

# **DRAFT Informed consent practice standard**

## Foreword

### Standards framework

The Dental Council (the Council) is legally required to set standards of clinical competence, cultural competence and ethical conduct to be observed by all registered oral health practitioners (practitioners).<sup>a</sup> This means that compliance to the Council's standards by practitioners is mandatory.

The Council has established a standards framework which defines the ethical principles, professional standards, and practice standards that all practitioners must meet.

There are five ethical principles that practitioners must adhere to at all times.

Practitioners must:

- put patients' interests first
- ensure safe practice
- communicate effectively
- provide good care
- maintain public trust and confidence.

Each of the five ethical principles is supported by a number of professional standards which articulate what a practitioner must do to ensure they achieve the ethical principles. The professional standards are, in turn, supported by practice standards which relate to specific areas of practice that require more detailed standards to enable practitioners to meet the professional standards and ethical principles.

A copy of the standards framework is available on the [Council's website](#).

### Compliance

The standards set by the Council are minimum standards which are used by the Council, the public of New Zealand, competence review committees, professional conduct committees, the Health and Disability Commissioner, the Health Practitioners Disciplinary Tribunal, and the courts to measure the competence, performance, and conduct of practitioners.

A failure to meet the Council's standards and adhere to the ethical principles could result in Dental Council involvement and may impact on the practitioner's practice.

Sometimes factors outside of a practitioner's control may affect whether or not, or how, they can meet the standards. In such circumstances, practitioners are expected to adhere to the ethical principles, demonstrate insight and use their professional judgement to determine appropriate behaviour.

Practitioners must be able to justify their behaviour when this is contrary to the standards, and document their reasons.

<sup>a</sup> Oral health practitioners include dentists, dental specialists, dental hygienists, dental therapists, oral health therapists, clinical dental technicians, dental technicians, and orthodontic auxiliaries.

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## Introduction

This introduction provides commentary on the informed consent practice standard and context for the standards and guidance within it. It does not form part of the practice standard.

The informed consent practice standard contains:

- The Council *standards* (the standards) for informed consent that all registered oral health practitioners (practitioners) **must** meet. These are presented in the numbered coloured boxes -



The standards that practitioners must meet.

and

- *Guidance* which describes the actions and behaviour that enable practitioners to meet the minimum standards. If a practitioner does not follow the guidance, they must be able to demonstrate to the Council that they meet the standards.

This is presented in the grey-shaded boxes directly following the relevant standard -

### Guidance

- The actions and behaviour that enable practitioners to meet the minimum standards.

For convenience, the standards are listed at the beginning of the practice standard; the standards with guidance follow.

## Purpose

The purpose of the informed consent practice standard is to set minimum standards for the process of obtaining informed consent in oral health practice.

## Practitioners' obligations

Practitioners are legally and ethically obliged to obtain a patient's informed consent before providing care.

These obligations are set out in the Health and Disability Commissioner Code of Health and Disability Consumers' Rights Regulation 1996 (HDC Code of Rights), the Council's standards framework, and the informed consent practice standard.

The HDC Code of Rights provides that every consumer has the right to effective communication<sup>1</sup>; the right to be fully informed<sup>2</sup>; and the right to make an informed choice and give informed consent<sup>3</sup>.

<sup>1</sup> Right 5(1) Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996

<sup>2</sup> Right 6(1) Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996

<sup>3</sup> Right 7 Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996

The standards framework requires practitioners to put patients' interests first and communicate effectively by: giving patients the information they need, or request, in a way they can understand, so they can make informed decisions; ensuring informed consent remains valid at all times; and respecting the autonomy and freedom of choice of the patient.

The practice standard contains more detailed standards in this practice area which reflect patients' legal rights, and practitioners' legal and ethical obligations, as expressed in the HDC Code of Rights and the standards framework. Practitioners are advised to read the HDC Code of Rights in conjunction with the practice standard.

## Defining and understanding informed consent

The HDC describes informed consent as a *process* requiring effective communication between the practitioner and the patient (Right 5), provision of all necessary information to the patient (Right 6), and the patient's freely given and competent consent (Right 7).<sup>4</sup> It is not just the signing of a form, or the practitioner telling the patient what's best for them. It is an interactive process between a practitioner and a patient where the patient:

- gains an understanding of their condition
- receives an explanation of the possible options for care, including an assessment of the potential risks and side effects, benefits, and costs of each option—in a way they can understand
- has the opportunity to ask questions and discuss the information given to them.

