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Name: Informed Consent (Adults and Children)

Policy

To ensure that proper processes relating to informed consent are followed so that all health and disability services provided to patients meet the legal requirements for first obtaining the patient's informed consent or, where services are provided without the patient's consent, those services are provided lawfully.

Scope

All health professionals who provide health and disability services to patients for and/or at CCDHB hospitals and clinics or in the community.

Executive Summary

Staff are required to be familiar, and comply with the legal requirements of informed consent under Rights 5, 6 and 7 of the Code of Health and Disability Services Consumers' Rights 1994 ('Code of Rights' or 'Code') This summary sets out the Code's framework for obtaining informed consent that all health professionals must abide by before providing health and disability services.

Appendix 1: Code of Health and Disability Services Consumers' Rights 1996

Obtaining consent for Treatment

- You must ensure that the patient, if capable of doing so, has made an informed choice and has consented before providing services.
- If you are not the clinician who has taken consent, you must ensure that the patient's circumstances have not changed significantly and the consent remains valid before providing services. If there are significant changes a new consent process must be undertaken.

For consent to be valid, the consent giver must be sufficiently competent

- You must assess whether the patient is capable of giving consent for that health and disability service (every patient is presumed competent to give consent unless there are reasonable grounds for believing that they are not capable of doing so).
- If the patient does not have capacity to give consent to that service, then you must check if there is another person legally entitled to give consent (for example, a child's legal guardian or an adult's welfare guardian, or an adult's person with enduring powers of attorney).

- If the patient does not have capacity to consent to that service and there is no person capable of giving consent for the patient, then you must follow steps within Right 7(4) of the Code of Rights to gain authorisation to proceed with the service without consent.
- There are very few exceptions to the above; these are covered in separate legislation, such as under the Mental Health (Compulsory Assessment and Treatment) Act 1992.

The consent giver must be adequately informed

You must have provided an explanation of:

- the patient's condition (including test results)
- all relevant treatment options and the recommended treatment options including an assessment of the benefits and risks of each option and any costs associated
- the estimated time to treatment
- any proposal for the patient to take part in teaching or research
- any other information relevant to this patient's circumstances, for example:

  implications of existing advance directives, issues related to the use of blood products, issues related to use, disposal or return of body parts or tissue, recovery and recuperation from the procedure

You must check and confirm the patient's (or consent giver's) understanding and be satisfied that consent is informed before relying on their consent.

Consent Must Be Freely Given After Real Opportunity to Discuss and With No Coercion

- You must have given the patient information in a form, language and manner that enables them to understand the treatment or advice. That information must include all relevant options and the recommended service.
- You must obtain consent in an environment that supports the patient making an informed choice, including the option to refuse services.
- You must allow the patient or other consent giver sufficient time to consider the options and make a decision.
- You must facilitate provision of support for the person giving consent where the patient wishes it, such as from whānau.
- The patient has the right to refuse consent or withdraw consent at any time.

Requirements for Documentation of Consent

You must obtain written consent when:

- Treatment will be carried out under anaesthesia, including separate written consent for each of anaesthesia as well as the procedure
- Treatment involves off-label prescribing when such treatment is assessed as experimental
- Treatment is part of research
- Blood transfusion (CCDHB specific)

- A student is to undertake an examination or procedure (while being supervised) while the patient is under anaesthesia or sedation (where the student is to perform a sensitive examination or any procedure involving material risk the written consent must be explicit as to the exam or procedure)
- All other treatments carrying a significant risk of harm (CCDHB specific)

You must have documented consent for:

- Use or disposal of the patient's tissue
- Taking clinical images that could be used for teaching or research purposes in the future

If you are providing services without consent under Right 7(4) of the Code, the process undertaken must be documented.

There are also specific procedures where certain statutory requirements may apply before health and disability services may be provided. These are detailed in the "Summary of statutory requirements".

Appendix 2: Summary of Statutory Provisions Relating to Consent

A summary of some decisions on the outcomes of complaints to the Health and Disability Commissioner and other forums concerning informed consent is included. These decisions illustrate the application of informed consent requirements to specific situations.

Appendix 3: Health & Disability Commissioner/ HPDT / MPDT Decisions

This executive summary is not a substitute for the full policy where the requirements of informed consent and application to particular circumstances are covered in detail.

Where difficult situations arise you should seek advice from the Clinical Director/Professional Adviser and/or CCDHB Legal Services.

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Introduction

The Code of Health and Disability Services Consumers' Rights 1994 ('Code of Rights' or 'Code') states that consumers have the right to make an informed choice and to give or refuse consent to services and also to withdraw their consent. The term "services" is used throughout this policy to refer to health and disability services, treatment or procedures including the taking of images as the context requires.

The applicable patient rights in the Code of Rights are:

(a) Right 5 to effective communication;

(b) Right 6 to be fully informed; and

(c) Right 7 to make an informed choice and give informed consent, and to refuse services.

Full text of the Code of Rights see Code of Health and Disability Services Consumers' Rights 1996

With specific exceptions, health professionals should not provide services unless:

- the patient has received all the information that a reasonable patient, in that patient's circumstances, would expect to receive about their condition and treatment options;
- there have been sufficient checks that the patient has an adequate understanding of that information;
- the patient has been provided with a genuine opportunity to consider and discuss the information; and
- the patient has made an informed choice and consented to receiving the health or disability service.

Informed consent is not about filling out forms, but rather about the meaningful exchange of information concerning all health and disability services. CCDHB strives to ensure there is a continual and appropriate sharing of information throughout the patient's care and treatment.

Sensitivity to cultural needs is required in all areas of informed consent. It is also acknowledged that individual autonomy is not recognised in some ethnic groups, and this will need special consideration when dealing with the voluntariness of any consent decision.

There are situations where a patient does not have the mental capacity to make an informed choice and the Code of Rights or other law provides alternative processes that allows for services to be provided. This may involve a legal representative acting in the place of the patient to make an informed choice and give informed consent (for example a parent where the patient is a child or a welfare guardian or person with enduring power of attorney for an adult). Where there is no legal representative services can generally be provided without consent in accordance with Right 7(4) of the Code of Rights, or by way of a court order.

There is also other legislation that includes specific law relating to informed consent

that must be complied with where the relevant circumstances apply (refer to Appendix 3).

Treaty of Waitangi (Te Tiriti o Waitangi)

The principles of the Treaty of Waitangi – partnership, participation and protection – underpin CCDHB's obligations and commitment to achieving Māori health equity and improving Māori health outcomes. This is also in accordance with the New Zealand Public Health and Disabilities Act 2000.

Additionally, in line with Right 1(3) of the Code of Rights, every consumer has the right to be provided with services that take into account their needs, values and beliefs.

Related CCDHB Policies:

Bicultural safety

Hauora Maori - Maori Health

Support Services for Māori and their Whānau

'Health literacy' refers to a person's ability to obtain, process and understand basic health information and services in order to make informed and appropriate health decisions, including providing informed consent. Health professionals should recognise that Māori, as individuals and as part of whānau, hapū or iwi, are partners in actively managing their own health and wellbeing, or the health of those they care for. In regards to seeking informed consent, this requires that health professionals ensure Māori individuals and whānau:

- are supported to obtain, process and understand all relevant health materials and information from everyone they have contact with in the health system, and
- are empowered to make informed decisions to access and navigate appropriate, quality and timely health services.

Kōrero Mārama, a Ministry of Health survey on Māori and health literacy, notes that most New Zealanders have limited health literacy and Māori have poorer health literacy when compared with non-Māori. In regards to obtaining informed consent, Whānau Care Services have expertise in working and communicating with Māori patients and their whānau and health professionals are advised to seek advice where appropriate.

Related CCDHB Policies:

Partnering with whānau who are supporting patients

Referral to Whānau Care Services

Related sections within this policy:

Effective Communication

Appendix 4

Essential Requirements of Consent

There are four key elements to informed consent. When obtaining a patient's consent to services health professionals must ensure:

- The patient has the necessary capacity, to make the decision to undergo, or to refuse, the service; and
- The patient is provided with sufficient information to enable the patient to make an informed decision about the proposed service; and
- Effective communication that provides the patient with a real opportunity to consider and understand the information; and
- The patient decides and that consent given is voluntary.

Where one of these four elements is absent the patient cannot give a legally valid consent to the service.

Competence

For consent to services, or a refusal of services, to be legally valid, it must be made by a person competent to make the particular decision (the terms "capacity" and "competence" are used interchangeably in this policy). Competence to make decisions is not "all or nothing" but is decision-specific (for example, the level of competence required to give consent to routine treatment will be lower than competence required to refuse life-sustaining treatment).

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 (Right 7(2) Code of Rights). It is important to note that a decision that may be considered unwise by others does not, in and of itself, establish grounds for finding a person lacks capacity. However, it may mean that closer attention should be paid to the question of whether or not the person has the capacity to make the decision asked of them.

In assessing competence assess whether the patient can:

- understand the nature, purpose and effects of the proposed treatment;
- weigh up the options – pros and cons – balancing the risks and benefits;
- foresee the consequences of a decision or action;
- comprehend and retain the information; and
- communicate the decision.

The determination of whether a patient is sufficiently competent to consent to a service is a matter for the clinical judgment of the health professional responsible for obtaining consent.

Related sections within this policy: Adults with Diminished Competence to Consent

Where difficult situations arise you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

Sufficient information

Under Right 6 of the Code of Rights, a patient has the right to receive information that a reasonable patient in that patient's circumstances would expect to receive to make a fully informed decision about the proposed service.

Right 6 provides that:

> Right to be fully informed
> *(1) every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including—*
>
> *(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.*
>
> *(2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.*
> *(3) Every consumer has the right 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.*
>
> *(4) Every consumer has the right to receive, on request, a written summary of information provided.*

Right 6 of the Code recognises that the consumer's particular circumstances must be considered in deciding what information the consumer needs in order to make an informed decision about a service.

What is important is to assess the adequacy of information from the viewpoint of the particular patient. A "one size fits all" pro forma approach is not sufficient. A health professional must provide the patient with information that a reasonable patient, in the patient's circumstances, would find material in making a decision about the proposed service and would be likely to attach significance to. The health professional needs to provide any standard information concerning the service and also provide further if the patient's circumstances require it.

A patient has the right under Right 6(1)(b) to an assessment of the expected risks of each option. Risks that are far-fetched or fanciful need not be disclosed. However, a

risk is "material" if a reasonable person would expect the particular patient to attach significance to it. For example, the patient must be informed of rare risks that are more likely because of their particular circumstances (e.g. risk of bleeding in someone taking anticoagulants) or which would have greater significance for that particular patient (e.g. consequences of arm nerve damage for a carpenter). What is not material to one patient may be material to another.

Patients are entitled to information about reasonable options. This information should include clinically appropriate alternatives which the clinician may not favour or which may not be available at CCDHB. Without this information the patient is not in a position to make an informed choice and provide informed consent. The health professional should also advise the patient which of the alternatives (if any) they recommend. If any appropriate option is available privately, or may be available at CCDHB sometime in the future, the patient should be informed of this and provided with appropriate information to enable the patient to make an informed choice. Health professionals should have regard to potential conflict of interest issues when informing patients of options and providers.

In most situations treatment should not proceed unless the patient has received all the relevant information and you have determined that they have an adequate understanding of that information to have given informed consent to the proposed service. A statement by a patient that they do not want to hear the details does not obviate the obligation that the health professional has to properly inform.

