AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

FACT SHEET
for clinicians

Informed consent in health care

Informed consent is a person's decision, given voluntarily, to agree to a healthcare treatment, procedure or other intervention that is made:

- Following the provision of accurate and relevant information about the healthcare intervention and alternative options available; and
- With adequate knowledge and understanding of the benefits and material risks of the proposed intervention relevant to the person who would be having the treatment, procedure or other intervention.

Ensuring informed consent is properly obtained is a legal, ethical and professional requirement on the part of all treating health professionals and supports person-centred care. Good clinical practice involves ensuring that informed consent is validly obtained and appropriately timed.

Informed consent is integral to the right to information in the **Australian Charter of Healthcare Rights**, and recognised in **Professional Codes of Conduct**. Additionally, the **National Safety and Quality Health Service Standards** require all hospitals and day procedures services to have informed consent processes that comply with legislation, lawful requirements and best practice.

Informed financial consent is an important but separate consent process. Consumers required to pay directly for health services should be consented before receiving care.

Key principles for informed consent

- Other than in exceptional circumstances, adults have the right to determine what will be done to their bodies and what healthcare treatments and interventions they will undergo
- Where a person lacks legal capacity, the framework for obtaining substitute consent that applies in each state or territory must be used to obtain consent to treatment
- Any healthcare treatment, procedure or other intervention undertaken without consent is unlawful unless legislation in a state or territory, or case law, permits the treatment, procedure or other intervention without consent. For example, treatment provided in an emergency, or for certain mental health interventions
- Healthcare providers have a duty to warn about the material risks[1] of the treatment, procedure or other intervention as part of obtaining a person's consent. Failure to adequately warn a person of these risks is a breach of the healthcare provider's duty of care
- A person has the right to refuse treatment (with some legislated exceptions) or withdraw consent previously given prior to treatment
- It is important to contemporaneously document consent discussions and include written consent forms (where appropriate) in the person's healthcare record
- Any healthcare treatment, not just operations and other procedures, requires valid consent either verbally, written, or implied. This includes prescribing drugs and other therapeutic substances.

How to obtain valid informed consent

Informed consent is achieved through a process of communication, discussion, and shared decision making. It involves understanding the person's goals and concerns, and discussing with the person (or their substitute decision-maker) their options for treatment, the potential outcomes (positive, negative and neutral), risks and benefits and what this might mean for them. The person or their substitute decision-maker will make an informed decision based on this information.

For there to be valid informed consent, the person consenting must:

- Have the legal capacity to consent
- Give their consent voluntarily
- Give their consent to the specific treatment, procedure or other intervention being discussed
- Have enough information about their condition, treatment options, the benefits and risks relevant to them, and alternative options for them to make an informed decision to consent. This includes the opportunity to ask questions and discuss concerns.

1 *Material risks* are risks where a "reasonable person, in the position of the person being recommended the treatment or procedure, is warned of the risks that they would likely attach significance to; or if the healthcare provider is or should be reasonably aware that the particular person if warned of the risk, would likely attach significance to it" – Rogers v Whitaker (1992) 175 CLR 479

A person can give consent expressly (in writing or verbally) or it can be implied. Consent by a person must be in writing when required by law or by the policies of the state, territory or healthcare organisation where the person is receiving care and treatment. The most appropriate form of consent will depend on the degree of risk and complexity of the treatment for that person.

Considerations include:

- The degree of significance of the treatment, procedure or intervention in terms of outcomes for the person
- The potential risks and benefits
- The shorter and longer-term consequences for the person
- The complexity of the treatment, procedure or intervention
- The characteristics of the person giving consent.

The need to obtain informed consent may be required at different stages over the course of a treatment pathway, including prior to giving treatment or undertaking a medical examination.

KEY POINTS:

- **Check if an interpreter, or other communication aid, is needed**
- **Tailor your information to ensure it is understandable and sufficient**
- **Allow sufficient time for the person to consider the information and an opportunity for them, or their support people, to ask questions and raise any concerns. In more complex or higher risk cases, this may require discussion over more than one consultation**
- **Check that the person understands the information provided**
- **It is expected professional practice to have informed consent documented in writing by way of a signed consent form, or notes in the healthcare record, for all healthcare interventions other than the most minor of healthcare interventions. Consent can be reasonably implied by a person's actions, for example taking a person's blood pressure if the person is holding out their arm**
- **Examples of interventions where a written consent form is recommended include: operations and procedures requiring some form of sedation or anaesthesia; or the prescribing and administering of therapeutics that are newly developed, experimental or have known high risk complications.**

Principles for assessing legal capacity

Legal capacity is assessed in respect to the particular decision on treatment to be made, and at the time when consent is sought. The person needs to be able to understand the nature and effect of the decision to consent, and demonstrate their understanding by communicating this in some way.