On this basis, the patient can make an informed choice, and decide whether or not to give their consent.

The informed consent process acknowledges patients' rights to autonomy and freedom of choice—it recognises that patients have the right to make their own decisions about their health taking into account their own beliefs and values, their culture and family life, and make choices which are most appropriate to their own circumstances.

## Communication and partnership

Effective communication between the practitioner and the patient is fundamental to the informed consent process.

Every patient has the right to the information that a reasonable patient, in the patient's circumstances, would expect to receive<sup>4</sup>. Practitioners need to be sure therefore that patients receive all of the information they need and request to make an informed choice, and that they truly understand their condition and their options for care.

Practitioners can meet this obligation by working in partnership with their patients—by providing relevant, sufficient and balanced information, and by encouraging their patients to ask questions, discuss the various options, and express their views and preferences. This approach enables patients to understand their options and genuinely exercise their autonomy; and assists in achieving better outcomes.<sup>5</sup>

Informed consent is not a one-off event. It is an ongoing process of communication between the patient and practitioner which provides multiple opportunities for the patient to make informed decisions about their oral health, both before and within a period of care; and to give, withhold, affirm, or withdraw their consent.

While a practitioner may recommend a particular option for care they must not put pressure on the patient or coerce them into accepting their recommendation. The patient must be able to freely give or withhold their consent.

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<sup>4</sup> Right 6(1)Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996

<sup>5</sup> Office of Health and Disability Commissioner, *Informed choice- Not a matter of negotiation*

<http://www.hdc.org.nz/media/184508/informed%20choice%20not%20a%20matter%20of%20negotiation%20feb00.pdf>

## Competence

Every patient must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the patient is not competent<sup>5</sup>; this applies regardless of the patient's age.

Competence in the context of informed consent means the patient must be able to:

- understand the nature and purpose of the proposed care and the explanations given about the possible options—including the potential risks and side effects, benefits, and costs of each option
- weigh up that information as part of the process of making their choice
- understand that they are free to choose whether or not they give their consent (including the consequences of their decision to give or withhold consent)
- communicate their decision (whether by talking, using sign language or any other means).

Patients may lack competence for a number of reasons—they might be unconscious, or suffering from some temporary or permanent form of mental impairment; or be of an age or maturity level which limits their competence. A patient's competence may vary over time.

Practitioners must assess the patient's competence where there are grounds for believing their capacity to give informed consent may be impaired. Guidance in making this assessment is provided under Standard 6 of the practice standard.

When a patient is not competent or has diminished competence, the HDC Code of Rights requires that practitioners seek to involve someone in the informed consent process who is legally entitled to consent on the patient's behalf, and to obtain their consent before providing care.

This person may be:

- a parent, guardian, or carer with legal authority
- welfare guardian, appointed under the Protection of Personal and Property Rights Act 1988
- someone with enduring power of attorney for the patient's health and welfare.

Being a relative of the patient does not in itself give legal authority to consent on behalf of the patient.

Where a patient has diminished competence, that patient retains the right to make informed choices and give informed consent, to the extent appropriate to their level of competence; regardless of age.<sup>6</sup> This means that while someone with legal authority needs to be involved in the informed consent process and provide their consent, practitioners need to make every effort to encourage and enable the continued involvement of the patient in the informed consent process, to the extent their level of competence allows.

Under the Care of Children Act 2004 young people over the age of 16 have the right to give consent, or refuse to give consent, for any medical, surgical or dental treatment or procedures as if they were of full age.

A patient under the age of 16 may give consent to care without the need for a parent/guardian/carer's approval, provided they are able to understand the nature, purpose, and possible consequences of the proposed treatment as well as the consequences of refusing care.<sup>7</sup>

Practitioners are advised to carefully consider the situation where the patient under 16 years of age is deemed competent to give consent. Even though parental consent is not legally required, practitioners are advised to consider involving the

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<sup>5</sup> Right 7(2) Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996

<sup>6</sup> Right 7(3) Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Regulation 1996

<sup>7</sup> Ministry of Health *Consent in Child and Youth Health: Information for Practitioners*.

parent/guardian/carer in the informed consent process, and to gain their approval for care. In this event, it is expected that the patient will continue to be involved in the decision-making process.