Effective Communication

Right 5 of the Code of Rights provides that:

> *(1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.*
>
> *(2) Every consumer has the right to an environment that enables both consumer and provider to communicate openly, honestly, and effectively.*

Therefore, the patient must be provided with a genuine opportunity to understand and consider the information. This may involve arranging an interpreter. The environment should allow the patient to feel that they are able to communicate openly, honestly and effectively (e.g. every effort should be made to ensure privacy for discussions of diagnosis and treatment options). Sufficient time should be allowed for the patient to read written information or access information in their preferred language via an interpreter and discuss this and any verbal information with whomever they wish.

Related CCDHB Policies: Use of interpreting services

'Health literacy' refers to a person's ability to obtain, process and understand basic health information and services in order to make informed and appropriate health decisions, including providing informed consent. Being committed to good health literacy practice, including knowing and understanding the extent to which people are able to read and comprehend health instructions and messages, is essential to achieving informed consent.

Every patient is presumed competent to give consent unless there are reasonable grounds for believing that they are not capable of doing so. 'Supported decision

making' recognises that a patient with an intellectual disability may be competent to make their own decisions when the right supports are in place (e.g. involving support persons who are able to advise what the patient's wishes and choices are, providing information in plain language, and allowing enough time to get to know and involve the patient). To provide supportive communication for persons with communication difficulties consider using different forms of communication e.g. providing written materials or providing information in a more accessible form (e.g. drawings) and ensure the environment is appropriate. It is important that health and allied health professionals have a good understanding of the practical ways to assist every patient to make their own decisions to the greatest extent possible and ensure participation in the process.

In many instances, it will be appropriate for a health professional to initiate services immediately after discussing it with the patient, for example, taking a routine blood test or performing a particular physiotherapy technique as part of an ongoing episode of care. However, where the patient needs additional supports or proposed treatment carries significant risks, or where written consent is required, the health professional must consider whether the patient has had sufficient opportunity to take in the information needed for the patient to make an informed choice and give informed consent (e.g. consent should not be obtained after the patient has entered the operating theatre unless truly exceptional circumstances exist).

In most cases where written consent to services is required, options will be discussed with the patient well in advance of the actual treatment being carried out. The consent process may then involve the provision of information, discussion of options and an initial decision of the patient, followed by confirmation in writing that the patient wishes to go ahead with the planned treatment. This second stage may occur at any appropriate time before the treatment, including in out-patients, at a preadmission clinic, or when the patient is admitted for treatment.

Useful Resources: *Three Steps to better health literacy* IHC. Supported Decision-Making. A Guide for Supporters of People with an Intellectual Disability

Voluntary Choice

For consent to be legally valid the patient must decide whether to accept the particular service. The patient must not feel under undue pressure or that they must proceed or cannot change their mind (again, for this reason consent should not in normal circumstances be obtained after the patient after the patient has entered the operating theatre). What is important is that the patient has had time to take in and understand the information and options available and does not feel under any undue pressure from health professionals or others to consent. Notwithstanding the requirement of voluntary choice, the Code of Rights places a professional duty on health professionals to make recommendations as to the best course of treatment available. It is acceptable that the patient or their legal representative be persuaded in their choice by the arguments of health professionals and others, as long as the persuasion does not overbear the patient's decision.

Health professionals should also be sensitive to threats to the voluntariness of a patient's decision, which may come from other sources, such as the patient's close family members.

Responsibility for Obtaining Consent

The health professional who is to provide the service must ensure the patient has given informed consent before proceeding. This responsibility continues in the situation where another practitioner is delegated responsibility for obtaining consent. The health professional performing the service must ensure that the patient possesses a reasonable understanding of what is proposed, and has given informed consent before proceeding. Where the service is being performed under supervision, the health professional responsible for the service must also ensure that the patient possesses a reasonable understanding of what is proposed, and has given informed consent before proceeding.

It is recognised that other members of the team may be involved in imparting information or may be delegated the responsibility of seeking consent to services. Where another practitioner obtains the patient's consent, while the treating practitioner retains overall legal responsibility and accountability for the consent process, the practitioner with delegated responsibility will be responsible for their own actions in obtaining the consent. The person exercising such delegated responsibility must be sufficiently familiar with the treatment to be able to answer the patient's questions knowledgeably and provide the patient with information necessary for the patient to give legally effective consent. Any clinician delegated the task of obtaining informed consent who does not have sufficient knowledge has a responsibility to inform their consultant/supervisor so that alternative arrangements to obtain consent can be made. Each team member must document the information/discussion covered so that their colleagues may be assured that sufficient information to enable informed consent has been given.

The patient should be informed if the person obtaining consent will not be the person carrying out the service. Where written consent is required, regardless of who is obtaining consent, the name of the clinician performing the treatment must be documented on the consent form. If this is unknown at the time of obtaining consent then the patient must be advised. Anyone involved in the care or treatment of a patient, who believes the patient is not adequately informed, should convey this to the clinician performing the procedure prior to the treatment being performed.

Statutory Provisions Relating to Consent

There are specific procedures where certain statutory requirements may also apply before health and disability services may be provided (refer to: Appendix 2).

For example, law concerning consent as it relates to children is also provided for in the Care of Children Act 2004 and in the Oranga Tamariki Act 1989.

Related sections within this policy: Impact of Age on Ability to Give Informed Consent

Some legislation enables assessment and treatment without consent where this is necessary but subject always to the specific requirements detailed in the Act (for example, compulsory treatment provisions of the MH (CAT) Act 1992, the ID (CCR) Act 2003 and the Substance Addiction (CAT) Act 2017).

Related sections within this policy: Compulsory Assessment and Treatment

A number of Acts include specific provisions concerning consent in the particular circumstances (including: the Contraception, Sterilisation and Abortion Act 1977;

Health Act 1956; Crimes Act 1961; Criminal Investigations (Bodily Samples) Act 1995; Coroners Act 2006; Human Tissue Act 2008; Judicature Act 1908; Land Transport Act 1988; Protection of personal and Property Rights Act 1998 (PPPR Act).

For example, under the Contraception, Sterilisation and Abortion Act the woman's informed consent to an abortion is not sufficient authority to carry out a termination procedure: section 29 of the Act provides that no abortion shall be performed unless and until it is authorised by 2 certifying consultants.

Related CCDHB Policies: Certification within Te Mahoe policy

Documenting Consent (verbal or written)

Consent, whether verbal or written, must generally be recorded in the patient's clinical record. However, it is acknowledged that for the many day to day services involved in providing care and treatment (such as taking blood or giving IV fluids) it is not practicable to routinely record consent. However, verbal consent should be reaffirmed immediately prior to providing the service involved.

As a guideline the following information should be documented:

- Information about options discussed and the treatment option agreed along with the risks involved including those specific to the patient in their circumstances given to the patient (including written information, for example information sheets provided and discussed with the patient).
- Name and status of the person obtaining consent, and if different, the name and/or status of the person(s) who will carry out the treatment or procedure (if this is known at the time the consent form is signed).
- Specific concerns or wishes and any important questions asked by the patient and answers given
- Any timeframe discussed
- Statement of consent (whether given verbally or written)
- Patient indication that they understood the information given about the proposed treatment and any important steps taken to enable understanding (for some examples, whether an interpreter assisted, or if specific capacity assessment was first undertaken, or if cultural or other support was accessed for the patient)
- Who was present with the patient
- Where the patient lacked capacity to give consent, who gave consent (if a legal representative was available), the extent to which the patient could indicate their wishes, and who was consulted and their views (in the absence of a legal representative).

Written Consent

In certain situations written consent is required by law. Under Right 7(6) of the Code of Rights written consent is required if:

- The patient is to participate in any research
- The procedure is experimental

- The patient will be under general anaesthetic
- There is a significant risk of adverse effects on the consumer.

Where anaesthesia (whether regional or general) is required for treatment to be carried out then separate written consent is needed for the anaesthesia (separate from the written consent for the surgical procedure).

CCDHB also requires written consent where:

- Either party requests it
- A student is to undertake an examination or a treatment under the direct supervision of a registered health professional whilst the patient is under general anaesthetic or sedation (where the student is to perform a sensitive examination or any procedure involving material risk the written consent must be explicit as to the exam or procedure)
- Clinical video or photographic recordings (including digital photographs) are taken for educational or research purposes
- It is planned to retain any tissues, body parts or bodily substances that are removed or obtained in the course of a health care procedure
- Transfusion of blood or blood products is required
- Use of either an unapproved medicine or of an approved medicine outside of its registered indications is experimental
- Tissue removed from the patient during the course of a health care procedure (that the patient does not wish returned or disposed of) is to be stored or preserved or used for a further purpose (subject to the limited exceptions where consent is not required)

Legislation may include specific requirements for written consent, for an example, the Mental Health (CAT) Act requires that written consent be obtained prior to treatment after the first month of compulsory treatment (with the exceptions noted in section 59) and consent must be in writing prior to electro-convulsive treatment (section 60).

Request for Treatment/Procedure(s) Form and Treatment/Procedure(s) Without Consent Form

Written consent should be documented on the CCDHB generic form.

If the patient lacks capacity to give informed consent to treatment that requires consent in writing, there is no legal representative, and treatment is to be provided without consent under Right 7(4) of the Code of Rights, then the health practitioner providing the treatment should complete the generic form for Treatment/Procedure(s) Without Consent.

Documentation includes recording the information outlined under the heading ‘Documenting informed consent’ and any other relevant information. In practical terms, this information may be documented on the notes page provided on the reverse of the Consent Form. Information may also be documented in the patient’s medical record as may be the case where information is provided over time and/or by more than 1 person before the patient makes the informed decision to proceed (and then provides written consent). If information is not documented this creates risk for

the patient, particularly in a hospital where multiple staff are involved in a patient's care.

CCDHB does not encourage the use of procedure specific consent forms. It is recommended services use the generic forms and include the specific information discussed. Information sheets and service protocols can be developed to cover information routinely provided to patients and that this information has been imparted then documented in the generic consent Form.

Related CCDHB Policy:

Request for Treatment/Procedure(s) Form

Treatment/Procedure(s) Without Consent Form

Related sections within this policy:

Appendix 5: Request for Treatment/Procedure Form

Appendix 6: Treatment/Procedure without consent Form

Duration of Validity of Written Consent

Care should be taken if consent has been obtained well in advance of treatment. Whether such consent remains legally valid will depend on several factors including:

- the period since consent was given – months earlier rather than days
- the nature of the procedure
- likelihood of change in health status between consent and procedure
- progression of condition
- change in competence
- significant change in the patient's personal circumstances
- a change to the clinician who will be undertaking the procedure

Services should continue to engage with a patient awaiting a service to ensure that any changes in circumstances, clinical and personal, may be addressed.

Related CCDHB Policies: Patient Surgical Safety policy

Composite Procedures

The patient must give informed consent for each treatment or procedure before it begins. For example, where anaesthesia (regional or general) is required for treatment to be carried out then written consent is needed for the anaesthesia separate from the written consent for the surgical procedure.

Interdependent Treatments and Treatment Programs

There are times when a group of procedures or treatments are closely linked, and should be discussed as a composite procedure for the purpose of obtaining consent.

Interdependent treatments are when the treatments are routine and necessarily interdependent, for example, the insertion of intra-vascular lines accompanying major surgical procedures, to be followed by a period of mechanical ventilation. In such

cases all the component procedures must be outlined to the patient as part of the explanation of the treatment they are being asked to consent to. Consent to composite procedures must never be used to imply prior consent to treatment or procedures that are not routinely used in the clinical procedure for which the patient has consented.

