



## Short title: Informed consent

### 1. Purpose

The purpose of this statement is:

- 1.1 To support compliance with regulatory and jurisdictional requirements.
- 1.2 To assist practitioners in understanding the process of informed consent.
- 1.3 To promote best practice in obtaining consent.

### 2. Scope

This document is intended to apply to:

- 2.1 All anaesthetists administering anaesthesia to a patient.
- 2.2 All other registered practitioners providing sedation services.

### 3. Definitions

For the purposes of this document:

- 3.1 **Anaesthesia** – includes general anaesthesia, major regional anaesthesia, and (IV or parenteral) sedation.
- 3.2 **Anaesthetist** – registered specialist anaesthetist, SIMG, vocationally registered (NZ only), anaesthesia trainee, JCCA credentialed GP.
- 3.3 **Sedationist** – any practitioner administering sedation within their scope of practice.
- 3.4 **Patient** refers to the patient or person with legal powers to consent on behalf of the patient.

### 4. Background

It is a legal requirement in both Australia and New Zealand to obtain consent for all medical treatment. It is a basic tenet of our society that everyone has a right to determine what is done to their own body and is entitled to know the implications of any treatment before it is administered, and seek clarification of any issues that may be of concern. Respect for patient autonomy and provision of relevant information are the cornerstones of consent.

The standard for consent in Australia is established by the common law. In New Zealand doctors are referred to the Code of Health and Disability Services Consumers' Rights (the Code). Although legal processes that test the validity of consent differ, both Australian and New Zealand law state that the provision of information is an integral part of obtaining consent for a medical procedure. This document should be read in conjunction with the relevant standard for the country in which one is practising. In particular, New Zealand doctors are bound by "the Code".

A statement as to the necessity for anaesthesia, which may form part of the consent for an operative procedure, does not constitute informed consent for anaesthesia.

The process of consent for medical treatment is one of shared decision making and agreement to treatment that involves discussion in which both the patient and the anaesthetist/sedationist participate actively and openly. The process should be open, honest, and effective from both the anaesthetist/sedationist and patient's perspective.

The statements below are a general guide, and do not take precedence over local legal requirements. The term “must” is used in this document to reflect any legal requirements rather than any college mandate.

## 5. The elements of consent

5.1 Consent must be given voluntarily without coercion. The environment, timing of the consent process<sup>1</sup>, and presence of support people are important considerations.<sup>2</sup>

- Where urgency permits there needs to be sufficient time to consider, review, and seek advice relating to matters discussed.
- The time pressure associated with high turnover day stay procedures resulting in abbreviated consultations is acknowledged, however, the essential process of consent nonetheless still applies.

5.2 Consent may be given only by persons competent to do so.

5.2.1 All persons are presumed to be competent to give consent, unless there are reasonable grounds for believing otherwise. A judgement that the patient is incapable of giving consent must be supported by evidence, such as a known diagnosis of dementia or certification of incapacity with an appointed person having medical power of attorney. Where patients are of very young age, have diminished mental capacity, are unconscious or under the influence of sedative medication, they may not be capable of providing informed consent.

5.2.2 The age at which a young person is able to consent independently to medical treatment depends on the nature of the proposed treatment and local legislative requirements. To be able to give consent, the young person must be able to understand the nature, purpose and possible consequences of the treatment, as well as the consequences of non-treatment. If in any doubt, consult relevant management representatives or legal advisers.

5.2.3 In the absence of capacity to give consent, another person can give consent on behalf of the patient in circumstances that are legally defined, such as the parent or legal guardian of a child or designated legal authority for an adult. In such circumstances, the person giving consent has a legal duty to always act in the best interests of the person for whom consent is being given.

5.2.4 For patients treated in Australia, if no person is able to give consent, then treatment can proceed only if all of the following are satisfied<sup>3</sup>:

- 5.2.4.1 It is in the patient's best interests.
- 5.2.4.2 Reasonable steps have been taken to ascertain the views of the patient.
- 5.2.4.3 The doctor believes that it would have been the patient's choice had they been competent to do so.
- 5.2.4.4 The doctor takes into account the views of other persons with a genuine interest in the welfare of the patient.
- 5.2.4.5 Any delay is likely to be detrimental to the patient.

Legal advice should be sought to guide actions, especially where it may be necessary to arrange for a legal guardian to be appointed.

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<sup>1</sup> Refer to *PS07 Guideline on the pre-anaesthesia consultation and patient preparation* for further details.

<sup>2</sup> These matters are addressed differently in New Zealand and doctors treating patients in New Zealand must follow the Code of Health and Disability Services Consumers' Rights (the Code). A basic principle of the code is that consumers have rights and providers have duties.

<sup>3</sup> Item 5.2.4.5 does not apply in New Zealand. For details specific to the legal requirements for practice in New Zealand reference should be made to the Code.

For patients receiving treatment in New Zealand where no person is able to give consent doctors must follow the Code “Right 7(4)”.