## Expression of consent

Patients typically give oral or written consent.

Oral consent is considered sufficient when minor procedures are involved in the patient's care, and no sedation or general anaesthesia is used.

Written consent is advisable when the patient's care is complex and/or major procedures are involved; and is required in specific circumstances (see Standard 7).

Practitioners are reminded that regardless of the way in which the patient gives their consent, the integrity of the informed consent process relies on effective communication and working in partnership with their patients to ensure patients are fully informed and enabled to make a free and informed choice.

Practitioners are advised to include a summary of the discussions held during the informed consent process in the patient record.

## Acknowledgements

The informed consent practice standard is founded on a number of different sources, including the Health and Disability Services Consumers' Rights Regulation 1996, the New Zealand Dental Association's code of practice *Informed consent*, the Ministry of Health's *Consent in Child and Youth Health: Information for Practitioners*, Dental Protection's publication *Consent*, (Australia), and the Medical Council of New Zealand's *Information, choice of treatment and informed consent*.

# Informed consent practice standard



## List of standards

There are eight standards in the informed consent practice standard; these are listed below. The standards with associated guidance follow.

1	You must provide an environment that enables open, honest and effective communication.
2	You must give patients information in a way they can understand, and confirm their understanding, so they can make informed choices about their oral health.
3	You must ensure patients are fully informed during the informed consent process; and give honest and accurate answers to questions relating to their care.
4	You must obtain the informed consent of the patient before providing care, unless there is some other clear authority to treat.
5	You must ensure informed consent remains valid throughout the period of care.
6	<p>You must assess a patient's competence to give informed consent where there are grounds for believing their capacity may be impaired.</p> <p>When they are not competent or competence is diminished, you must wherever possible involve someone in the informed consent process who is legally entitled to consent on the patient's behalf and obtain their consent.</p> <p>Where no such person exists or is available to consent on behalf of the patient, provide care only when you can do so lawfully (in accordance with the HDC Code of Rights or under the doctrine of necessity).</p>
7	<p>You must have the written informed consent of the patient when:</p> <ul style="list-style-type: none"><li>• the patient is to participate in any research; or</li><li>• the procedure is experimental; or</li><li>• the patient will be sedated or under a general anaesthetic; or</li><li>• there is a significant risk of adverse effects on the patient.</li></ul>
8	You must respect the patient's right to refuse care and to withdraw their consent at any time; and accept their decisions without prejudice.

## Standards with guidance

1

You must provide an environment that enables open, honest and effective communication.

2

You must give patients information in a way they can understand, and confirm their understanding, so they can make informed choices about their oral health.

### Guidance

- Understand that you are responsible for ensuring effective communication takes place between yourself and your patients during the informed consent process.
- Approach the process of informed consent as a partnership which through open communication enables the patient to truly understand their options for care, and genuinely exercise their autonomy.
- Listen to your patients and treat them as individuals. Take their specific communication needs and preferences into account, respecting cultural values and differences.
- Support a patient's choice to have family, whānau or other support persons involved in the informed consent process. This may assist them in understanding the information being given and making an informed choice.
- Give information to patients in a form, language, and manner that enables them to understand the information being given to them. Use plain language, pitched at a level the patient understands; and use visual aids, diagrams or models as appropriate.
- Recognise communication barriers, and where necessary and reasonably practicable, arrange for a competent language or sign language interpreter, as appropriate.
- Be aware of your choice of words, tone of voice, and body language when communicating with your patients—patients may be unduly influenced by the way in which you communicate with them.
- Encourage your patients to ask questions and give them the opportunity to discuss with you the various options for care, and their preferences and concerns.
- Check whether your patient needs any additional support to understand information, communicate their wishes, or to make a choice; and assist in arranging this, as needed.
- Confirm your patients' understanding of the information given to them by using communication techniques such as the teach-back method, and engaging in discussion with them.
- Give your patients the time they need to consider the information you have given them, and your discussions; and allow them the time they need to make an informed choice.

