Procedure Informed Consent

Principles

Informed consent is the provision of sufficient information in a form understandable to the consumer, for the purpose of a treatment or procedure where the consumer is deemed competent to make that decision.

The Code of Health and Disability Consumers' Rights ("the Code") provides for the rights of consumers to be fully informed, to make an informed choice and to give informed consent.

Services may only be provided to a consumer/patient if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of the Code provides otherwise.

Process for Informed decision-making

A person's freely given, informed and competent consent is gained by exchanging information throughout all stages of the assessment, treatment and procedure so that an informed decision can be made.

The information required for consent will typically come from many sources and **all critical steps in the process should be documented**.

The process for a consumer to make an informed decision requires that the consumer is provided with:

a) an explanation of their condition, and
b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
c) advice of the estimated time within which the services will be provided; and
d) notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and
e) any other information required by legal, professional, ethical, and other relevant standards; and
f) the results of tests; and
g) the results of procedures.

The consumer is also entitled to honest and accurate answers to questions relating to services, including questions about:

a) the identity and qualifications of the provider; and
b) the recommendation of the provider; and
c) how to obtain an opinion from another provider; and
d) the results of research.

Every consumer has the right to receive, on request, a written summary of information provided.

Written Consent

Written consent protects the consumer/patient and their rights by ensuring health professionals take steps to secure informed consent and to explain the procedures and potential risks and complications.

Right 7, clause 6 of the Code requires written evidence of informed consent to a health care procedure, when -

a) the consumer is to participate in any research; or
b) the procedure is experimental; or
c) the consumer will be under general anaesthetic; or
d) there is a significant risk of adverse effects on the consumer.

Invasive procedures

For invasive procedures, consumers/patients should receive adequate verbal explanation of what is proposed, and verbal consent should be obtained.

a) Details of the verbal consent including information discussed must be documented in the clinical records.
b) Where the risk to the consumer/patient of the invasive procedure is thought to be significant written consent should be gained.
c) Where the consumer/patient has declined to give their consent, and they are competent to do so this shall be documented in the clinical records and the procedure will not be carried out.

Presence in Theatre

Students and any visitors to theatre, who do not constitute part of the theatre team, must obtain prior consent from the credentialed specialist, patient and theatre charge nurse if they are to be present in theatre during the procedure.

This consent must be documented in the patient's notes by the Surgeon/Anaesthetist or nurse responsible.

Student Nurses involved in Patient Care

With the patient's consent, a student may be involved with the patient's care under the supervision of a Registered Nurse. This permission must be recorded in the patient's notes.

Photography and related recordings

Informed Consent must be obtained prior to the taking of any recordings (photos, audio, and video) that do not form part of the clinical record. Consent must be documented on the Consent Form, including how images are stored and destroyed.

Blood and blood products

Written consent for the use of blood and blood products must be obtained from the patient or a person legally entitled to consent on their behalf.

Additionally, when consent is being obtained for an operation, consent should also be obtained for the use of blood products if there is a significant risk (i.e., 1% or more) identified in the circumstances.

In an emergency where the patient cannot give informed consent (e.g., because the patient is unconscious) blood products, as with other medical treatment, may be given if it is necessary to preserve the patient's life, health or wellbeing, and the treatment is in the patient's best interests, **unless the patient has made a valid advance directive, directing that no blood or blood products be given**.

Section 29 medications

Where a medication is prescribed that is not yet approved/ registered for use in NZ, or the medication is being used for a purpose other than which it is registered the patient must be informed and consent obtained. It is the responsibility of the credentialed medical practitioner to gain consent prior to the administration of the medication. If a section 29 medication is administered in an emergency, the administering credentialed specialist will discuss this retrospectively with the patient.

Storage or use of body parts

Informed consent must be obtained for the storage, preservation or other use of a body part or bodily substance removed or obtained during a health care procedure, except when this is done so for -

a) the purpose of research that has received the approval of an ethics committee; or
b) for the purpose of an activity to improve the quality of services being a professionally recognised quality assurance programme, an external audit or services or an external evaluation of services.

When consent is not able to be given

Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where –

a) it is in the best interests of the consumer; and
b) reasonable steps have been taken to ascertain the views of the consumer; and
c) either, -
    i) if the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if they were competent; or
    ii) if the consumer's views have not been ascertained, the provider takes into account the views of the other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

Further details on patient competence (including children) are identified in appendix 1.

There are several other exemptions to the requirements for informed consent as identified in appendices 2, 3 & 4.

References:

Ngā Paerewa Health & Disability Service Standards NZS8134:2021 standard 1.7
Health and Disability Commissioner (Code of Health & Disability Consumer's Rights) Regulations 1996
Care of Children Act 2004
Crimes Act 1961
Protection of Personal and Property Rights Act 1988

Appendix 1: Patient 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.

It is the credentialed medical practitioner's responsibility to determine if the patient is competent to give informed consent. Medication, intellectual disability, mental illness, inebriation, or physical injuries may affect the informed consent process. 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.

Where a patient is deemed not competent to consent and has a welfare guardian and/or person with Enduring Power of Attorney, this authority needs to be supplied and a copy retained in the patients notes.

Those individuals entitled to consent on behalf of the patient include:

- A parent or legal guardian.
- Welfare guardian, or person with enduring power of attorney.

If the credentialed medical practitioner has not been able to ascertain the patient's views and there is no suitable person available to give advice and the delay will not be harmful, it is wise to seek a second opinion from an experienced colleague before providing care. This process must be documented in the patient's notes.

Children

The Code of Rights does not specify an age for consent. A provider must assess a child's competency to decide whether he or she is able to give informed consent.