In some medical treatments, informed consent to an overall treatment program will be obtained at the outset. For example, where a series of transfusions are required for a course of treatment then the need for repeated transfusions is part of the information disclosed prior to obtaining the patient's informed consent, and one written consent will generally cover the course of treatment.

Potential Pathology Confirmed During Surgery

When potential pathology may be confirmed during surgery whilst the patient is under anaesthetic, or otherwise unable to consent for any reason, the possibility of appropriate further surgery/procedure must be discussed with the patient as part of obtaining consent for the original surgery/procedure. For example, the surgeon may obtain consent to proceed to a more extensive operation following a biopsy that is confirmed as malignancy during frozen section analysis. The patient should be informed of the possible nature of the additional surgery/procedure, risks, alternative options and the consequences of non-consent, for example, further surgery. Information given to the patient and the patient's consent or refusal to consent to additional procedures must be documented on the consent Form or in the patient's clinical record.

Unforeseen Pathology during Surgery

In the event of unforeseen pathology being discovered during the procedure for which the patient 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 obtained from the patient.

Other treatment that the patient has not given consent for, and therefore is not listed on the consent form or in the patient's clinical record, should not be performed unless it is necessary to preserve the life or health of the person (and provided such treatment is not inconsistent with a valid advance directive).

There must be:

- a necessity to act when it is not practicable to communicate with the person to whom treatment is being provided
- the proposed action must be one that a reasonable person would take in the circumstances
- it must be in the best interests of the patient.

As a general rule, when consent is being obtained for surgery, consent would also be obtained for additional procedures deemed essential to be carried out if there is an unexpected finding or event (the Consent to Treatment/Procedure(s) Form should indicate informed consent for essential treatment has also been given).

Related sections within this policy: Emergency Treatment

Blood and blood products

Consent to Blood and Blood Products

As with all health and disability services, informed consent must be obtained to blood and blood products before treatment is given.

As a general rule, when consent is being obtained for an anaesthetic/surgery, consent would also be obtained for the use of blood products if in the particular circumstances there is a significant risk of these products being required. In an emergency, where the patient cannot give consent, blood products may be given if it is necessary to preserve the life or health of the person. There must be:

- a necessity to act when it is not practicable to communicate with the person to whom treatment is being provided
- the proposed action must be one that a reasonable person would take in the circumstances
- it must be in the best interests of the patient.
- once the emergency situation passes further blood products cannot be given without the consent of the patient.

If there is prior knowledge that the patient would not agree to blood transfusion (for example, an advance directive) this must be respected unless the health professional has reasonable grounds for questioning the validity of the directive.

Related sections within this policy: Refusal of Blood Products

Documenting Consent

Consent for transfusion of blood or blood products must be in writing on CCDHB's Consent to Treatment/Procedure(s) Form (refer to appendix 4). Where a series of transfusions are required for a course of treatment and the need for repeated transfusions is part of the information disclosed prior to obtaining the patient's informed consent, one written consent will generally cover the course of treatment.

Where transfusion may be needed during surgery, the Consent to Treatment/Procedure(s) Form (refer appendix 4) should also indicate informed consent for transfusion of blood or blood products has been given.

Related sections within this policy: Composite Procedures

Related CCDHB Policies: Blood component and product transfusion policy

Refusal of Blood Products

Where blood or blood products are refused by a competent adult for any reason (for example, religious beliefs) this decision must be respected, ensuring that those making the decision fully understand the implications this may have on the treatment options and clinical outcome.

A patient's decision to refuse blood or blood products must be clearly documented in the patient's clinical record. This documentation should include details of the advice given to the patient, including discussion of alternative options, such as not performing surgery, and their implications.

Urgent Blood Transfusion without consent for children (under 18 years)

When a guardian refuses to consent to blood products for their child and time permits then there may be a legal basis to seek orders from the courts.

In an emergency, section 37 of the Care of Children Act 2004 provides some legal protections for a health practitioner who administers a blood transfusion without consent where it was reasonable to do so to save the life of the patient or to prevent permanent injury to mental or physical health, or to save the patient from prolonged and avoidable pain and suffering.

Section 37 provides limited immunity against legal (civil and criminal) and disciplinary proceedings. The immunity can only be removed if the Judge considers that the protective circumstances detailed in section 37 were not met. Section 37 provides that the Judge must not grant leave to bring legal proceedings against the health practitioner if the Judge is satisfied that:

- In the reasonable opinion of the health professional the transfusion was necessary to save the life of the patient or to prevent permanent injury to mental or physical health or to save the patient from prolonged and avoidable pain and suffering; and
- Either a reasonable attempt had been made to obtain consent, **or** it was necessary to administer the transfusion promptly and therefore impracticable to obtain consent; and
- In all the circumstances it was reasonable to administer the transfusion.

If challenged in court, in considering the "reasonableness" of the health professional's opinion, the Judge must take into account the following:

- the condition of the patient before the transfusion
- circumstances in which it was administered
- whether it was practicable to consult other health professionals
- opinion of other health professionals consulted
- all other relevant circumstances (section 37(4))

Section 37 does not in any way affect the health professional's duty to seek prior consent with the assistance of the Court where necessary, and where time and circumstances permit.

Where difficult situations arise you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

Use of Unapproved Medicines and Use of Approved Medicines Outside of Registered Indications

A patient must be informed that a medicine is unapproved (unregistered) and give informed consent to the unapproved medicine being administered.

A patient must also be informed of any use of an approved medicine outside its approved (registered) indications and give informed consent to it being administered for any such unregistered use.

In circumstances where consent must be obtained in writing, for example when such treatment is assessed as experimental, then consent should be recorded in CCDHB's consent Form.

Related CCDHB Policies:

Prescribing unregistered medicines and use of medicines for unapproved indications

Prescribing unregistered medicines and use of medicines for unapproved indications

Related sections within this policy:

Appendix 6: Treatment/Procedure without consent Form

Return, Disposal or Use of Tissue, Body Parts and Bodily Substances (obtained during a health care procedure)

The Code of Rights (Right 7) governs the rights and obligations regarding the patient's informed consent to the disposal, return or use of tissue that is obtained from a living patient during the course of a health care procedure.

Return or Disposal of Tissue

Right 7(9) of the Code gives every patient the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.

To give effect to this right, where tissue, body parts, or bodily substances (excluding blood or other bodily fluids) is to be removed or obtained in the course of treatment, information must be provided to the patient to enable the patient to make an informed choice about the return of tissue (the Human Tissue Return/Release Form is to be completed) or to give informed consent to the use and/or disposal of the tissue, body part, or bodily substance.

Related CCDHB Policies:

Human tissue management and handling (6 Related Items)

Human tissue information for patients (Annotated) (1 Related Item)

Use of Tissue

Right 7(10)(a) of the Code

> *No body part or bodily substance removed or obtained in the course of a health care procedure may be stored, preserved or used without the informed consent of the patient*

The patient (or in the case of an incompetent child or adult, a person legally entitled to consent) should be offered the opportunity:

- To reclaim the patient's tissue or body part (or in regards to bodily fluids as may be the custom regarding any option for return at present); or
- To give their informed consent for the tissue, body part or bodily substance to be stored or preserved and used for further diagnostic purposes or research.

The only exception to the requirement for informed consent for use of tissue that the patient does not wish to be returned or disposed of is where the body part or bodily substance will then be used for: research (that has been approved by an ethics committee) or for the purposes of a professional quality assurance programme, external audit of services or an external evaluation of services.

Whānau Care Services have expertise working and communicating with Māori patients and their whānau to support tissue return discussions.

Related CCDHB Policies:

Human tissue management and handling policy

Specimen management in operating theatres - Wellington

Related sections within this policy: Research or Audit involving Body Parts or Bodily Substances (obtained during a health care procedure)

Documenting Consent

CCDHB requires the patient's consent for further use of tissue to be in writing except where the limited exceptions when consent is not required apply.

When consent is being obtained for surgery, consent would also be obtained for tissue to be submitted for pathological examination and for such tissue to be kept and referred to for clinical purposes and for audit, teaching and Ethics Committee approved research where this is applicable

Related sections within this policy: Appendix 5: Request for Treatment/Procedure Form

Consent to Use Of Tissue Governed by the Human Tissue Act

The rights set out in the Code apply to living people receiving health and disability services. In contrast, the Human Tissue Act 2008 is largely concerned with collection and use of tissue from deceased persons and only applies to tissue collected from a living person in the following very limited circumstances:

- Donor analysis: use of tissue from a living person for donor analysis of whether that person has a condition or trait when the collection is not in the course of a

health care procedure (for example, when the tissue sample is collected by a scientific researcher for donor analysis outside of a health care procedure

- Secondary uses: where tissue was collected from a living person and after the person's death is to be used for a different purpose (i.e., for a purpose other than one that the donor consented to while alive).

In these situations the Code of Rights does not apply (as the Rights set out in the Code apply to living people receiving health and disability services). Therefore each of these situations requires consent is obtained instead in accordance with the consent framework established by the Human Tissue Act.

As regards donor analysis, the researcher must obtain informed consent from that individual, in much the same way as an individual consents to a health care procedure under the Code of Health and Disability Services Consumers' Rights. This means the individual is the only person allowed to make the decision to consent.

Related CCDHB Policies:

Research policy
Human tissue information for patients (Annotated)

Consent to Blood Test Following Accidental Blood or Body Fluid Exposure

Where a staff member has been exposed to another person's blood or body fluid and the source is known it may be clinically appropriate to assess the risk of viral infection (HBV, HCV, HIV/AIDS) from the source. Separate informed consent for blood testing for the specific viral infections must be obtained from the person the source of the exposure.

As a general rule, when consent is being obtained for an anaesthetic, consent would also be obtained for blood being taken for testing in the event of a staff member being exposed to blood or body fluids (refer to appendix 4).

Related CCDHB Policies: Blood/body substance and body fluid exposure policy

Digital Images and Recordings for Clinical Management

Clinical photographic, video and audio recordings of patients may be made as part of patient diagnosis and management. Such imaging falls within the definition of health and disability services and the patient has the right to make an informed choice and give or refuse consent to clinical images or recordings being made.

Where recordings are made as part of the services being provided to the patient, the recordings must not be used for any other purpose including clinical teaching or research without the patient's consent.

Related sections within this policy: Digital Images and Recordings for Clinical Teaching

Related CCDHB Policies: Medical photography and video recordings policy

Consent to Student Involvement for Clinical Teaching

Right 6(1)(d) gives every consumer the right to be notified of any proposed participation in teaching. The Code of Rights applies to occasions when a patient is participating in, or it is proposed that a patient participate in, teaching (Right 9). Under Right 7(8) every consumer also has the right to express a preference as to who will provide services and have that preference met where practicable.

Every patient has the right to decide whether they agree to or decline to participate in teaching, including observational teaching and participation in providing the patient with any health and disability services.

If any health professional, student or other person attends a procedure as an "observer" this is a teaching situation. Observers (including students) are defined as those additional to the normal health professionals immediately involved in the procedure or directly concerned with ongoing care. The clinician is expected to exclude any observers during the discussion to allow the patient to make a decision without pressure.