You must ensure patients are fully informed during the informed consent process; and give honest and accurate answers to questions relating to their care.

### Guidance

- Provide the information the patient requests or needs to make an informed choice, including:
  - an explanation of their condition and the purpose of care
  - an explanation of the possible options for care, including their likelihood of achieving the purpose of care; the associated risks, side effects, and benefits—and their likelihood; and the costs of each option
  - possible consequences of not receiving care
  - who will be providing the care—this includes informing patients when aspects of the care are provided remotely, for example, laboratory services, radiograph interpretation and reporting, and orthodontic treatment planning
  - advice of the estimated time within which care will be provided
  - notification of any proposed participation in teaching or research, including whether the research requires and/or has received ethical approval
  - the results of tests, procedures, and findings.
- Do not make assumptions about the information the patient might want or need—encourage questions and engage in discussion with your patients to ensure they have all of the information *they feel they need* to make an informed decision.
- Be sure to explain all of the possible options for care; do not make assumptions about how the patient might view the affordability or the value of particular options.
- Provide relevant, accurate and balanced information. Assess any written material you give to your patients to ensure it does not create a one-sided picture which downplays risks and limitations; over-emphasises benefits; or unduly criticises other treatment options.
- Answer any questions your patient has related to their care honestly and accurately, including questions about:
  - the identity, qualifications, and experience of the practitioner providing the care
  - the recommendations you have given
  - how the patient can get an opinion from another practitioner
  - the results of research
  - the source of materials used in the construction and repair of fixed or removable dental appliances and prostheses.

- Provide a written summary of the information provided when this is requested by the patient, or when you or the patient considers this would be helpful, for example, when the care is complex and/or the timeframe for care is long.
- Make sure the patient is aware of their right to seek a second opinion; in particular where the options for care are complex and/or involve major procedures, where the care is experimental, or where there is a significant risk of adverse effects on the patient.
- Inform the patient if care is to be provided by a student practitioner, and obtain the patient's written consent for this circumstance.
- Respect the patient's right to express a preference as to who will provide care, and meet that preference where practical.

4

You must obtain the informed consent of the patient before providing care, unless there is some other clear authority to treat.

5

You must ensure informed consent remains valid throughout the period of care.

### Guidance

- Recognise and respect the right of the competent patient to make an informed choice and give informed consent before you provide care for them.
- Recognise that when the patient is not competent or has diminished competence, someone who is legally entitled to give consent on behalf of the patient needs to be involved in the informed consent process and give their consent before you provide care.

When no such person exists or is available, meet the requirements of Standard 6.

- Do not put pressure on anyone, or coerce them into giving their consent; consent must be given freely
- Recognise that in an emergency medical situation, where immediate treatment is necessary to prevent serious and imminent injury to a patient's health, obtaining informed consent may not be possible and care may be provided under the doctrine of necessity.

The doctrine of necessity is a common law defence which justifies the provision of treatment where a practitioner believes in good faith, on grounds which are objectively reasonable, that treatment is necessary in order to preserve human life, or to prevent serious physical harm. It is typically applied in emergency treatment situations.

- Understand that any patient over the age of 16 years of age has the right to consent, or refuse to give consent, as if they were of full age; even if they are not paying for their treatment.

