acknowledge the elements of informed consent as well as taking into account the judgment of *Rogers v Whitaker* above.

The *Mental Health Act 2007* No 8 (NSW) refers to "informed consent" only in the context of Electro Convulsive Therapy, stipulating "informed consent requirements" in that context as follows:

91 Informed consent requirements (cf 1990 Act, s 183)

(1) A person is taken to have given informed consent to the administration of electro convulsive therapy if the person gives a free, voluntary and written consent after this section is complied with.

(2) The following steps must be taken before consent is obtained—

(a) a fair explanation must be made to the person of the techniques or procedures to be followed, including an identification and explanation of any technique or procedure about which there is not sufficient data to recommend it as recognised treatment or to reliably predict the outcome of its performance,

(b) a full description must be given, without exaggeration or concealment, to the person of any possible discomforts and risks of the treatment (including possible loss of memory),

(c) a full description must be given to the person of any expected benefits of the treatment,

(d) a full disclosure must be made, without exaggeration or concealment, to the person of any appropriate alternative treatments that would be advantageous to the person,

(e) an offer must be made to the person to answer any inquiries concerning the procedures or any part of them,

(f) the person must be given notice that the person is free to refuse or to withdraw consent and to discontinue the procedures or any part of them at any time,

(g) a full disclosure must be made to the person of any financial relationship between the person proposing the administration of the treatment or the administering medical practitioner, or both, and the facility in which it is proposed to administer the treatment,

(h) the person must be given notice of their right to obtain legal and medical advice and to be represented before giving consent,

(i) any question relating to the techniques or procedures to be followed that is asked by the person must have been answered and the answers must appear to have been understood by the person,

(j) a form setting out the steps in this subsection is to be given to the person and an oral explanation of the matters dealt with in the form is to be given to the person in a language with which the person is familiar.

(3) The regulations are to prescribe forms setting out the steps to be taken before obtaining informed consent to electro convulsive therapy.

The *Mental Health Act 2014 (Vic),* in contrast to NSW, has a very lengthy, very carefully drafted definition and criteria for informed consent as follows:

Part 5—Treatment

Division 1—Capacity and informed consent

68 Capacity to give informed consent under this Act

(1) A person has the capacity to give informed consent under this Act if the person—

(a) understands the information he or she is given that is relevant to the decision; and

(b) is able to remember the information that is relevant to the decision; and

(c) is able to use or weigh information that is relevant to the decision; and

(d) is able to communicate the decision he or she makes by speech, gestures or any other means.

(2) The following principles are intended to provide guidance to any person who is required to determine whether or not a person has the capacity to give informed consent under this Act—

(a) a person's capacity to give informed consent is specific to the decision that the person is to make;

(b) a person's capacity to give informed consent may change over time;

(c) it should not be assumed that a person does not have the capacity to give informed consent based only on his or her age, appearance, condition or an aspect of his or her behaviour;

(d) a determination that a person does not have capacity to give informed consent should not be made only because the person makes a decision that could be considered to be unwise;

(e) when assessing a person's capacity to give informed consent, reasonable steps should be taken to conduct the assessment at a time at, and in an environment in, which the person's capacity to give informed consent can be assessed most accurately.

69 Meaning of informed consent

(1) For the purposes of treatment or medical treatment that is given in accordance with this Act, a person gives informed consent if the person—

(a) has the capacity to give informed consent to the treatment or medical treatment proposed; and

(b) has been given adequate information to enable the person to make an informed decision; and

(c) has been given a reasonable opportunity to make the decision; and

(d) has given consent freely without undue pressure or coercion by any other person; and

(e) has not withdrawn consent or indicated any intention to withdraw consent.

(2) For the purposes of subsection (1)(b), a person has been given adequate information to make an informed decision if the person has been given—

(a) an explanation of the proposed treatment or medical treatment including—

(i) the purpose of the treatment or medical treatment; and

(ii) the type, method and likely duration of the treatment or medical treatment; and

(b) an explanation of the advantages and disadvantages of the treatment or medical treatment, including information about the associated discomfort, risks and common or expected side effects of the treatment or medical treatment; and

(c) an explanation of any beneficial alternative treatments that are reasonably available, including any information about the advantages and disadvantages of these alternatives; and

(d) answers to any relevant questions that the person has asked; and

(e) any other relevant information that is likely to influence the decision of the person; and

(f) in the case of proposed treatment, a statement of rights relevant to his or her situation.