In the context of a teaching hospital, it may not be necessary to obtain specific informed consent for every stage of the teaching process. What *is* necessary is that:

- the patient is informed that they are receiving treatment in a teaching hospital and that junior staff or students under supervision may carry out parts of the patient's management and treatment, and will have need to access the patient's clinical record
- the patient has the right to know the name and professional status of any person who wishes to interview and/or examine them, or carry out specific treatment or investigative procedures for teaching purposes
- the patient has the right to ask questions, to have those questions answered honestly and accurately, and can refuse to be involved in teaching at any stage
- If a student is to undertake an examination or a procedure (e.g. endotracheal intubation or closing wounds) under the direct supervision of a registered health professional while the patient is under general anaesthetic or sedation then such examinations or procedures require explicit consent. It is also courteous that where possible the student should meet with the patient before the examination or procedure.
- Where a sensitive examination (includes breast, rectal, vaginal, and of external genitalia) is to be performed by a student while the patient is under general anaesthetic or sedation then this requires explicit consent.

Teaching or Clinical Demonstration Sessions

Educators must obtain a patient's consent if they wish the patient to be involved in a teaching or clinical demonstration session. Information explained must include precisely what will be involved and how many students will be present. Consent must be sought when the students are not present, to avoid placing undue pressure on the patient. Patients have the right to withdraw from the teaching session at any stage, and must receive a clear prior assurance that refusal to participate will not jeopardise their care in any way.

Documenting Consent

As a general rule, when consent is being obtained for an anaesthetic, consent would also be obtained for observation of and participation in treatment and/or procedure(s) by students under appropriate supervision (refer to appendix 4).

Where a student is to undertake an examination or a procedure under the direct supervision of a registered health professional whilst the patient is under general anaesthetic or sedation then CCDHB requires that the patient's consent is obtained in writing. The patient's consent to a sensitive examination or procedures with any material risk must be explicit and in writing.

Useful Resources: Medical students and informed consent: A consensus statement prepared by the Faculties of Medical and Health Science of the Universities of Auckland and Otago, Chief Medical Officers of District Health Boards, New Zealand Medical Students' Association and the Medical Council of New Zealand https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2015/vol-128-no-1414-15-may-2015/6534 .

Digital Images and Recordings for Clinical Teaching

Recordings of patients may be shown or played only for the purposes for which they were made and for which consent was granted. Such recordings are the patient's health information and the requirements of the Privacy Act and the Health Information Privacy Code must be observed.Therefore, recordings clinical photographs, can only be used for teaching purposes with the written informed consent of the patient for that use. These recordings and photographs should be non-identifying. When medical video or photographic recordings are to be taken for the purpose of use in teaching the patient's consent to their being taken for this use must be in writing. Written consent for use of images and recordings should be documented on the CCDHB generic Request for Treatment/Procedure(s) Form.

Related CCDHB Policies:

Medical photography and video recordings policy

Privacy policy

Request for Treatment (Consent form) (Annotated)

Clinical Research

Consent to Participation in Research

Right 6(1)(d) of the Code states:

> *(1) Every patient has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including –*
>
> *(d) Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.*

Right 9 of the Code states:

> *The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.*

The Code requires that patients are informed about involvement in research and must give informed consent before participating in research. Patients must not feel pressured to take part and must be aware that they can withdraw from the research at any time without their care being compromised.

Research must have been reviewed and approved by an approved Health Research Council accredited Ethics Committee, which considers, among other things, what information the participant will be given and how consent is to be obtained. The patient must be adequately informed of the aims, methods, anticipated benefits and potential risks of the research and is also entitled to know whether the research requires and has received ethical approval.

There is potential for patients who lack sufficient capacity to give consent to have involvement in ethics approved research. Circumstances that lead to people being unable to give consent to participation in research vary. these may include acute and possibly temporary incapacity (e.g., in emergency or intensive care situations). In general, a legal representative should be able to give consent for a patient, who is unable to consent, to participate in research (the PPPR Act prohibits legal representatives from agreeing to participation in 'medical experiments' unless to save life or prevent serious risk to health). In those situations where the patient does not have a legal representative then any involvement in research (that must have ethics approval) must meet the requirements of Right 7(4) of the Code.

Right 7(4) of the Code allows a health professional to provide services without consent provided the requirements of Right 7(4) of the Code are met. Right 7(4) requires that services must be in the patient's best interests and reasonable steps must be taken to ascertain the patient's likely views (e.g. in an advance directive that applies in the circumstances). Where the patient's views aren't known then views of family and whānau need to be considered. They should be consulted on any such decision prior to enrolment where the circumstances permit. Where they indicate they do not believe the patient would want to participate the patient should not be enrolled. Where there is no reasonable opportunity to consult with family or whānau and the clinician believes participation is in the patient's best interests then their views, as to whether the patient should continue in or be withdrawn from the study, should be sought at the earliest opportunity. Where a patient enrolled in such research regains sufficient capacity their consent to continue to be involved in the research must be sought. The patient has the right to withdraw from research.

Related sections within this policy:

Providing Services without Consent under Right 7(4)

Related CCDHB Policies: Research policy

Documenting Consent

The Code requires that consent is in writing if the patient is to participate in medical or scientific research (Right 7(6)).

Research or Audit involving Body Parts or Bodily Substances (obtained during a health care procedure)

Patients have the right to require the provider to return or dispose of tissue (i.e. body parts or substances) obtained during the course of a health care procedure (Right

7(9)). However, if the patient does not wish to have their tissue returned then this raises the possibility for other use of such tissue with the patient's informed consent.

CCDHB must comply with the law and regulatory framework concerning the collection, storage and use of tissue for research purposes, including for future unspecified research ('tissue banking').The potential use of tissue for future unspecified research purposes requires that the patient give specific consent for the storage of their tissue in an approved 'tissue bank' (i.e. since 2014 tissue banks must be approved by a Health and Disability Ethics Committee ('HDEC')). Ministry of Health Guidelines on Tissue Banking outline the information which must be provided to donors prior to their donating tissue for future unspecified use.

Right 7(10) allows only two strictly limited exceptions to the need for informed consent for storage, preservation, or use of the parts/substances that the patient does not want returned:

- use for the purposes of research (that has been approved by an ethics committee)
- use for the purposes of a professionally recognised quality assurance programme, external audit or external evaluation

These exceptions will only apply where the patient has not required the provider to return or dispose of their tissue. Informed consent for the use of body parts or bodily substances in research will still be required in the vast majority of cases, and research proposals will need to address the question of consent by research participants. In exceptional cases, where the proposal seeks to avoid the need for individual consent, the ethics committee will need to carefully assess the proposed research and the validity of the stated reasons for dispensing with individual consent.

Related CCDHB Policies: Research policy

Adults with Diminished Competence to Consent

Presumption of Competence

Every person is presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the person is not competent.

Whether or not a person can give or refuse consent to the provision of health and disability services does not depend on age, or whether or not that person has an intellectual disability, is mentally ill, or suffers from a particular health condition. It depends on whether a person is able to make an informed decision about the decision they are being asked to make and also communicate their decision.

A person has capacity if they are able to understand the information provided, weigh up the options, balance the risks and benefits, make a decision appreciating what the consequences might be and communicate their decision. Should there be doubt about a patient's competence, an opinion from a senior colleague is prudent. In such cases, the opinion should be recorded in the clinical file.

Diminished or Varying Competence

Where the patient can make some decisions, but not others, they retain the right to make informed choices and give informed consent to the extent appropriate to their

level of competence (Right 7(3) of the Code). The more serious the decision the greater the responsibility to ensure the patient is competent to make an informed decision. However, the fact that a patient has diminished competence to decide one health and disability service does not automatically mean that he or she is incompetent to consent to or refuse another particular service.

A patient's diminished competence may be due to either temporary or permanent factors. Permanent factors might include having an intellectual disability or severe mental illness. Temporary factors might include unconsciousness, confusion, shock, severe fatigue, pain, or use of prescription or illegal drugs.

The effect of medication is a matter of clinical judgment as some medication may improve the person's capacity to consent (for example, analgesics for a patient in pain). It would be impractical to suggest that consent must never be sought from a patient on any medication with the potential to affect concentration and thinking.

The patient's competence to consent should be assessed and a clinical decision made about the ability of the patient to consent to the extent appropriate to that patient's level of competence. A capacity assessment may inform what measures can be implemented to support someone to make their own decisions, even where their capacity may be impaired.

Except in cases of emergency, if the patient is rendered temporarily incompetent, the planned health care procedure should be delayed until the consumer is able to provide informed consent.

Decisions about the health services for any patient who is not competent to make an informed choice will involve the patient as much as possible. Where a patient is not competent to make a particular decision, health professionals should endeavour to obtain consent for any parts of the services that the patient has the capacity to consent to. 'Supported decision making' recognises that a patient who lacks some competence (e.g. where the person has an intellectual disability or a learning disability) may be competent to make their own decisions when the right supports are in place (e.g. involving support persons who are able to advise what the patient's wishes and choices are, providing information in plain language, and allowing enough time to get to know and involve the patient). It is important that health and allied health professionals have a good understanding of the practical ways to assist patients to make their own decisions to the greatest extent possible and ensure participation in the process.

Useful Resources:

A Douglass, G Young and J McMillan: A Toolkit for Assessing Capacity in A Douglass "Mental Capacity: updating New Zealand's Law and Practice" (Report for the New Zealand Law Foundation, July 2016. http://www.alisondouglass.co.nz/ Mental Capacity: updating New Zealand's Law and Practice"

IHC. Supported Decision-Making. A Guide for Supporters of People with an Intellectual Disability
Supporting Decision-Making - IHC

Legal Representatives with Authority to Give Consent (WG or EPA)

In those situations where a patient is not competent to consent to a particular health and disability service there are legal options available to provide services, where:

- the patient has made a valid advance directive which applies in the situation
- consent is obtained from a welfare guardian (WG) appointed by the Court under the Protection of Personal and Property Rights Act 1988 (PPPR Act), or from a person holding enduring power of attorney (EPA) for personal care and welfare
- services may be provided without consent in accordance with the requirements of Right 7(4) of the Code
- Court authorisation (e.g. a personal order for treatment under the PPPR Act)
- Under relevant legislation (Appendix 2)

If the patient is not competent to make an informed decision it must be clarified if there is a valid advance directive that applies and whether there is a WG or EPA. 'Substituted decision making' is where one person (e.g. an EPA) makes a decision about services for the patient when they are not capable (i.e. even with the right support the patient is not capable of making or communicating a decision). The PPPR Act offers a system of guardianship which intends that any substitute decision maker appointed ensures that every effort is made to involve the person to make decisions.

There are some restrictions on powers of a WG or EPA to decide services. In particular, WGs and EPAs cannot:

- refuse consent to any standard medical treatment or procedure intended to save a patient's life or to prevent serious damage to a patient's health
- consent to electro-convulsive treatment

In addition, WGs and EPAs may not make decisions that are outside the scope of their powers as set out in the court order appointing the welfare guardian or the deed appointing the attorney. For example, a WG's power to deal with 'routine medical treatment' would not be taken to confer a power to consent to sterilisation for contraceptive purposes (non-therapeutic sterilisation).

Related CCDHB Policies:

Guide for Staff PPPR Protection of Personal and Property Rights Act 1988

Enduring Power of Attorney: Guide for Staff

Where difficult situations arise you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

Requirement for Certificate of Mental Incapacity before EPA can Consent to Major Medical Procedures or Residential Care

Persons with enduring power of attorney (EPA) can give consent to services that are not 'significant matters' (for example, routine medical and dental care) provided the attorney reasonably believes that the patient is not competent to make an informed choice about the service.