Under Right 7(2) there is a presumption that a person of any age is competent to give consent unless there are reasonable grounds to believe otherwise.

Equally as important is that the person can communicate a decision. Accordingly, credentialed medical practitioners are legally obliged to inform children about operations and treatments in a manner relevant to their level of competence and, if appropriate given that level of competence, to obtain their informed consent.

Generally, parents /whanau or guardians will be involved in the informed consent process for the very young.

Appendix 2: Summary of statutory exceptions to informed consent

Blood transfusions for persons under 18 years	S37 of the Care of Children Act 2004 provides immunity against civil and criminal liability and disciplinary proceedings to a medical practitioner in defined circumstances; necessary to save the life or prevent permanent injury to mental, physical health and where reasonable attempts to obtain consent of a guardian have been made, or such consent has been refused.
Treatment of **persons lacking capacity to consent**	Right 7(4) of the Code of Health and Disability Services Consumers' Rights **may** apply.
Post-Mortems	The Coroners Act 2015 empowers the Coroner to require a post-mortem.
Offence likely to cause immediate/**serious injury to person/property**	S41 of the Crimes Act 1961 allows restraint without consent where there is the likelihood of suicide or an offence likely to cause immediate/serious injury to any person or property.
Welfare Guardians	The Protection of Personal and Property Rights Act 1988 allows the Court to appoint a Welfare Guardian to make decisions on behalf of a person 18 years of age or over who lacks capacity to make or communicate a decision. It also enables a person to appoint an attorney to act for them in advance of incapacity.

Summary of statutory provisions of who can give consent

Persons in Respect of Whom Consent can be given	Who can Give Consent	Consent to what treatment or procedure	Statutory Provisions
Persons 16 years of age or over who have capacity to give consent	Such persons can consent for themselves.	Any medical, surgical, or dental procedure.	S36(1), Care of Children Act 2004
Persons under 16 years of age who lack capacity to give consent	A guardian. In the absence of a guardian, a person in NZ who has been acting in the place of a parent. In the absence of such a person, a District Court Judge or the Chief Executive of the Department of Child, Youth and Family Services.		
Persons under 18 years of age who lack the capacity to give consent	A guardian. In the absence of a guardian, a person in NZ who has been acting in the place of a parent. In the absence of such a person, a District Court Judge or the Chief Executive of the Department of Child, Youth and Family Services.		

Incapacitated" persons 18 years of age or over in respect of whom a welfare guardian has been appointed	Welfare Guardian	Any medical treatment or procedure other than electro-convulsive treatment, brain surgery designed to change the person's character, and medical experiments not conducted to save the person's life or prevent serious illness to their health.	S12(2), S18(1)(d), (e), and (f) Protection of Personal and Property Rights Act 1988
Source: Collins DB, Medical Law in NZ, Brooker & Friend Ltd, Wellington 1992.			

Appendix 3: Emergencies

In an emergency**,** a health professional can (and in most cases, must) treat a patient who is not competent to consent to treatment, where the treatment is necessary to preserve the patient's life, health or wellbeing, and where the treatment is in the patient's best interests. In this situation health professionals should not do anything more than is reasonably required to secure the patient's immediate needs.

A competent adult can decline emergency life-sustaining treatment even in an emergency situation.

A health professional cannot justify medical intervention on the basis of the principle of necessity or the patient's best interests when it is contrary to the known wishes of a person who either has the capacity to decline medical treatment or who has previously made a clear and binding advance directive that applies to the situation.

If you have not been able to ascertain the patient's views and no suitable person is available to give advice and the delay will not be harmful, it is wise to seek a second opinion from an experienced colleague before providing care. This should be documented in the patient record.

(MCNZ statement on Information, choice of treatment and informed consent Section 23).

Appendix 4: Specific Clinical Situations

Pathology during surgery

1. Potential pathology confirmed during surgery

Where potential pathology additional to that already known may be confirmed during the consented procedure, the possibility of appropriate further surgery must be discussed with the patient as part of obtaining consent for the surgery. The patient should be informed as to the possible nature of the additional procedure, potential risks and benefits and the consequences of non-consent, e.g. further surgery.

If the patient is unable to make an informed decision without a confirmed diagnosis, consent to a composite procedure should not be sought and the second procedure should not be performed until informed consent is received, unless it is necessary to perform the procedure immediately in order to preserve the patient's life or health.

2. Unforeseen pathology during surgery

Where unforeseen pathology is discovered during the procedure for which the patient has consented, the surgeon should **not** perform a definitive procedure for that pathology during that procedure. The diagnosis should be considered separately and separate consent to treatment gained from the patient, unless it is necessary to perform the procedure immediately in order to preserve the patient's life or health.

Religious or cultural beliefs

The religious or cultural beliefs of some patients or their representatives may lead them to withhold consent for some procedures - for example, the beliefs of Jehovah's Witnesses compel them to decline blood transfusions and blood products. In such cases the person responsible for obtaining consent must discuss (i) the risks of declining the proposed procedure and (ii) any available alternative procedures. However, a competent adult has the right to decline any health service or treatment, including a blood transfusion.

Advance Directives

The Code of Health & Disability Services Consumers Rights 1994, (Right 7, Clause 5), states that "Every consumer may use an advanced directive in accordance with the common law".

An advance directive is written when a person is competent and sets out in advance those circumstances or situations when they would want treatment withheld or withdrawn. Every competent person may create an advance directive which will authorise or decline a healthcare procedure in the event that the patient is incompetent to make the particular decision.

A directive cannot provide guidance for every possible circumstance, so it is important that advance directives are constantly re-evaluated.