(3) For the purposes of subsection (1)(c), a person has been given a reasonable opportunity to make a decision if, in the circumstances, the person has been given a reasonable—

(a) period of time in which to consider the matters involved in the decision; and

(b) opportunity to discuss those matters with the registered medical practitioner or other health practitioner who is proposing the treatment or medical treatment; and

(c) amount of support to make the decision; and

(d) opportunity to obtain any other advice or assistance in relation to the decision.

The Victorian *Charter of Human Rights and Responsibilities Act 2006* (Vic) has the following provision relevant to informed consent:

10 Protection from torture and cruel, inhuman or degrading treatment

A person must not be—

(a) subjected to torture; or

(b) treated or punished in a cruel, inhuman or degrading way; or

(c) subjected to medical or scientific experimentation or treatment without his or her full, free and informed consent.

The *Australian Human Rights Commission Act 1986* (Cth), which among several international human rights covenants and treaties which it attaches via schedules, attaches article 7 of the ICCPR, being:

Article 7

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

Though, this Article is not mentioned (or enshrined) in any other part of that Act.

Finally, as we know;

- the *Biosecurity Act 2015* (Cth) prohibits the use of force for vaccination (s95); and

- The *Biosecurity Act 2015* (Cth) prohibits vaccination or treatment without an individual Biosecurity Control Order with stringent requirements (s92).

Common Law

The common law which directly refers to informed consent is sporadic in the sense that 'informed consent' is generally raised as an element of wider proceedings, and is taken as a given by the Courts rather than something which is explained, elaborated on, defined or argued over. Nonetheless the following extracts refer to informed consent in various ways;

Case	Extract	Ref
Malette v Shulman (1990) 67 DLR (4th) 321	"[a] competent adult is generally entitled to reject a specific treatment or all treatment, or to select an alternative form of treatment, even if the decision may entail risks as serious as death and may appear mistaken in the eyes of the medical profession or of the community…it is the patient who has the final say on whether to undergo the treatment".	
Dr Noel Rodney Campbell v The Dental Board of Victoria [1999] VSC 113	[In the context of an appeal against the decision of a Dental Board for professional misconduct and negligence where one of the grounds was that he did not obtain his patients' informal consent for the use of an experimental drug]: I am satisfied that the appellant used the drug DMSA, in the treatment of the said four patients, without informing them of the status of the drug in Australia, its possible adverse side effects (or the risk thereof) and the state of medical knowledge concerning DMSA. I should add that it was undisputed that there was material readily available from the manufacturer and in the US pharmacopoeia and other medical literature concerning possible adverse side effects which the appellant had not troubled to find. The appellant gave evidence before the Board that he had read "hundreds of references" but this seems most improbable (alternatively, it makes the position worse). Instead it appears that the appellant had relied in the first instance on statistically limited and scientifically uncontrolled information derived from the experience of a New Zealand colleague and subsequently from his own experience of a like nature. I am satisfied that the appellant failed to obtain the informed consent of the four patients to their treatment with the drug and even failed (in the two cases where the form was available) to obtain their signature to the inadequate consent form which had been devised for the purpose. I am satisfied that the appellant failed to establish any protocol, let alone an adequate one, to monitor the condition of the four patients during their said treatment or to ask them to report any infection. I am persuaded, as a result of the uncontradicted and undisputed evidence of Dr Mashford, that a competent practitioner (whether a physician or a dentist) who took it upon himself to prescribe DMSA in all the circumstances of these four patients ought not to have failed to take all of the steps and precautions to which I have referred. The appellant conceded that he ought to have taken them but he maintained that he acted in good faith, was ignorant of the potentially serious side effects (such as liver damage and neutropaenia) and relied upon the favourable experience of the said colleague and later upon his own experience.	56