- 5.2.5 If the situation is so urgent that immediate intervention is necessary to preserve life or prevent serious harm, it may not be possible or sensible to obtain full consent. In such cases, there must be provision of information and discussion of the treatment undertaken with the patient, or other responsible persons, as soon as possible.
- 5.2.6 In some circumstances, statutory bodies, such as a Guardianship Board, or the Office of the Public Advocate (Australia only and State dependent), may give consent or authorise others to give consent.
- 5.2.7 It must be recognised that any patient can change their mind, and withdrawal of consent at any time must be respected (e.g. during multiple attempts at regional blockade).

### 5.3 Consent must be informed.

The nature and extent of information should be determined by consideration of all factors relevant to any particular patient. In this context it is reasonable to advocate for rational application of the consent process as opposed to providing all patients with exhaustive information that is either not applicable to them, results in overload and loss of perspective, or has no bearing on their outcome.

- 5.3.1 It is a legal requirement that patients are provided with the information that a reasonable person in the position of that patient might wish to know, and to which they might attach significance. It is necessary to provide information about all material risks<sup>4</sup> inherent in any proposed treatment. This should include advice regarding any interactions between medications being taken by patients and those administered as part of anaesthesia management (refer accompanying background paper).

Therefore, in deciding which risks to disclose the doctor should attempt, as much as is practicable, to view the procedure from the patient’s perspective. Necessarily, this will be an individual judgement based on what is reasonably known about the person before them and will be made within the particular circumstances of the consultation.

- 5.3.2 Basic information about the proposed treatment should be provided, even if the patient requests no information. Where any patient clearly does not wish for further information, and states this wish, confirmation should be sought and documented, without further forcing information on them<sup>5</sup>.
- 5.3.3 The discussion of risks and benefits should include those associated with the proposed treatment, alternative treatments, or no treatment at all.
- 5.3.4 Where there may be financial implications of the proposed treatment these also need to be discussed as part of the consent process.
- 5.3.5 In considering risks to be discussed with patients, the two fundamental questions to answer are:
  - 5.3.5.1 Whether a reasonable person, in the position of the patient, would be likely to attach significance to the risk.

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<sup>4</sup> The High Court of Australia has said that material risks are those risks to which a reasonable person in the patient’s position or that particular patient would attach some significance; and that the medical practitioner is or should be reasonably aware of the particular patient if warned of the risk, would be likely to attach significance to it (Refer to item 16 in the Judgement, p.8-9).

<sup>5</sup> In New Zealand the law pertaining to “the right NOT to know” has not been tested in an appellate court and consequently remains uncertain.

5.3.5.2 Whether the particular patient would be likely to attach significance to that risk. In other words, is it possible that the patient, if informed of that risk, would change their mind about having the procedure?

#### 5.3.6 Risks

5.3.6.1 Discussion of risks should be based on the provider's assessment of the proposed treatment, the seriousness and nature of the patient's condition, the complexity of the proposed treatment, the questions asked by the patient, and the patient's attitude and apparent level of understanding.

5.3.6.2 Known risks should be explained when an adverse outcome is rare but the detriment severe, and an adverse outcome common but the detriment slight.

5.3.6.3 Where applicable, the uncertainty of adverse outcomes/events should be explained, as should the difficulty of relating the incidence of such events to the patient (see Appendix 1).

5.3.6.4 Where blood products may be required, discussion should take place concerning the advantages, disadvantages and alternatives to blood products.

5.3.6.5 The risk of alternative options such as modifying the procedure or even doing nothing should also be discussed, where relevant.

5.3.6.6 It is important that patients be given the opportunity to discuss the nature and risks of the treatment, and the alternative treatment(s), and to have questions answered honestly and accurately.

5.3.7 Information should be provided in a form that the patient is likely to understand. This may include the option of presenting information in printed form or via computer or other electronic means (e.g. by video). Printed and visual aids are useful. Prepared information sheets or "consent forms" can help understanding but are not a substitute for any discussion with the patient.

#### 5.4 Advanced Care Directives (ACD)/Advanced Directives<sup>6</sup> and End-of-Life Directives

Since the last review in 2005, the community has been encouraged to prepare Advanced Care Directives, the uptake of which has been increasing. These are essential documents of legal standing, containing information that must be considered when deciding on treatment and when discussing risks with patients. Specific requirements must be met for ACDs to be in effect and there are numerous factors that need to be considered (refer to accompanying background paper).

The existence of ACDs should be confirmed preoperatively so that they can be consulted and incorporated into the consent process. While these differ from End-of-Life Directives the latter are also relevant and must be considered and respected.

## 6. Documentation of consent

The extent of documentation may be dictated by local legislation and practice, but it is wise<sup>7</sup> to record significant details of the consent as part of the patient's notes, including reference to the discussion of relevant material risks and the agreement by the patient to undergo the treatment.