However, the situation is different when the service involves any 'significant matter' such as, for example, a major medical procedure or entering residential care. In these situations the law requires that the EPA can only give consent where a relevant health practitioner has completed a certificate of mental incapacity ("certificate") confirming that the patient is not competent to decide about the service. CCDHB considers that specialist medical practitioner credentialed within a vocational scope of practice have the relevant scope of practice to undertake the assessment and complete a certificate where the assessment supports that a certificate is indicated. It may also be appropriate for some specialist medical practitioners in training (registrars) and other relevant health practitioners (for example, clinical neuropsychologists) to undertake the assessment and complete a certificate (where a certificate is indicated).

The certificate must include the particular information prescribed under the PPPR Act and CCDHB's Form includes that required information

Appendix 8: Mental incapacity for EPA

A certificate must be completed each time the EPA needs to decide any significant matter unless the assessment supports an opinion that the person is unlikely to recover competence. In this situation a certificate may be completed for an indefinite period and the EPA can give legally effective consent to other major medical procedures or entering residential care without requiring any further certificates to be completed.

Other Resources:

Health Practitioners certificate of mental incapacity for EPA in relation to personal care and welfare

Enduring Power of Attorney: Guide for Staff

Documenting Consent of Legal Representative

In the situation where a legal representative is to provide informed consent then this must be recorded. Documentation should include assessment of the patient's competence in relation to the services being offered, the patient's wishes to the extent they can be ascertained, advice given to the legal representative and the patient (to the extent the patient could be involved in decision making) and the consent discussion.

- Where a WG is providing consent then a copy of the court order appointing WG should be placed on the patient's records
- Where an EPA is providing consent then a copy of the EPA deed appointing the attorney should be placed on the patient's records. In those situations where the EPA cannot give consent unless a health practitioner has completed a certificate of mental incapacity a copy of the relevant certificate should also be placed on the patient's records.

In situations where consent to the service must be obtained in writing then written consent of the WG or EPA should be documented on the CCDHB consent form

Appendix 5: Request for Treatment/Procedure Form

Providing Services without Consent under Right 7(4)

No Legal Representative (WG or EPA) Available

In the absence of a person who has legal authority to consent on behalf of the patient, Right 7(4) of the Code of Rights allows a health professional to provide services without consent provided the requirements of Right 7(4) are met.

Right 7(4) provides:

> *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*
>
> *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 he or she were competent; or*
>
> *(ii) if the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.*

Services in the patient's best interests may be provided, but only after taking reasonable steps to find out, and conform with, any previously expressed views about care and treatment. Check whether the patient has an advance care plan (or advance directive) and ascertain if they have expressed any preferences that apply in the current situation. If not, then the views of others interested in the patient's welfare should be sought.

Other suitable persons would include such people as the patient's next of kin, whānau, permanent care givers, or their GP. They must be reasonably available to advise the health professional. A lack of legal authority to give consent does not remove the important role that family/whanāu have when decisions about services need to be made and the likely views of the patient aren't known. Where there is time staff must take reasonable steps to contact and consult with family/whānau. The clinician does not have to secure the agreement of family but Code obligations require that the provider consider the views of those reasonably available to be consulted in the circumstances when coming to a decision.

Once the health professional has taken into account the views of others interested in the welfare of the patient, the health professional has the final decision as to whether or not to provide the proposed service to the patient. However, in some circumstances it may be appropriate to seek a second opinion. Given that the provider does not have to secure the agreement of interested persons, a provider should not delay needed treatment because no family/whānau or other advisor can be contacted in the time available.

Related CCDHB Policy: Advance care planning

Limitations on Providing Services under Right 7(4)

The scope of Right 7(4) is not specified and there may be some situations where other authorisation for providing services without consent may be required or recommended in the particular circumstances. An example of where reliance on Right 7(4) may be sufficient is medically necessary sterilisation (therapeutic sterilisation) however, Court authorisation should be sought where sterilisation is for the purpose of contraception. A decision about any permanent move to residential care (e.g. at a rest home level of care, dementia level of care, high dependency level of care or hospital level of care) is also a circumstance where Court authorisation should be sought. In some circumstances the Court authorisation may need to be sought by CCDHB (where there is no-one available to make the applications).

Related sections within this policy: Providing Services without Consent under Right 7(4)

Where difficult situations arise you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

Documenting services without consent (including treatment / procedure(s) without consent form)

If services are provided in reliance on Right 7(4) of the Code of Rights, it is important that the health professional maintains accurate written records. In situations where verbal consent would be sufficient then document the steps taken to ascertain the patient's likely wishes, who was consulted and their relationship to the patient, and the views of those consulted.

In those situations where consent would be required in writing but there is no legal representative and therefore services are provided in reliance on Right 7(4) the Treatment/Procedure(s) without consent Form should be completed by the relevant clinician (refer to appendix 5).

Related CCDHB Form: Treatment/Procedure(s) without consent

Emergency Treatment

Competent Patient

In an emergency the primary need is to treat the patient. However, even in an emergency a patient who is competent to consent has the right to consent to or refuse services. The proposed treatment, the benefits and risks associated with consenting and refusing consent to the proposed treatment, and any other reasonable alternatives must be explained to the patient but the decision remains that of the patient.

Patient with Diminished or Varying Competence

In an emergency, where the patient is not competent to give consent, immediate treatment can be provided without consent. The principle of necessity is a common law justification for providing treatment without consent where there is a need to preserve the life or health of the person and the treatment is in the person's best interests. The treatment must be no more than what a reasonable patient would expect to receive in all the circumstances.

Medical intervention cannot be justified even in an emergency situation where it is contrary to the known wishes of the patient (for example, where there is a valid advance directive).

The responsible health professional should document the actions taken, including the reason for consent not being obtained where services are provided without consent. After the emergency has passed, the patient, or person legally entitled to consent on behalf of the patient must be told of the treatment provided.

Children

In the situation where a child requires emergency treatment and a guardian cannot be found, or there is no time to attempt to obtain the consent of a guardian, treatment necessary to preserve the life or health of the child and which is in the best interests of the child can be provided. The treatment must be no more than what a reasonable patient would expect to receive in all the circumstances.

The specific situation where urgent blood transfusion is needed in circumstances when consent cannot reasonably be obtained in the time available is provided for under the Care of Children Act.

Related sections within this policy: Urgent Blood Transfusion without consent for children (under 18 years)

Do Not Attempt Resuscitation (DNAR)

All patients should be resuscitated if clinically indicated, unless a Do Not Attempt Resuscitation (DNAR) decision has been documented, or the patient has a valid advance directive that applies in the particular circumstances.

Patients who are competent to make a decision, and those who are now incompetent but have previously issued a valid advance directive not to receive resuscitation must have their wishes respected.

Where a cardiac arrest response is deemed to be an inappropriate procedure by the medical staff it is the responsibility of senior medical staff to determine the information provided to each patient (and family/whānau if the patient has diminished competence). The discussion should include the overall aims of the treatment and the reasons for the decision not to offer cardiac arrest response. The emphasis here is not on the consent of the patient or family (as applies) but is instead on consultation about the decision with the patient and/or family/whānau.

Related sections within this policy: Right to Refuse Services

Related CCDHB Policies: Clinical emergency (resuscitation) policy

Right to Refuse Services

The Competent Patient

A competent adult patient who has the capacity to consent, may decline to consent to services or withdraw consent even if it results in that patient's injury or death, including in an emergency situation. A health professional has no right to proceed in the face of a competent patient's refusal and the choice must be respected. A health professional may have further discussion with the patient who is refusing the service in an effort to change their mind. The right to refuse is not limited to decisions that

are sensible; it exists notwithstanding that the reasons for making the choice are rational, irrational, unknown or even non-existent.

When faced with a competent patient's refusal to consent to life-sustaining treatment:

- The responsible health professional should immediately consider whether there is any reason to doubt the patient's competence to consent to or refuse the treatment
- If the competence of the patient is seriously in doubt, it should be assessed as a matter of priority. In most cases the responsible doctor will be able to assess competency. In some cases, it may be appropriate for a psychiatrist or other specialist to assess the patient and this should be considered and discussed where the circumstances suggest it is appropriate
- If a competent patient refuses consent to the treatment, the clinician should check the patient's understanding of the information including the risks and likely consequences if the treatment is not provided. The clinician should also consider other steps to enable understanding of information, for example involving family / whānau/ support persons as appropriate.

The information and advice given to the patient and any additional supports involved should be documented. The health professional should document the refusal in the patient's clinical record. There is no requirement that a patient's refusal to consent to medical treatment be in writing in order to be valid. Health professionals should, however, endeavour to obtain such a refusal in writing.

Where difficult situations arise you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

WG or EPA Refuses Services for Incompetent Patient

A welfare guardian (WG) and persons with enduring power of attorney (EPA) may not refuse consent to any standard medical treatment or procedure intended to save a patient's life or to prevent serious damage to a patient's health. However, if the WG or EPA refuses consent it will often be necessary to rely on a legal justification such as necessity in case of an emergency to provide services without the WG's or EPA's consent. Where time permits court authorisation should be sought.

Related sections within this policy: Adults with Diminished Competence to Consent

Related CCDHB policy: Elder abuse and neglect (EAN)

Where difficult situations arise you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

Advance Directive Refusing Services

Right 7(5) of the Code of Rights provides that every consumer may use an advance directive. An advance directive refusing services should be carefully scrutinised to ensure it is valid in the patient's current circumstances. For an advance directive to be valid:

- it must have been made when the patient was competent
- the patient must have made the decision free from undue influence
- the patient was sufficiently informed to make the decision

- the patient intended the directive to apply in the prevailing circumstances.

An advance directive cannot be ignored unless there are reasonable grounds to doubt its validity or other lawful excuse applies, such as where treatment may be compulsorily provided under specific legislation. A health professional would be justified in fully scrutinising the validity of an advance directive if it involves a refusal of treatment necessary to save the patient's life or prevent serious damage to their health.

A welfare guardian (WG) or person with enduring power of attorney (EPA) cannot by law refuse consent to standard medical treatment or procedure intended to save the patient's life or prevent serious damage to their health. However the health professional should comply with a valid advance directive if the EPA or WG has made them aware of its existence.

While (as the law currently stands) the MH (Compulsory Assessment and Treatment) Act 1992 will override any valid advance directive, any decision to override such a directive should be considered carefully, and should only occur in exceptional circumstances (i.e. when there are no valid treatment options left).

Related CCDHB Policies: Advanced Directives relating to Mental Health policy

Where there is conflict between the recommendations of the health professional, the patient's advance directive or the views of the WG or EPA and there is risk to the patient's life or health you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

Compulsory Assessment and Treatment

Statutory Exceptions to Requirement to Obtain Consent

The following Acts provide for limited situations where certain treatment may be compulsorily provided without the patient's consent:

- Mental Health (Compulsory Assessment and Treatment) Act 1992
- Criminal Procedure (Mentally Impaired Persons) Act 2003
- Intellectual Disability (Compulsory Care and Rehabilitation) Act 2003
- Substance Addiction (Compulsory Assessment and Treatment) Act 2017

Assessment and treatment authorised under the relevant Act as being able to be given without the patient's consent may be given without consent. It is still necessary to first attempt to obtain consent.

Mental disorder or intellectual disability or impairment do not of themselves necessarily preclude a patient having capacity to consent to services. The Code (Right 7(2)) requires that 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. Further, the Protection of Personal and Property Rights Act stipulates that a person must not be presumed to lack competence just because the person is subject to compulsory treatment or has special patient status under the Mental Health (Compulsory Assessment and Treatment) Act 1992.