Hunter and New England are Health Service v A by his Tutor [2009]	Whenever there is a conflict between a capable adults' exercise of the right of self-determination and state's interest in preserving life – the right of the individual must prevail	17
Brightwater Care Group (Inc) v Rossiter [2009] WASC 229	In a Guardian Tribunal decision in WA, Senior Member Mr J Mansveld noted that: The common law was considered by the Supreme Court of Western Australia in Brightwater Care Group (Inc) v Rossiter [2009] WASC 229 (Rossiter). The following principles were stated at [23] to [27]: - an adult person is assumed to be capable of having the mental capacity to consent to, or refuse, medical treatment (reflecting the statutory presumption of capacity in s 4(3)(b) of the GA Act). - An adult person has the right of autonomy or self-determination, the right to choose how he or she should live his or her life. - The informed consent of the patient is required before any medical treatment can be undertaken lawfully (but note Pt 9D of the GA Act as it relates to the provision of urgent treatment). - An individual of full capacity is not obliged to give consent to medical treatment regardless of whether the reasons for the withholding of consent are rational, irrational, unknown or even non-existent (the withholding of consent is reflected in the definition of treatment decision in s 3 of the GA Act). - As to the factors to be considered in the ability to give informed consent, the decision in Rossiter included the capacity to comprehend and retain information given to the person in relation to his or her treatment, the capacity to weigh up that information, to weigh up alternative options, to understand the consequences of the treatment decision and the capacity of expressing reasons for the decision (although as stated, a capable person is not obliged to give reasons) (Rossiter at [13] and [14]).	23 to 27
Wallace v Kam [2013] HCA 19	The common law duty of a medical practitioner to a patient is a single comprehensive duty to exercise reasonable care and skill in the provision of professional advice and treatment […] The component of the duty of a medical practitioner that ordinarily requires the medical practitioner to inform the patient of material risks of physical injury inherent in a proposed treatment is founded on the underlying common law right of the patient to choose whether or not to undergo a proposed treatment.	8

Reeves v the Queen [2013] HCA 57 18 December 2013 S44/2013	[A case where a victim of a botched medical procedure tried to argue that the doctor was negligent by way of not ensuring the patient gave informed consent, but both the CCA and the HC both instead ruled that 'informed consent' is a misconstrual of the test, which should actually instead be the test in Rogers v Whitaker (which is a lower bar)] *The directions on informed consent* The jury were supplied with written directions of law, which included directions on "informed consent". The oral directions on this topic were in the same terms as the written directions. Relevantly, the written directions stated. "There will not be 'lawful cause or excuse' for the surgery performed by the [applicant] if the Crown proves beyond reasonable doubt that the [applicant] did not honestly believe at the time of the operation that the patient had given her informed consent to the full extent of the operation, including removal of the labia and clitoris". (emphasis in original) Under the heading "What Does 'Informed Consent' mean?" the written directions included the following: "To be valid, consent must be 'informed'. This means that the medical practitioner must at least explain to the patient the purpose of the operation, the part or parts of the body to be cut or removed, the possible major consequences of the operation, and any options or alternative treatments which may be reasonably available." (emphasis in the original) *Consent to medical procedures* The Court of Criminal Appeal found, correctly, that it was an error to direct the jury in terms of "informed consent". Specifically, it was an error to direct that a medical practitioner must explain the "possible major consequences of the operation" together with "options" and "alternative treatments" before the patient's consent to the procedure will afford the medical practitioner lawful cause or excuse for performing it. The nature of the consent to a medical procedure that is required in order to negative the offence of battery is described in the joint reasons in Rogers v Whitaker. It is sufficient that the patient consents to the procedure having been advised in broad terms of its nature. Provided CDW was informed that the surgery involved the removal of her labia and clitoris, the applicant had a lawful cause or excuse for performing it. This was so regardless of any failure to inform CDW of its possible major consequences and any alternative treatments. A failure in either of these respects might be a breach of the applicant's common law duty of care exposing him to liability in negligence but it would not vitiate the consent to the surgery.	33 - 35
PBU & NJE v Mental Health Tribunal &	Contains a discussion of whether a patient lacked the capacity to give informed consent in the context of the Mental Health Act Victoria, and how that Act defines the concept. For eg, see:	77