Documentation should also include reference to the presence of any ACD or discussion of End-of-Life Directives.

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<sup>6</sup> New Zealand uses the term 'Advanced Directives' and the relevant information is contained within Right 7(5).

<sup>7</sup> In New Zealand it is a legal requirement under Right 7(6) of the Code to have written consent if a consumer in New Zealand will be under general anaesthetic.

In order to defend claims that “informed consent” information was not given or was inadequate, it is highly recommended that detailed notes of the discussion and all risks considered are kept by the provider.

## **7. Standard consent forms and information sheets**

The use of standard “consent forms” and information sheets will not necessarily be sufficient to satisfy “informed consent” in specific circumstances. Standard information forms are useful but no substitute for the provision of information to individual patients. Under the requirements of “informed consent”, the information to be given to patients should be specific to the particular patient. It should take into account the particular circumstances, and requirements, of the patient.

Similarly, a simple form signed by a patient is not conclusive proof that valid consent has been obtained. The process of valid informed consent revolves around the discussions between the doctor and patient, rather than the presence of a signature.

Prepared consent forms and prepared information sheets have their place and can be used as an aid or educational tool, as well as a prompt or checklist for the discussion that must take place between doctor and patient. They are also useful for the patient to take away a copy after the discussion, as a reminder of some of the issues that have been considered. However, they are not, in themselves, adequate to ensure that informed consent has been obtained.

## **8. Personnel**

- 8.1 Disclosure of information and discussion is best performed by a person who understands and is able to discuss the risks and benefits of the proposed treatment and the alternative treatments, which includes no treatment.
- 8.2 In Australia, a qualified interpreter (not a family member) should be actively encouraged wherever necessary in patients who are non-English speaking or have limited English. In New Zealand, where increasing proportions of patients and staff speak Te Reo or NZ Sign, this issue is addressed in the code “Right 5(1)”.
- 8.3 Ideally, disclosure of information and discussion is best performed by the anaesthetist/sedationist who will be conducting the treatment as the liability for consent lies with the treating doctor.
- 8.4 When the procedural anaesthetist can only see the patient immediately prior to anaesthesia or sedation, a separate anaesthetist may consult with the patient and provide information for the elements of consent noted above.
- 8.5 The procedural anaesthetist should still discuss the proposed treatment with the patient to ensure that all appropriate preparation has occurred. The need for this discussion should be considered when sedative premedication is to be given.
- 8.6 Those involved with the consent process are individually responsible for documentation.

## Appendix 1

Examples of risk which might be discussed with the person giving consent include:

- a) Common adverse effects of general anaesthesia, which include fatigue, altered mental state (including delirium in older patients), sleep disturbance, nausea, vomiting, sore throat, bruising from venepuncture.
- b) Less common but not rare adverse effects such as spinal headache and dental trauma.
- c) Rare adverse effects which are unpredictable, such as anaphylaxis, awareness, neurological damage or death in healthy people.
- d) Adverse effects which are related to pre-existing disease, such as death in a patient with recent myocardial infarction undergoing emergency surgery.

### Related ANZCA documents

The information provided in this Position Statement should be considered in conjunction with the following College Professional Documents:

PG06(A) Guideline on the anaesthesia record

PG07(A) Guideline on pre-anaesthesia consultation and patient preparation

**This document is accompanied by a background paper (PS26(A)BP) which provides more detailed information regarding the rationale and interpretation of the Position Statement.**

### Further reading

Medical Board of Australia. Good medical practice: a code of conduct for doctors in Australia. [Internet]. 2020 Oct. Available from: <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx>

Medical Council of New Zealand. Information, choice of treatment and informed consent. [Internet]. 2011 Mar. Available from: <https://www.mcnz.org.nz/assets/standards/edc0457381/Information-choice-of-treatment-and-informed-consent.pdf>

Medical Council of New Zealand. Cole's medical practice in New Zealand. [Internet]. 2017 Nov. Available from: <https://www.mcnz.org.nz/assets/standards/da3a9995b9/Coles-Medical-Practice-in-New-Zealand.pdf>

Medical Council of New Zealand. Statement on best practices when providing care to Maori patients and their whanau. [Internet]. 2006 Aug. Available from: <https://www.mcnz.org.nz/assets/standards/2afd3f32b0/Statement-on-best-practices-when-providing-care-to-Maori-patients-and-their-whanau.pdf>

Health and Disability Commissioner. The code of health and disability services consumers' rights. Regulations 1996. [Internet]. 2014. Available from: <https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/>

Yentis SM, Hartle AJ, Barker IR, Barker P, Bogod DG, Clutton-Brock TH, et al. AAGBI: Consent for anaesthesia 2017: Association of Anaesthetists of Great Britain and Ireland. *Anaesthesia*. 2017 Jan; 72(1):93-105.

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Promulgated: 1994  
Reviewed: 1999, 2005  
Current document: Apr 2021

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