- When the patient is under 16 years of age and is deemed competent, consider involving the parent/guardian/carer in the informed consent process, and gain their approval for care—even though this is not legally required. In this event, make sure you continue to involve the patient in the decision-making process.
- Make every effort to encourage and enable patients of any age with diminished competence to be involved in the informed consent process; they retain their right to make informed choices and give informed consent to the extent appropriate to their level of competence, regardless of age.
- Do not assume that consent given by a parent/guardian/carer, or anyone else with legal authority to give their consent, necessarily implies consent by a child or an adult with diminished competence. Encourage discussion between the parties to reach a consensus before providing care, where appropriate and practical.
- Be sure that at all times, the care you obtained consent for is the care that you provide. If care is wrongly provided that has not been consented to, the informed consent that was obtained is not considered 'valid'.
- Seek the patient's informed consent when a change to the planned and consented to care is needed, for example, as a consequence of a change in the patient's condition or when the anticipated outcome of care has not been achieved.
- In the event that a change of practitioner is necessary during a period of care, obtain the patient's consent for this change and confirm their consent for the planned care before proceeding.
- Recognise that for informed consent to be valid throughout the period of care, an ongoing process of communication is required between yourself and your patient that keeps them fully informed regarding their condition and the progress of care. This provides them with multiple opportunities to review and re-assess their choice, and to affirm or withdraw their consent for care. This is particularly relevant for treatment with long timeframes, such as orthodontic care.
- Respect the patient's right to decide about the return or disposal of any body parts or bodily substances removed or obtained during care; offer to return a patient's extracted teeth to them.
- Keep an accurate and contemporaneous written record of the discussions held in the informed consent process; and document the patient's oral consent when this is given.
- Where consent is obtained from or involving a welfare guardian or the holder of an enduring power of attorney, ensure you retain a copy of the Court Order appointing the welfare guardian, or as the case may be, the enduring power of attorney, on the patient file together with a record of what was agreed.

## 6

You must assess a patient's competence to give informed consent where there are grounds for believing their capacity may be impaired.

When they are not competent or competence is diminished, you must wherever possible involve someone in the informed consent process who is legally entitled to consent on the patient's behalf and obtain their consent.

Where no such person exists or is available to consent on behalf of the patient, provide care only when you can do so lawfully (in accordance with the HDC Code of Rights or under the doctrine of necessity).

### Guidance

- Presume that the patient is competent to make an informed choice and give informed consent, unless you have reasonable grounds for believing otherwise.
- In assessing the patient's competence to give informed consent, ask yourself:
  - Is the patient able to understand the purpose of the proposed care and the explanations given about the possible options, including the associated risks, side effects, benefits, and costs?
  - Is the patient able to weigh up that information as part of the process of making their choice?
  - Can the patient understand that they can choose whether or not they give their consent for care?
  - Is the patient able to communicate their decision?
- Understand that the patient's ability to make an informed choice and give consent may vary over time and may be influenced by factors such as the complexity of the information they are being asked to consider, their age, their level of maturity, and their mental, physical and emotional state.
- Be aware of the potential effect prescribed medicines and illicit drugs may have on the patient's ability to understand and process information.
- Take all reasonable steps to support the patient in making an informed choice for themselves before deciding they are not competent, or their competence is diminished. This may include revised explanations of the options for care; or the involvement of family, whānau or other support persons, with the patient's permission.
- Do not consider the patient is not competent to give informed consent simply because they disagree with your recommendation for care or refuse to give their consent.
- Recognise that the seriousness of the patient's condition and the gravity of the proposed care are important considerations in assessing whether the patient is competent to give informed consent.

For example, a child of 14 may be considered competent to give their consent for an examination, scale and polish, but not competent when they need to weigh up options for care that involve pulp treatment versus extraction. The same clinical example may also be applicable to a patient affected by dementia.

- Contact someone who is legally entitled to consent on the patient's behalf and involve them in the informed consent process when the patient is not competent or has diminished competence, and obtain their consent before providing care.

This may be a parent/guardian/carer, a welfare guardian (appointed under the Protection of Personal and Property Rights Act 1988), or someone with enduring power of attorney for the patient's personal care and welfare. Someone who is just a relative of the patient does not have the legal authority to consent on behalf of the patient.

- In accordance with Right 7.4 of the HDC Code of Rights, when the patient is not competent to give informed consent and it is not possible to involve someone in the informed consent process who is legally entitled to consent on the patient's behalf, you may provide treatment where:
  - a) It is in the best interests of the patient; and
  - b) You have taken reasonable steps to ascertain the views of the patient; and
  - c) Either,-
    - i) Having ascertained the patient's views and having regard for them, you believe, on reasonable grounds, that providing the care is consistent with the informed choice the patient would make if they were competent; or
    - ii) Having been unable to ascertain the patient's views, you take into account the views of other suitable persons who are interested in the welfare of the patient and are available to advise you.

A flow diagram which may assist practitioners in meeting these obligations is provided as Appendix A.