Ors [2018] VSC 564; 56 VR 141	Seeking, and presuming the capacity to give, informed consent It would be discriminatory and a grave violation of human rights to regard a person having mental illness as lacking capacity to give informed consent merely because the person has that illness and the legislation does not operate upon this basis. Section 70(2) provides that anyone seeking the informed consent of another to treatment or medical treatment must presume that the other person has the capacity to give informed consent. This is the position under the common law (see below) and applies to an authorised psychiatrist who considers that a person needs treatment for mental illness. Before treatment or medical treatment is administered, 'the informed consent of the person must be sought' (s 70(1)), unless the person does not have the capacity to give that consent at the relevant time (s 70(3)).	

Policy And Regulation

"Informed Consent" is referred to and defined as follows in various policies and regulations, issued primarily by regulatory bodies.

The ALRC states**:**

> 'Informed consent' refers to consent to medical treatment and the requirement to warn of material risk prior to treatment. As part of their duty of care, health professionals must provide such information as is necessary for the patient to give consent to treatment, including information on all material risks of the proposed treatment. Failure to do so may lead to civil liability for an adverse outcome, even if the treatment itself was not negligent.[9]

The *Health Care Complaints Commission* in NSW states that**:**[10]

> Medical and dental treatment requires valid consent from the patient. Informed consent means a patient will be given clear information about what is involved in any proposed treatment and their treatment options. Health care providers need to obtain valid consent from a patient before examining or treating them. If a patient lacks capacity, consent should be sought from the person with the proper authority, except in situations where the treatment is urgent and necessary to save a person's life or prevent serious damage to their health.

For consent to be valid the provider needs to ensure that the patient has:

- the capacity to provide consent.
- a good understanding of any side-effects, risks, benefits and alternatives regarding the proposed treatment.
- been informed about the fees involved
- given consent voluntarily, without being pressured.

[9] https://www.alrc.gov.au/publication/equality-capacity-and-disability-in-commonwealth-laws-dp-81/10-review-of-state-and-territory-legislation/informed-consent-to-medical-treatment/

[10] https://www.hccc.nsw.gov.au/health-consumers/frequently-asked-questions-health-consumers/consent-for-treatment

…

> The Health Care Complaints Commission can assist with complaints based on concerns that valid consent was not obtained prior to treatment or care being provided to a patient. You can contact our Inquiry Service on 1800 043 159 for more information or make a complaint online.

The NSW Department of Health has a "Consent to Medical and Healthcare Treatment Manual" which has a section titled "Requirements for Consent"[11]. It says:

> Adults with capacity have a right to decide what happens to their own bodies. This means that they have the right to consent to treatment, refuse to consent to treatment for any reason, or withdraw their consent, even if refusal or withdrawal of treatment is likely to lead to serious injury or death. These principles are reflected in the law that governs consent to medical treatment. As a general rule, no operation, procedure or treatment may be undertaken without prior consent from the patient or, if the patient lacks capacity, from the patient's substituted decision maker.
>
> The only exceptions are:
>
> > in an emergency when the patient lacks capacity and the patient's express wishes are unknown; or
> >
> > where the law otherwise allows or requires treatment to be given without consent.
>
> Consent to the general nature of a proposed operation, procedure, or treatment must be obtained from the patient or, if the patient lacks capacity, from the patient's substituted decision maker.
>
> Failure to do this could result in legal action for assault and battery against the Health Practitioner who provided the care, irrespective of whether the patient suffered harm as a result of the procedure.
>
> Health Practitioners also have a legal obligation to provide patients (or substituted decision makers) with information, including warnings, about any material risks involved in the proposed procedure or treatment.
>
> Failure to do so may also give rise to legal action for negligence. For further information on material risks see section 4.8.
>
> Obtaining consent and adequately informing patients about their treatment options and the risks and benefits arising are an established part of good clinical practice.