As long as the assessment/treatment is given in accordance with the relevant Act this will not breach the Code of Rights. Relevant Mental Health Addiction and Disability services (MHAIDS) policies and guidelines, and any guidelines promulgated by the Director-General under section 148 Intellectual Disability (Compulsory Care and Rehabilitation) Act and any relevant legislation must be followed.

Related CCDHB Policies: Section 111 Registered Nurses Power to detain a person for urgent assessment under the Mental Health (Compulsory Assessment and Treatment) Act 1992

Treatment for Other Clinical Conditions

The scope of compulsory treatment is provided for under the relevant legislation. For example, patients receiving compulsory treatment under the Mental Health (Compulsory Assessment and Treatment) Act 1992 may be given treatment without consent for 'mental disorder' but not other treatment without consent. Treatment for mental disorder has been defined broadly however it would not cover treatment for other clinical conditions (for example, acute appendicitis).

Where difficult situations arise you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services. The matter should be discussed with the Director of Area Mental Health Services where appropriate.

Restraint Minimisation and Safe Practice

Enablers and Safe Practice Procedures

There are a number of standard clinical procedures that the require the safe holding of a limb or the person, and in some cases sedation, to ensure the clinical procedure can be carried out safely and effectively (for example, taking blood, traction, and the application and removal of plaster casts).

The use of:

- enablers, such as wheelchairs, chair trays and IV splints that can restrict the patient's normal freedom of movement but where the intent is to promote the patient's independence, comfort and safety and where the patient voluntarily agrees to its use; and
- clinical interventions that include safe practice procedures that can restrict the patient's normal freedom of movement.

Each requires the patient to give informed consent and are not considered as restraint events.

Restraint

On occasion the use of a form of restraint (such as personal or physical restraint) may be the only way to ensure a person's immediate safety. Restraint may be appropriate when there is a legal basis for treatment, a legal basis for restraint and when the patient's behaviour indicates that they are a danger to self or others

Where restraint is necessary, the use of restraint in all its forms must be with full regard for safety, personal dignity, cultural, legal and other requirements (including but not limited to the NZ Standards: Restraint minimisation and safe practice, 2008). Wherever possible, prior consent will be gained to a case management plan that minimises the likelihood of restraint occurring.

Document facilitator: Specialist Anaesthetist / Legal Service

Senior document owner: Legal Services

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Related CCDHB Policies:

Restraint minimisation and safe practice

Related Sections in this policy:
Appendix 3: Health & Disability Commissioner/ HPDT / MPDT Decisions

Children and Young Persons (under 18 years)

Background

In New Zealand, the Care of Children Act 2004 (COCA) and Code of Rights are important sources of the law on consent for children. The Code applies to children as it does to adults therefore the general provisions outlined in this policy apply to children and young persons. Under COCA a child is defined as a person under the age of 18 years.

In any difficult situations where there is conflict between what the health professional believes is in the child's best interests and what the child and/or their guardian (or other person with legal authority) believes to be in the child's best interests and there is risk to the child's life or health you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

Related sections in this policy:

Urgent Blood Transfusion without consent for children (under 18 years)

Emergency Treatment

Impact of Age on Ability to Give Informed Consent

Competence is not directly linked to age. Under the Code of Rights there is no "age of consent," with all patients presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing the consumer is not competent (Right 7(2)). Extreme youth is an obvious ground for believing a child is not competent.

Whether a child will be competent to consent to a particular treatment will depend on the nature of the treatment, the risks involved and the maturity of the child. It is important to remember that regardless of the child's age, their consent will be legally valid if the child is competent to give consent for the particular treatment in question.

The definition of "consumer" includes a person entitled to give consent on behalf of that consumer for the purposes of provision of information and consent. Where possible, the child's assent must also be sought. Therefore, in addition to imparting information in order for parents/guardians to make a decision on a child's behalf, information must be provided with information about the treatment that is suitable to the child's age, maturity and interest. Information should be communicated in a form, language and manner that enables the child to understand to their level of competence. Of course this will vary with the age of the child, but the general principle is to involve the child as much as possible.

16 And 17 Year Olds

COCA provides that the consent of a child **16 years or over** is to be treated as if the consent was given by an adult (section 36). A competent child of 16 years or over can consent, and refuse consent, to any medical, surgical or dental procedure (including blood transfusion) for the child's benefit as if the child were of full age. A health professional may presume that a child of 16 years or over has the capacity to consent, and refuse to consent to such treatment unless there are reasons other than age to doubt competency.

However, COCA does not state whether a guardian can give legally effective consent to treatment against a competent 16 or 17 year old's wishes.

COCA is also unclear as to whether a guardian can legally give or refuse consent for a 16 or 17 year old who is not competent to decide about services. However, in this situation, a guardian may well be able to give legally effective consent.

A competent child of 16 or 17 years of age has the right to consent and refuse consent to treatment. However, where the competent 16 or 17 year old is refusing lifesaving treatment against the recommendation of a health professional you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

Under 16 year olds

COCA does not state whether under 16 year olds can give legally effective consent (or refuse consent).

It is therefore not clear from reference to the Act alone whether a guardian's consent is always necessary for services for under 16 year olds (except as regards consent to a termination). However the accepted legal view is that a competent child's consent can be relied on as legally effective. The presumption of competence in Right 7(2) of the Code applies equally to children. Further, in New Zealand the practical effect of the 1985 decision of the House of Lords in *Gillick v West Norfolk and Wisbech Area Health Authority* is that it is generally agreed that children under 16 years of age can consent to their own treatment if competent to decide.

Ultimately an assessment of whether a particular child is competent to consent to the proposed service will depend on the understanding and maturity of the child in the particular circumstances. Obviously age is a relevant factor to be considered when determining a child's competence to decide whether to consent to a particular service, but the Code of Rights recognises that the age of the patient is only one of a number of factors to be taken into account.

What COCA does state is that where the consent of another person is "*necessary or sufficient*" a child's guardian may consent or refuse consent to treatment in respect of a child under their guardianship (section 36(3)(a)).

Where an under 16 year old's safety is at risk of any of the following then you should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services:

- a competent under 16 year old refuses treatment against the wishes of their guardian or against the advice of the health professional concerned; or
- where there is any dissent between the parent/guardian and the child; or
- where the child's guardians disagree between themselves.

Termination of pregnancy

COCA (section 38) states that a girl of any age may consent to, or refuse consent to, a termination of pregnancy as if she were an adult provided that she is competent to make the decision.

Legal Representative with Authority to Consent (for an incompetent child)

Under section 36(3) of the Care of Children Act 2004 where the consent of another person is "*necessary or sufficient*" consent may be given by:

- a guardian of the child; or
- where there is no guardian in New Zealand (or that can reasonably be found or who is capable of giving consent), a person acting in the place of a parent to consent; or
- if there is no person acting in place of a parent, or no such person can reasonably be found or is capable of consenting, consent can be given by a District Court Judge or the chief executive of Oranga Tamariki – Ministry for Children ('Oranga Tamariki' or 'OTMC').

The Act also provides that where a child has been lawfully placed for adoption in the home of a person, that person is to be treated as a guardian of the child for the purposes of consent to treatment (section 36(4)).

In situations where it may be difficult to determine who, if anyone, may give consent you should seek advice from the Clinical Director/Professional Adviser, CCDHB's Child Protection Coordinator or CCDHB Legal Services.

Guardians

Generally, a child's parents will be the child's legal guardians. The child's mother will always be a guardian (unless her guardianship has been removed by the Court). Under COCA if the father was married to or living in a de facto relationship with the mother at any time during the period beginning with the conception of the child and ending with the birth of the child he will share automatic guardianship of the child with the mother.

A guardian has duties, powers, rights and responsibilities relating to the upbringing of the child, including determining for or with the child, or helping the child to determine, questions about important matters. The definition of important matters includes "non-routine medical treatment". Therefore, the ability to consent to medical treatment for the child that goes beyond routine medical care is an aspect of guardianship (not custody).

Whilst guardians have an obligation under COCA to consult with one another on **non-routine medical treatment** (but not routine medical treatment) with the aim of securing agreement, a health practitioner is entitled to act on the consent of any one guardian. However, if one guardian is willing to consent to medical treatment and the other objects, the health professional may be left with a dilemma. Strictly speaking the health professional can act on the consent of the consenting guardian. However, it would be advisable to check about consultation with the other guardian and consider whether other reasonable alternatives may be in the child's interests in all the circumstances.

The Court may make a number of orders relating to guardianship of a child or young person which may change who is entitled to consent on behalf of a child or young person. A court may appoint itself a child's guardian and authorise a person, such as the child's doctor, to act as the court's agent either generally or for a particular purpose (section 31 COCA). Once a court has been appointed a guardian of the

child then the Court or its agent (generally the child's doctor) can make decisions with respect to the medical treatment that the child receives.

The parents of the child, or any other person expressing an interest in the welfare of the child, may or not have any rights in respect of the care of the child and the manner in which the child is treated. Generally parents retain guardianship rights to decide matters with or for the child. If any court orders have been made in respect of the child, the responsible health professional must establish immediately who is authorised to consent to treatment on behalf of the child or young person.

Person Acting in Place of a Parent

COCA addresses the difficult situations where:

- a guardian is not available in New Zealand to give consent
- a guardian is located in New Zealand but cannot reasonably be found
- a guardian can be located but is not competent to give consent to the proposed services.

Section 36(3)(b) of the Care of Children Act provides

> *(3) If the consent of any other person to any medical, surgical, or dental treatment or procedure (including a blood transfusion) to be carried out on a child is necessary or sufficient, consent may be given—*
>
> *(a) by a guardian of the child; or*
>
> *(b) if there is no guardian in New Zealand or no guardian of that kind can be found with reasonable diligence or is capable of giving consent, by a person in New Zealand who has been acting in the place of a parent; or*
>
> *(c) if there is no person in New Zealand who has been so acting, or if no person of that kind can be found with reasonable diligence or is capable of giving consent, by a District Court Judge or the chief executive.*

This is an important practical provision as in many cases a child's carer is not a parent but the carer otherwise does not have any legal status in respect of the child (i.e. is not a legal guardian of the child). Where the child is not competent to give consent and is cared for by someone other than a guardian it is important to take reasonable steps to locate a guardian and to contact the guardian before obtaining consent from the carer. If a parent cannot be located or is not capable of giving consent then the carer is legally entitled to give informed consent for the child, provided of course that the carer is competent to do so.

All steps taken in attempting to locate a guardian and any reasons why the treatment could not reasonably delayed until a guardian was located should be clearly documented. Information concerning the 'person acting in place of a parent' , such as their relationship to the child, and any other information that is relied upon in obtaining informed consent from the carer should also be clearly documented.

Providing Services without Consent under Right 7(4) of the Code

In the absence of a person who is entitled to consent on behalf of an incompetent child a health professional may still be able to provide services under Right 7(4) of

the Code of Rights provided the criteria in Right 7(4) are met.

Related sections within this policy: Providing Services without Consent under Right 7(4) of the Code

In those situations where an inability to locate a guardian raises concerns for the child's safety then you should seek advice from the Clinical Director/Professional Adviser, CCDHB's Child Protection Coordinator or CCDHB Legal Services.

Refusal of Services and Duties of Health Professionals

Legislation

Under COCA **a competent child 16 years or over** can refuse to consent to any donation of blood or to any medical, surgical, or dental treatment or procedure. Careful consideration must be given to whether the child is competent to make the particular decision.