7

You must have the written informed consent of the patient when:

- the patient is to participate in any research; or
- the procedure is experimental; or
- the patient will be sedated or under a general anaesthetic; or
- there is a significant risk of adverse effects on the patient.

## Guidance

- Additionally, obtain written consent when the patient's care is complex and/or involves major procedures OR when you are uncertain as to whether the care involves minor or major procedures, and/or is complex.
- Avoid the use of standardised forms or templates when obtaining written consent, particularly those from international sources where the legal requirements for consent may differ from those in New Zealand.

- Develop written information specifically for the patient's circumstances using language that is readily understandable and that at minimum, covers:
  - an explanation of the patient's condition and the purpose of care
  - an explanation of the possible options for care, including their likelihood of achieving the purpose of care; the associated risks, side effects, and benefits—and their likelihood; and the costs of each option
  - possible consequences of not receiving care
  - advice of the estimated time within which care will be provided
  - the option to which the patient has agreed.
- Be aware that obtaining the patient's written consent does not lessen your responsibilities for the outcomes of care.
- Where care is to be delivered by a student practitioner, obtain the written consent of the patient for this circumstance.



8

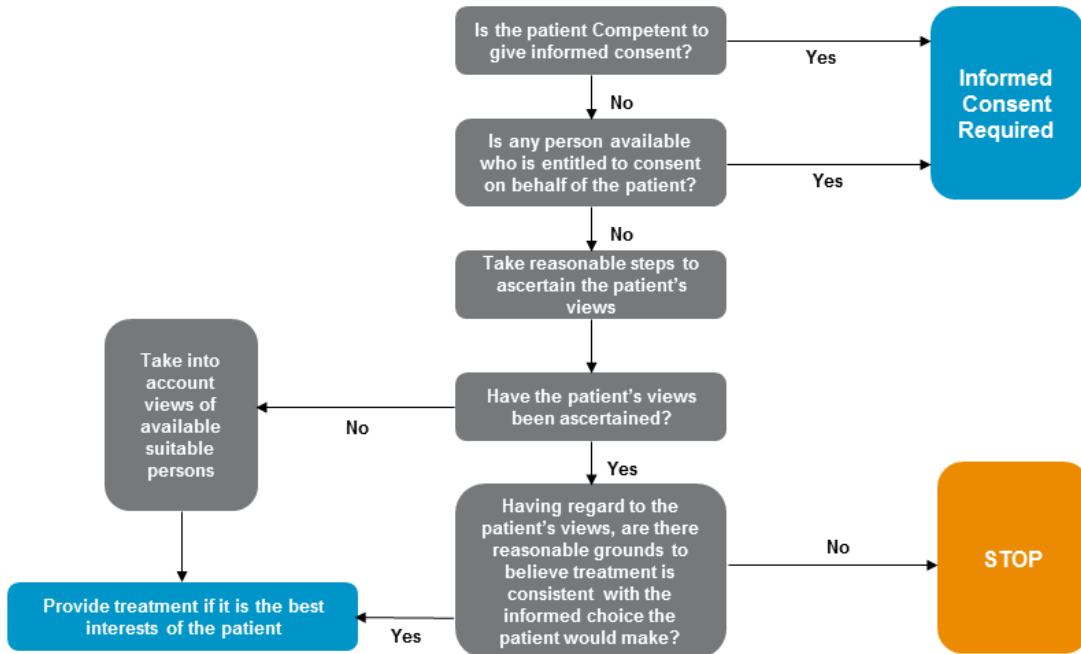
You must respect the patient's right to refuse care and to withdraw their consent to care at any time; and accept their decisions without prejudice.

### Guidance

- Make it clear to your patients that they are free to choose whether they give their consent or refuse care, without fear of prejudice.
- In the event the patient refuses care, record the patient's decision in the patient record, along with any discussion.
- Make it clear to your patients that they can re-visit their decision at any time and change their minds; and that they may withdraw their consent at any time.

## Appendix A

### Flow Diagram of Right 7(4) of the Code of Rights, Process



*This flow chart is general guide only and is not intended as a substitute for legal advice*

Martin, A. (2012, October). *Who decides in hard cases? - The boundaries of competence and consent*. Paper presented at the Health and Disability Medico-Legal Conference, Auckland, New Zealand.