Informed consent relies on skilled and knowledgeable healthcare providers who can effectively communicate and partner with the person they are providing care to, to ensure they fully understand and agree to the healthcare treatment, procedure or other intervention.

If a person has difficulty in demonstrating this level of capacity, you should first work out the reasons for their difficulty. This may include reasons other than lack of capacity, such as health literacy; cultural differences; education levels; or physical issues (for example hearing or speech impairment).

Information must be presented in ways that overcome these difficulties. A person should be given the opportunity to choose a support person, such as a carer, to be part of discussions.

A person has legal capacity to make a particular decision when they are able to do all of the following:

- Understand the facts involved
- Understand the treatment choices
- Understand how the consequences of treatment affect them
- Retain the information and recall the details
- Weigh up the consequences of those choices, including the choice to refuse treatment
- Communicate their decision and understanding of its implications.

Understanding your legal obligations

There is case law in Australia about informed consent.

Each state and territory also has guardianship and/or medical treatment legislation about capacity and consent.

This legislation is different in each state and territory, and can be complex.

Informed consent to the medical treatment of minors is also required. There are special considerations for minors including determining when a minor is able to give informed consent on their own account, and when informed consent must be given by the relevant parent or guardian.

It is the responsibility of all healthcare providers to know and understand their legal obligations in whichever state or territory they are practising.

Where the person who will be undergoing treatment is unable to give consent, healthcare providers need to be fully aware of the legal requirements for proceeding with the treatment (for example in an emergency), or obtaining substitute consent, and whether the person who will undergo the treatment objects to such treatment, prior to providing or administering the treatment or procedure.

All healthcare providers should make careful and, if indicated, regular assessments of the capacity of the person to whom they are providing care, to ensure there is valid consent to treatment. It is important for caregivers to also be aware of their legal obligations regarding consent.

When in doubt healthcare providers or caregivers should contact the responsible guardianship authority in their state or territory. See **Further information** for contact details.

MORE INFORMATION ON STATE AND TERRITORY LAWS:

For a good overview and more information about capacity, consent and advanced care planning in each state and territory, visit End of Life Law in Australia and Advanced Care Planning Australia. The Royal Australian and New Zealand College of Psychiatrists has also provided a useful comparison of mental health legislation across the different states and territories.

This fact sheet is for general information purposes and is not a substitute for professional legal advice in individual circumstances and cases.

Further information

State and territory contacts details:

State/territory	Contact
ACT	Public Trustee and Guardian **02 6207 9800** **www.ptg.act.gov.au**
NSW	NSW Civil & Administrative Tribunal Guardianship Division **1300 006 228** and press **2** **13 14 50** (interpreter service) Email: **gd@ncat.nsw.gov.au** **www.ncat.nsw.gov.au**
NT	Office of the Public Guardian **1800 810 979** Email: **public.guardian@nt.gov.au** **http://publicguardian.nt.gov.au**
QLD	Office of the Public Guardian **1300 653 187** Email: **publicguardian@publicguardian.qld.gov.au** **www.publicguardian.qld.gov.au**

State/territory	Contact
SA	South Australian Civil and Administrative Tribunal **1800 723 767** Email: sacat@sacat.sa.gov.au www.sacat.sa.gov.au
TAS	Guardianship and Administrative Board Tasmania **1300 799 625** Email: guardianship.board@justice.tas.gov.au www.guardianship.tas.gov.au
VIC	Office of the Public Advocate **1300 309 337** mail: opa_advice@justice.vic.gov.au www.publicadvocate.vic.gov.au
WA	Office of the Public Advocate **1300 858 455** or **08 9278 7300** Email: opa@justice.wa.gov.au www.publicadvocate.wa.gov.au

Commission resources

- NSQHS Standards Implementing the colonoscopy clinical care standard – informed consent
- Advisory – AS18/10: Informed financial consent
- Helping patients make informed decisions: communicating risks and benefits (e-learning module)
- Shared decision making resources
- Health literacy resources
- A better way to care (second edition)

Other resources

- Health Translations Directory - Tools for professionals, Centre for Culture, Ethnicity and Health
- End of life Law in Australia – Australian Centre for Health Law Research: Capacity and Consent to Medical Treatment
- Avant Mutual (insurers) – Consent: the essentials
- Advanced Care Planning Australia

Questions?

For more information, please visit:
safetyandquality.gov.au/informed-consent

You can also email the Communicating for Safety team at comms.forsafety@health.gov.au

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