COCA is silent on whether a **competent child under 16 years** can refuse to consent to medical treatment. New Zealand law imposes on parents/guardians a legal duty to supply a child in the parent/guardian's actual custody with the "necessaries". This includes medical treatment. A child's refusal to consent to life-saving treatment where the child was under 16 years of age has been treated by a New Zealand court as not providing the child's parents/guardians with a lawful excuse for not obtaining medical treatment in accordance with this legal duty.

Advice should be sought if the health professional believes treatment is required to prevent a serious risk of harm or prolonged pain or suffering to the child and:

- the health professional and parents/guardians disagree as to the course of treatment to be administered to the child
- the parents/guardians disagree between themselves
- a child under 16 years who is assessed as being competent to consent to treatment makes a decision about treatment that is incompatible with their parent's/guardians decision and/or the recommendation of their health professional.

If parents/guardians refuse consent and the health professional believes that this is against the best interests of the child, the health professional may first consider identifying a mediator. It may then be necessary to seek a court order to enable the child to receive treatment. These processes can be fraught with difficulty and must be managed with extreme sensitivity and care. You should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

Fetus or the Pregnant Woman is at Risk

Special consideration is to be made in the situation where a pregnant woman refuses treatment. If the life of the fetus or the woman, or both, are at risk because of the woman's refusal of treatment this must be managed with extreme sensitivity and care.

You should seek advice from the Clinical Director/Professional Adviser or CCDHB Legal Services.

Examinations when Abuse or Neglect Suspected

Any examination of a child or young person in the context of suspected or known abuse must be informed by and comply with relevant legislation and CCDHB's policies. Before conducting any examination of a child or young person without consent of the child and/or guardian the health practitioner must be satisfied that the examination is lawful and meets the requirements of the Oranga Tamariki Act. For the purposes of the Act a 'child' is under 14 years and a 'young person' is 14 years or more and under 18 years (for purposes of Parts 2-3A of the Act that includes those sections concerning medical examinations).

The starting point is that any examination of a child or young person must be with the patient's informed consent or the consent of a guardian or other person lawfully entitled to consent as is applicable.

There are limited exceptions to requirement for consent to medical examinations of child or young person for suspected abuse or neglect (provided for under the Oranga Tamariki Act). The Court may order an examination or the chief executive of Oranga Tamariki – Ministry for Children ("OTMC") may require an examination.

Where the chief executive of OTMC has delegated any power or function to an OTMC social worker then the social worker may exercise that delegated authority subject to any restrictions or requirements of the applicable delegation.

*Cases of sexual abuse, or suspected sexual abuse should always be discussed with a doctor specifically trained in this field. Always refer to the Paediatrician on Call before you decide whether to examine or not***.**

Related Sections within this policy:

Appendix 9: Medical examination: child Form

Appendix 2: Summary of Statutory Provisions Relating to Consent (including Legislation Relating to Children and Young Persons – Oranga Tamariki Act)

Related CCDHB Policies:

Child abuse and neglect (CAN)

Suspected child abuse - management in ED

Suspected child abuse management - Kenepuru A&M Clinic

Request for medical examination: child Form

Where there is any doubt about the legal basis to examine a child seek advice from the Paediatric Consultant on Call, the Clinical Director/Professional Adviser, CCDHB's Child Protection Coordinator or CCDHB Legal Services.

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Information, choice of treatment and informed consent: Medical Council Statement (March 2011), Medical Council of New Zealand

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Ministry of Health. 2007. Guidelines for the use of human tissue for future unspecified research purposes. Wellington: Ministry of Health.

Related documents

CCDHB policies:

- Advance directives relating to mental health
- Bicultural safety
- Blood/body substance and body fluid exposure
- Blood component and plasma product transfusion
- Certification within Te Mahoe
- Child abuse and neglect
- Clinical Emergency (resuscitation)
- Elder Abuse and Neglect
- Human tissue – management and handling
- Medical photography and video recordings
- Partnering with whānau who are supporting patients
- Patient surgical safety
- Prescribing unregistered medicines and use of medicines for unapproved Indications
- Privacy
- Research
- Restraint minimisation and safe practice
- Section 111 Registered Nurse Power to Detain a person for urgent assessment under the Mental Health (Compulsory Assessment and Treatment) Act 1992
- Specimen and tissue management in operating theatres – Wellington Regional Hospital
- Use of interpreting services

Other CCDHB documents:

- Advance Care Planning Guidelines
- Protection of Personal and Property Rights Act 1988: Guide for staff
- Enduring power of attorney: Guide for staff
- Human tissue information for patients – Ngā Mōhiohio kikokiko Tangata mō ngā Tūroro

Appendix 1: Code of Health and Disability Services Consumers' Rights 1996

These are available as printed HDC brochures in the ward areas or use the hyperlink

Code of Health and Disability Services Consumers' Rights 1996

Appendix 2: Summary of Statutory Provisions Relating to Consent

Legislation	
New Zealand Bill of Rights Act 1990 (BORA)	
Affirms fundamental rights and freedoms including rights to refuse treatment and not to be subjected to experimentation without consent	Section 10 provides that every person has the right not to be subjected to medical or scientific experimentation without consent. Section 11 provides that everyone has the right to refuse to undergo any medical treatment.
Contraception, Sterilisation and Abortion Act 1977	
Abortions may be provided to persons who lack "mental capacity" to consent	Section 34 permits abortions to be performed on patients who lack the capacity to consent by reason of "any mental incapacity" provided that the requirement to consult is met. This requires that a doctor (or other person) qualified and experienced in the field is able to make an assessment of the patient's condition and the likely effect on it of the continuance of the pregnancy or an abortion).
Contraceptive advice and treatment may be provided to females whose mental incapacity meets the definition of "mentally subnormal"	Under section 4 of the Act a female who meets the definition as "mentally subnormal" (section 4) may be administered any contraceptive if it is in her best interests to do so. The Act provides for a guardian, person acting in place of a parent or having custody or care, or any doctor in the course of treating their patient, may administer the contraceptive (except that only a medical practitioner may fit an IUD or administer an injectable contraceptive).
Consent to abortion of itself is not sufficient authority for abortion procedure	Notwithstanding the consent of the person to an abortion, section 29 of the Act provides that no abortion shall be performed unless and until it is authorised by 2 certifying consultants.

Coroners Act 2006	
Coroner may require post mortem	Under the Coroners Act 2006 the Coroner may require a post-mortem, in certain circumstances. The deceased family may have a right to object to the post-mortem (sections 33 – 35).
Crimes Act 1961	
The crime of assault is the criminal offence that is most obviously relevant when health practitioners provide health and disability services involving bodily touching, in the absence of legally effective consent. Reasonable restraint without consent where likelihood of suicide or offence likely to cause immediate serious injury to person is a defence to a claim of assault	Offence of assault is provided by section 196. Without lawful justification for using reasonable force in the circumstances, the use of force is unlawful. Section 41 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 the person or property of anyone. Any restraint must only ever use "such force as may be reasonably necessary" in the situation. Section 48 of the Crimes Act provides for a defence where reasonable force was used in self-defence or defence of others in the circumstances that the person applying the force believed them to be.
Crimes Act has 2 provisions that deal expressly with surgical operations generally (and that impliedly extend to other medical treatment)	Section 61 provides that everyone is protected from criminal responsibility for performing with reasonable care and skill any surgical operation for the patient's benefit if it was reasonable to do so having regard to the patient's circumstances. Section 61 may have its main role where an operation has been performed without consent (e.g. where the patient lacked capacity and there was no discoverable legal proxy). Section 61A(1) provides that everyone is protected from criminal responsibility for performing with reasonable skill and care any surgical operation with the consent of that person (or their legal representative) for a lawful purpose.
Criminal Investigations (Bodily Samples) Act 1995	
Provides limited statutory exceptions to taking blood or bodily samples from criminal suspects without consent for DNA profiling	The Criminal Investigations (Bodily Samples) Act 1995 provides a statutory regime for obtaining blood or bodily samples for the purpose of DNA profiling from criminal suspects. The police may request a blood sample from a patient under the Criminal Investigation

	(Bodily Samples) Act 1995 if they have reasonable grounds to believe the analysis of the sample would tend to confirm or disprove the person's involvement in an offence. The Act also sets out the limited circumstances when a bodily sample may be taken without the person's consent. The Act makes special provision regarding children and young persons (refer to the section below on "Children and Young People").
Criminal Procedure (Mentally Impaired Persons) Act 2003 CP (MIP) Act	
Under the CP (MIP) Act a defendant found unfit to stand trial or acquitted on account of insanity may be detained in a hospital (as a special patient under the Mental Health (CAT) Act 1992; or in a secure facility as a special care recipient under the Intellectual Disability (CCR) Act 2003)	The relevant legislation, (MH (CAT) Act or ID (CCR) Act), regarding consent to treatment and to compulsory treatment (as the case may be) applies.
Where issues of mental impairment arise during sentencing, under the CP (MIP) Act, the Court may either commit the offender to hospital on conviction (as a special patient or as a special care recipient) or, instead of passing sentence, order treatment (as a patient or as a care recipient)	The Court may sentence the offender to a term of imprisonment and also detention in a hospital as a special patient under the Mental Health (CAT) Act or detention in a secure facility as a special care recipient under the Intellectual Disability (CCR) Act 2003. Alternatively, instead of passing sentence, the Court may order treatment as a patient under the Mental Health (CAT) Act or care as a care recipient under the Intellectual Disability (CCR) Act.
An order detaining a person in a hospital (or secure facility) under sections 23, 35 or 38(2)(c) CP (MIP) Act is authority only for treatment where the person has given consent. Where the person is incapable of giving consent the DAHMS for the hospital may authorise urgent treatment to prevent serious harm to the person or to others	When a person is (or may be) found unfit to stand trial or insane the Court may order the detention of a person in a hospital while inquiries are made or for purposes of assessment (under sections 23, 35 or 38(2)(c) CP (MIP) Act). An order for detention under these sections is authority only for the administration to the person of any medical treatment or procedure to which the person has given consent (section 43(1)). If the person is incapable of giving consent, the DAHMS for the hospital (or where it is a secure facility then the co-ordinator for the secure facility) may authorise any medical treatment or procedure that, in the DAHM's opinion, is immediately necessary to prevent: the physical or mental deterioration of the person; or serious suffering by the person; or

	the person causing harm to themselves or to others (section 43(2)(a)-(c)).
Health Act 1956	
Medical Officers of Health may seek Court orders requiring a person to undergo medical examinations for infectious diseases (sexually transmitted infections and tuberculosis) where the person has refused consent	Infectious diseases that must be notified are listed in Schedule 1 and Schedule 2 of the Health Act 1956. They are diseases at the serious end of the spectrum and may need a public health response as well as follow up treatment by health practitioners. Medical Officers of Health and others carrying out notification or infectious disease management functions under the (new) Part 3A of the Health Act will not face any civil or criminal liability for any conduct unless there is bad faith or lack of reasonable care. Medical Officers of health can direct medical examinations (provided statutory preconditions are met) and apply to the court for medical examination orders for use when a health practitioner has asked the 'case' to undergo an examination and the person has refused. Since 2017 the term 'venereal diseases' is no longer used with the Venereal Diseases Regulations and sections 88-92 of the Health Act concerning venereal diseases are replaced by infectious disease notification and management provisions in the Health Act. The Tuberculosis Act and Regulations have also been repealed (notification and management of tuberculosis has been 'mainstreamed' under the Health Act with other notifiable, infectious diseases. Link: http://www.health.govt.nz/publication/guidance-infectious-disease-management-under-health-act-1956
Medical Officer of Health may require persons to report for or submit to medical examination in response to an "epidemic notice"	The purposes of the Epidemic Preparedness Act 2006 are to try and prevent and manage outbreaks. An epidemic notice in force under the Epidemic Preparedness Act 2006 gives the Medical Officer of Health special powers that may include requiring persons to report or submit to medical examination. The Act can be invoked in relation to a "stated quarantinable