The oft quoted **Australian Immunisation Handbook** states:

> Valid consent is the voluntary agreement by an individual to a proposed procedure, which is given after sufficient, appropriate and reliable information about the

[11] *Consent to Medical and Healthcare Treatment Manual*, NSW Department of Health, https://www.health.nsw.gov.au/policies/manuals/Documents/consent-section-4.pdf

procedure, including the potential risks and benefits, has been conveyed to that individual.8-12

As part of the consent procedure, people receiving vaccines and/or their parents or carers should be given sufficient information (preferably written) about the risks and benefits of each vaccine. This includes:13

what adverse events are possible
how common they are
what they should do about them

Table. Side effects following immunisation for vaccines used in the National Immunisation Program schedule can be used to inform valid consent.

Criteria for valid consent

For consent to be legally valid, the following elements must be present:12,14

It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of receiving a vaccine.
It must be given voluntarily in the absence of undue pressure, coercion or manipulation.
It must cover the specific procedure that is to be performed.
It can only be given after the potential risks and benefits of the relevant vaccine, the risks of not having it, and any alternative options have been explained to the person.
The person must have the opportunity to seek more details or explanations about the vaccine or its administration.

The information must be provided in a language or by other means that the person can understand. Where appropriate, involve an interpreter or cultural support person.

Obtain consent before each vaccination, after establishing that there are no medical condition(s) that contraindicate vaccination. Consent can be verbal or written.

Consent on behalf of a child or an adolescent

In general, a parent or legal guardian of a child has the authority to consent to that child being vaccinated.

Some Australian states and territories have legislation that addresses the issue of a child's consent to medical treatment. Check with your state or territory health authority about these laws.

The common law applies in the states and territories that do not have specific legislation relating to children's consent to medical treatment. This common-law position is often referred to as Mature Minor or Gillick competence.

For certain procedures, including vaccination, a child or adolescent may be determined to be mature enough to understand the proposed procedure, and the risks and benefits associated with it. These young people may have the capacity to consent under certain circumstances.8,11

If a child or adolescent refuses a vaccination that a parent or guardian has given consent for, respect the child's or adolescent's wishes, and inform the parent or guardian.8

Consent on behalf of an adult lacking capacity
Carefully assess an adult's capacity to give valid consent to vaccination. If the adult lacks capacity, refer to relevant state and territory laws for obtaining consent from a substitute decision-maker. For example, this may occur for influenza vaccination of an elderly person with dementia.

See the enduring guardianship legislation in your state or territory for more details.

Resources to help communicate the risks and benefits of vaccines
Use plain language when communicating information about vaccines and their use. The person to be vaccinated (or their parent or guardian) must:15,16

be encouraged to ask for more details
have enough time to decide whether to consent
Provide printed information to supplement any verbal explanations.17

Evidence of consent

General practice or public immunisation clinics

People can give consent either in writing or verbally, according to the protocols of the health facility. All consent must meet the criteria for valid consent.

Document evidence of verbal consent in the clinical records.
For electronic medical records, include a typed record of verbal consent in the person's file, or scan a copy of written consent into the file.

If the practice or clinic routinely follows a standard procedure, show that the provider followed the procedure by using a stamp, a sticker or the provider's signature.

People need to give explicit verbal consent before receiving any vaccine, even if they gave written consent at previous vaccination encounters for the same vaccine. Document verbal consent in the person's file each time they give it.

School-based vaccination programs

Consent is required to provide individual vaccines or a vaccine course through school-based vaccination programs.

In school-based, and other large-scale, vaccination programs, the parent or guardian usually does not attend with the child on the day they receive the vaccine. Written consent from the parent or guardian is desirable in these circumstances.

If the parent or guardian cannot provide written consent, or if they need further clarification, they can give verbal consent to the immunisation provider by telephone. Clearly document this on the child's consent form.

> In some states and territories, older adolescents may be able to provide their own consent for vaccinations offered through school-based vaccination programs. See Consent on behalf of a child or an adolescent.
>
> Consent requirements and vaccines offered in these programs vary between jurisdictions. See your state or territory school-based vaccination program guidelines for more details.

The Australian Commission on Safety and Quality in Health Care says that "ensuring informed consent is properly obtained is a legal, ethical and professional requirement on the part of all treating professionals and supports person-centred care".[12]

Constitutional Arguments for Informed Consent

The most relevant (and in my view, the only potential) constitutional argument for informed consent is that surrounding s51(xxiiiA) of the Constitution, which states that:

> The Parliament shall, subject to this Constitution, have power to make laws for the peace, order, and good government of the Commonwealth with respect to:
>
> …
>
> (xxiiiA) the provision of maternity allowances, widows' pensions, child endowment, unemployment, pharmaceutical, sickness and hospital benefits, medical and dental services (but not so as to authorize any form of civil conscription), benefits to students and family allowances;

This argument was put to the Supreme Court of NSW in detail in *AL-Munir Kassam And Ors v The Hon Bradley Ronald Hazzard MLA and ORD* [CLD 2021/24960] (**Annexure A**) at paragraph 91 – 120 (whose decision is currently reserved).

It was put in two ways:

- First, an order mandating vaccination on its face is a civil conscription to which Constitution s 51(xxiiiA) applies;

- Second, if as a matter of construction section 51(xxiiiA) does not of its own force apply to State laws, nonetheless on the facts of this case the Order was made in furtherance of a joint scheme between the State and the Commonwealth having the effect of imposing a civil conscription on State citizens to which Constitution s 51(xxiiiA) applies on the principle in Magennis and ICM Agriculture [see below].

All in all, the second argument made by the Plaintiff, relying on a joint scheme, comes across as a bit of a stretch, while the first seems to misinterpret the Constitutional clause in question.

Lawyers for the State of NSW and Hazard exploited these weaknesses, arguing that (**Annexure B**, paragraph 102):

[12] Informed Consent, Australian Commission on Safety and Quality in Health Case, https://www.safetyandquality.gov.au/our-work/partnering-consumers/informed-consent

The argument that the Delta Order is invalid because it was made as part of a joint scheme of civil conscription contrary to the constitutional guarantee in s 51(xxiiiA) should be rejected for the following independent reasons:

(a) the Delta Order does not involve "civil conscription" within the meaning of s 51(xxiiiA);

(b) even if it did, the limitation is not relevantly infringed by the Commonwealth unless it requires action by the State in breach of the restriction; and

(c) even if the Commonwealth had required the State to act in that way, the Delta Order was still made in the independent exercise of State legislative and executive power and is valid.

I believe the position of the State of NSW is more consistent with the intention and meaning of sxxiiiA, as well as how it has been interpreted by the common law and is likely to be accepted by the Court in this instance. It is difficult, in my view, to frame an argument on sxxiiiA which is likely to succeed given the way the PHA has been used in NSW, independent of Cth Parliament, to mandate vaccination. If the federal Biosecurity Act had been used to mandate vaccination instead, perhaps we would have a better argument here.

How does Informed Consent Appear in International Instruments?

Various international instruments define and feature "informed consent". It is, in general, an internationally contemplated human rights doctrine. Unfortunately, like most human rights doctrines, Australian law hasn't done a very good job at enshrining it – so most of these international instruments (if not all of them) hold no real power domestically.

- Article 6 of the UNESCO statement on Bioethics and Human Rights, Section 1, states "Any preventative diagnostic and therapeutic medical intervention is only to be carried out with the prior free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason, without disadvantage and without prejudice".

- Nuremberg Code, Article 1, states "The voluntary consent of the human subject is absolutely essential".

    - Given how regularly the Nuremberg Code is referred to in reference to the Covid-19 vaccines, it is worth clarifying that:
        - The code contains ten ethical principles, which include that medical experimentation on humans must be consensual – via free choice, without coercion – that such research shouldn't cause death or disability and that scientists must conduct any such tests.

        - The oft made argument is that the vaccines are experimental, so their use and mandating is against the code. However, the counter-argument is that the Covid vaccines, despite being in Phase IV trials, have been provisionally approved in Australia, which is *not* equivalent to being "experimental" in the TGA procedure, but may be argued to be "experimental" in a general/common sense. If a court was to accept that they are **not** experimental, which unfortunately in Australia is possible,

then they may adjudge that the Nuremberg Code (even if it had some domestic weight) cannot apply to them. So, it would be necessary to put some pretty solid evidence before the Courts going towards their status as experimental in order for this Code to have any weight.

- On that note, the code is just that – a code of principles. It has not been enacted into international law, let alone the domestic laws of Australia.

- The accompanying notion that vaccine mandates are akin to Nazism is ironic given the Third Reich actually relaxed long-term inoculation requirements that applied in Germany. It's documented that the Nazis thought withholding vaccines would help destroy "inferior" peoples.

- The Siracusa Principles, adopted by the UN Economic and Social Council in 1984 provide authoritative guidance on government responses that restrict human rights for reasons of public health or national emergency. These Principles state that measures taken to protect the population that limit people's rights and freedoms must be lawful, necessary, and proportionate.

- Section 83.4 of the Criminal Code Act 1995 (Cth), which relates to interfering with political liberty states "Any person who, by violence or by threats or intimidation of any kind, hinders or interferes with the free exercise or performance, by any other person of any political right or duty shall be guilty of an offence".

The Tangential Concept of Bodily Integrity

Simultaneously, case law in Australia around the notion of "bodily integrity" has developed, along with the suggestion that a breach of said integrity can constitute an assault and/or battery.

In *Coco v The Queen (1994)*[13] the High Court referred to the "principle of legality", which they explained as follows:[14]

> The insistence on express authorization of an abrogation or curtailment of a fundamental right, freedom or immunity must be understood as a requirement for some manifestation or indication that the legislature has not only directed its attention to the question of the abrogation or curtailment of such basic rights, freedoms or immunities but has also determined upon abrogation or curtailment of them. The courts should not impute to the legislature an intention to interfere with fundamental rights. Such an intention must be clearly manifested by unmistakeable and unambiguous language.

So, this case is authority for the presumption that Parliament doesn't intend for statutes to operate in a way which limits fundamental rights and freedoms.

So, if bodily integrity can be said to be a fundamental right, there's a potential argument that when constructing s7 of the PHA, the Parliament should not be assumed to have intended for that section to be used to breach the fundamental right of bodily integrity (and therefore to authorise mandatory vaccination).

There are several authorities which point towards bodily integrity as a fundamental right:

[13] 179 CLR 427.
[14] *Coco v the Queen (1994)* 179 CLR 427 at 437

- *Collins v Wilcock* [1984], for example, which says that "the fundamental principle, plain and incontestable, is that every person's body is inviolate. It has long been established that any touching of another person, however slight, may amount to a battery…The breadth of the principle reflects the fundamental nature of the interest so protected";[15] and, from Blackstone's Commentaries[16],[17]

- The law cannot draw the line between different degrees of violence, and therefore totally prohibits the first and lowest stage of it; every man's person being sacred, and no other having a right to meddle with it, in any the slightest manner. The effect is that everybody is protected not only against physical injury but against any form of physical molestation.

- and, probably most relevant of all, *Marion's Case, 233*[18] (**Marion's Case**), in which it was adjudged that:

> "every man's person is sacred', points to the value which underlies and informs the law: each person has a unique dignity which the law respects and which it will protect. Human dignity is a value common to our municipal law and to international instruments relating to human rights"; and
>
> That there is a fundamental right, arising from the common law, to personal inviolability:[19]
>
> > As we have indicated, the conclusion relies on a fundamental right to personal inviolability existing in the common law, a right which underscores the principles of assault, both criminal and civil, as well as on the practical exigencies accompanying this kind of decision which have been discussed.

- The most famous quote from the case in general is that, as held by the majority, "consent ordinarily has the effect of transforming what would otherwise be unlawful into accepted, and therefore acceptable, contact. …The factor necessary to render a [medical treatment] lawful when it would other be an assault, is therefore, consent".

How does this relate to informed consent?

Bodily integrity is a related concept to that of informed consent. A breach of someone's bodily integrity usually involves a lack of informed consent. So, the way the court has discussed the right to bodily integrity could be relevant in the context of the relatively more limited discussion of "informed consent" directly (outside of the discussion in *Rogers v Whitaker* and other cases above, which were more so pointed towards the level of information a Doctor should have to give at risk

[15] *Collins v Wilcock [1984]* 1 WLR 1172, 1177 (Robert Goff LJ).
[16] *Blackstone's Commentaries,* 17th ed. (1830), vol. 3, p 120.
[17] I remember when I was in Uni, during one of the first lectures of a particular unit, one of the most pompous members of my class proceeded to brag to everyone about how Blackstone was his great grandfather. To a brown kid from a housing commission in the Western Suburbs, it was absolutely hilarious to be so proud of such a thing.
[18] (Mason CJ, Dawson, Toohey and Gaudron JJ).
[19] *Marion's Case,* 253 (Mason CJ, Dawson, Toohey and Gaudron JJ)

of being held negligent, rather than the status of informed consent as some kind of enshrined right, and even more particularly the legality or otherwise of informed consent being dismissed or cast aside somehow via Government directions).

As you may know, AFL Solicitors have tried to submit a version of the above argument in *AL-Munir Kassam And Ors v The Hon Bradley Ronald Hazzard MLA and ORD* [CLD 2021/24960] (**Annexure A**) at paragraph 73, in relation to whether vaccination violates a person's right to bodily integrity, they submitted that:

> Requiring a person to receive a vaccine constitutes a violation of a person's right to bodily integrity. *In Hart v Watt (2015)* A Crim R 221, Pritchard J held that '[a] requirement for a person to undergo a blood test, or to provide a mouth swab, constitutes an interference with that person's right to bodily integrity'. If this is accepted, then an injection of a vaccine being analogous to a blood test, and more invasive then a mouth swab, it would seem that a requirement that an individual receive a vaccine would constitute a violation of a person's right to bodily integrity. Vaccination is a medical procedure. Removing an individual's ability to consent to such a procedure is a departure from the general system of law. Therefore, a requirement that an individual be vaccinated breaches a person's fundamental right to bodily integrity, and therefore, cannot be a reasonable exercise of a discretionary power.

The decision in that case, currently reserved, will be instructive re the Court's attitude towards this argument. Though, for reasons express below, I can see the Court bypassing the argument entirely.

What is the Counter-Argument to this idea?

The counter-argument to this idea (as expressed by the State in their submissions in reply – **Annexure B**) is twofold: first, the authority that the Principle of Legality "can at most have limited application in the construction of legislation which has amongst its objects or purpose the abrogation or curtailment of that particular right, freedom or immunity in respect of which the principle is sought to be invoked".[20]

Second, that the Public Health Orders do not actually mandate vaccination, and therefore do not actually breach bodily integrity (or authorise a breach of it), but only encourage it through setting a condition which you must meet in order to do something. In their words, they say:

> First, it asserts in particular that the Delta Order has the effect of "mandating that a particular sub-group undertake a medical procedure". But nowhere does the Delta Order mandate that any person receive a COVID-19 vaccination. Rather, the Delta Order imposes a blanket prohibition on doing particular things (eg. leaving an area of concern, or entering a construction site or a workplace where disability support is provided), but then offers an exemption from that prohibition for any person who chooses to obtain a vaccination. The vaccination requirement is a condition on being able to obtain that exemption. No doubt that incentivises vaccination, but it does not mandate it. Choosing not to obtain a vaccination is not a breach of any part of the Delta Order.

Overall, the State's argument is an example of why the concept of informed consent is more helpful to us than that of bodily integrity. The State is right to say, albeit pedantically, that the Delta order (and s7 of the PHA for that matter) do not vitiate bodily integrity in and of themselves.

[20] [2021] FCA 1075, [82]-[83] (citations omitted), and see [79]-[83].

They do, however, vitiate informed consent, because they create an environment where it is impossible to give it.

So, if we can substantiate informed consent as some kind of lawful authority, it could form the basis of a powerful argument. Unfortunately, as discussed above, such lawful authority isn't easy to pin down.