	disease" within the meaning of the Health Act (Part 3 of Schedule 1 of the Health Act).
Human Tissue Act 2008	
The Human Tissue Act makes it an offence to collect or use human tissue from a body, or to use tissue collected whilst the person was alive for a secondary purpose after the donor's death, or to collect non-health-care tissue for donor analysis or other analysis without having obtained the required informed consent (with limited exceptions under s 20)	Under section 19(a) of the Human Tissue Act the required informed consent must be given for the following (unless done for a purpose specified in section 20): (i) collection or use of human tissue that is, or is collected from, a body: (ii) collection of non-health-care tissue for donor analysis: (iii) donor analysis of non-health-care tissue: (iv) use for a secondary purpose, after the donor's death, of human tissue collected from a living individual. Section 19(b) makes it an offence to collect or use tissue if the informed consent required has not been given (sections 22-24). Section 20 of the Act sets out a number of exceptions to the requirement for informed consent as follows: (a) the exercise by a person of that person's powers under any law to collect or use tissue without consent, including (without limitation) powers of that kind exercised for either of the following purposes: (i) the maintenance of the law, including the prevention, detection, investigation, prosecution, or punishment of offences; or (ii) the protection of the health or safety of members of the public: (b) the implementation, by using non-health-care tissue for donor analysis, of a direction or order of a court or tribunal: (c) the provision, for the medical benefit of another person or a child conceived but not

	born, and by using non-health-care tissue for donor analysis, of information about the individual from whom the non-health-care tissue was collected or derived, if— (i) it is not reasonably practicable to find that individual or, if they have died, a personal representative or family member of that individual; and (ii) all reasonable efforts have been made to ascertain whether that individual objected to the tissue being used for those purposes, and they appear not to have done so: (d) the performance of a post-mortem of a body that one of the following competent legal authorities has, under one of the following enactments, directed or ordered to be performed: (i) a coroner acting under section 31 of the Coroners Act 2006; and (ii) the High Court acting under section 41 of the Coroners Act 2006; and (iii) the Director-General of Health acting under section 78 of the Health Act 1956: (e) the carrying out, by using for a secondary purpose tissue that is a body or is collected from a living individual or a body, or by using non-health-care tissue for donor analysis, of research that has received the approval of an ethics committee (even though the ethics committee knew that informed consent had not been, and would not be, obtained for the research): (f) the carrying out, to assure or improve the quality of services, and by using for a secondary purpose tissue that is a body or is collected from a living individual or a body, or by using non-health-care tissue for donor analysis, of all or any of the following activities: (i) a professionally recognised quality assurance programme: (ii) an external audit of services: (iii) an external evaluation of services: (g) the testing or disposal of tissue that is a body or is collected from a living individual or a body, because— (i) that testing or disposal is or may be necessary to avoid endangering the health or safety of members of the public; or (ii) that disposal is necessary or desirable because all reasonable attempts have been made, but have failed, to return the tissue to a family member or other person to whom the tissue would otherwise be returned for disposal:

	(h) display by or on behalf of the responsible person and to enable people to pay their final respects to, or that is incidental to the funeral of, the dead individual: (i) burial, cremation, or other lawful disposal, by or on behalf of the responsible person, of the tissue concerned.
Intellectual Disability (Compulsory Care and Rehabilitation) Act 2003 (ID (CCR) Act)	
This Act provides a system for the compulsory care and rehabilitation of persons who have an intellectual disability and who have been charged with, or convicted of, an offence. Compulsory care may be provided to persons with intellectual disability who are a care recipient or potential care recipient subject to the requirements of the Act.	The ID (CCR) Act defines the circumstances in which persons may be subjected to compulsory assessment, care and rehabilitation for intellectual disability (section 37). The Act provides for the care recipient's obligation to accept care lawfully given (section 47); the specific rights of care recipients (sections 48 to 59); and the circumstances in which care recipients may be placed in seclusion, restrained, or receive medical treatment without their consent. A "care recipient" or "potential care recipient" (as defined in section 6) is required to accept an assessment examination by a specialist assessor designated under section 32(b) to ascertain whether the proposed care recipient has an intellectual disability and is in need of compulsory care. A care recipient may only be given medical treatment without the care recipient's consent if the treatment is authorised by section 62 of the Act.
Judicature Act 1908	
A Court may order a person who is party to proceedings to attend a medical examination however the examination cannot proceed without the person's informed consent	Section 100 of the Judicature Act 1908 provides that the High Court can order that a person submit to a medical examination where the physical or mental condition of a person party to the proceedings is relevant to any matter in question. Whilst the person ordered to attend the examination is obliged to attend and cooperate, the provision does not authorise an examination without the person's consent. Rather a failure to attend without reasonable cause empowers the Court to stay or strike out the proceedings concerned.

Land Transport Act 1988	
Subject to the health practitioner meeting the requirements of the Act, a health practitioner is obliged to take blood samples to detect drink driving offences at request of Police but is not authorised to use force to do so under the Land Transport Act 1988	Section 73 of the Land Transport Act 1998 allows the taking of blood samples from persons attending hospital or doctor's surgery suffering injury as a result of a motor vehicle accident (section 74 concerns the procedure for dealing with the specimens). Special requirements apply. Whilst it is mandatory that a health practitioner take a blood sample if requested by the Police, there is no authority under the Act to use force. Despite the requirement that the health practitioner must take a sample at request of Police there are a number of requirements that must be met before meeting the request. A blood specimen may be taken under this section only if: The medical practitioner has reasonable grounds to suspect that the person is in the hospital as a result of an motor vehicle accident (or an injury or a medical condition arising subsequent to a motor vehicle accident); and has examined the person and is satisfied that the taking of the blood specimen would not be prejudicial to the person's proper care or treatment; and tells the person (unless the person is unconscious) that the blood specimen is being or was taken under this section for evidential purposes (if a blood specimen is taken from a person who is unconscious, the medical practitioner must notify the person in writing as soon as practicable that the specimen was taken under this section for evidential purposes).
Mental Health (Compulsory Assessment and Treatment) Act 1992 (MH (CAT) Act)	
Subject to the requirements of the Act compulsory care may be provided to persons who are 'mentally disordered'. Despite the possibility of compulsion clinicians must make an effort to obtain consent to treatment wherever possible	Under the MH (CAT) Act, a person who is required to undergo assessment in terms of Part I of the Act or under an Order for compulsory treatment in terms of Part II has no right to refuse treatment for the person's mental disorder for the first month duration of that order. The responsible clinician shall, wherever practicable, seek to obtain the consent of the patient to any treatment even though that treatment may be provided without the patient's

	consent (section 59(4)).
There is a statutory right to be informed about treatment	Every patient is entitled to receive an explanation of the expected effects of any treatment offered to the patient, including the expected benefits and the likely side effects, before the treatment is commenced (section 67).
Every 'special' patient under the MH (CAT) Act must be given care and treatment as if subject to a compulsory treatment order under the Act	Special' means the person needs additional security for their or the public protection arising from their mental disorder. Section 44 provides that: subject to the provisions of any other enactment, every special patient shall be given such care, treatment, training, and occupation as the patient would be given if he or she were subject to a compulsory treatment order.
In certain circumstances the MH (CAT) Act allows for prisoners to be transferred from a prison to a psychiatric hospital on account of mental disorder or intellectual disability. Where the patient is transferred to hospital under section 46 the patient must consent to being admitted and detained in hospital	Mentally unwell prisoners may be transferred from a prison to a psychiatric hospital for assessment examination. If the assessment supports it, care and treatment on account of mental disorder is provided (section 45). Where a successful application is made (in terms of the required findings in a certificate of assessment) the inmate becomes a committed patient for the duration of any necessary treatment (but must be transferred to prison when no longer mentally disordered). Inmates who are not legally mentally disordered, but who would benefit from psychiatric care and treatment can be detained in hospital for treatment with the consent of the patient and Department Corrections and Director of Mental Health (section 46).
Section 111 of the MH (CAT) Act provides registered nurses the power to detain a person for urgent assessment under the MH (CAT) Act.	Section 111 allows a registered nurse to detain for the purpose of an assessment examination, a person who has been bought or admitted to hospital who is believed to be mentally disordered and in urgent need of assessment. A person can be detained for up to 6 hours by use of reasonable force if necessary (section 122B (2)) until they can be assessed under section 8B. This assessment is to be completed as soon as practicable and within six hours of place the person under section 111. Medical practitioners have similar powers under section 110 of the same Act. (A doctor cannot complete a section 111 form or instruct a registered nurse to do so).

Protection of Personal and Property Rights Act 1998 (PPPR Act)	
Validly appointed persons with Enduring Power of Attorney (EPA) are authorised to give consent when the person lacks capacity (subject to specific exceptions)	Under section 98 of the PPPR Act a person may be authorised to give consent for a patient who is mentally incapable under an enduring power of attorney in relation to personal care and welfare (EPA). The EPA will have the powers described in the EPA document. Unless it is an emergency, where an EPA has been appointed, the consent of the EPA must be obtained before providing any services. The PPPR Act limits the EPA's powers i.e. an EPA cannot consent to ECT, or brain surgery for purpose of changing behaviour, or experimental treatment that is not for the purpose of lifesaving or other necessary treatment.
An EPA must not decide a 'significant matter' relating to personal care and welfare unless a valid certificate of mental incapacity has been completed	An attorney will need a medical certificate of incapacity to make decision on significant matters (section 98(3)). A significant matter means "one that has a significant effect on health, wellbeing or enjoyment (e.g. a permanent change in the donor's residence, entering residential care, undergoing a major medical procedure".
Welfare Guardians appointed by the Court are authorised to give consent (subject to specific exceptions)	The PPPR Act allows the Court to appoint a Welfare Guardian (WG) to make decisions relating to aspects of the personal care and welfare of a person who 'wholly lacks capacity' to make or communicate a decision. Unless it is an emergency, where a WG has been appointed, the consent of the WG must be obtained before providing any services for the patient. A WG does not have the power to consent to ECT, or brain surgery for purpose of changing behaviour, or experimental treatment not for the purpose of lifesaving or other necessary treatment.
Substance Addiction (Compulsory Assessment and Treatment) Act 2017 (SACAT)	
Subject to the requirements of the Act compulsory care may be provided to persons who lack capacity to decide treatment for 'severe substance addiction'	SACAT (having repealed the Alcoholism and Drug Addiction Act 1966) provides for the compulsory assessment and treatment of individuals with severe substance addiction who lack the capacity to make decisions about services. The purpose is to enable people to

	receive compulsory treatment if they have a severe substance addiction and their capacity to make decisions about treatment for that addiction is severely impaired. Strict criteria for compulsory treatment are set (sections 7 to 10) along with indicators for when compulsory status begins and ends (section 11).
Legislation Relating to Children and Young Persons	
Care of Children Act 2004 (COCA)	
Guardianship of the child may be vested in the Court in order to provide consent to services	For the purposes of COCA a "child" means a person under 18 years. A Court may appoint itself a child's guardian and authorise a person, such as the child's medical practitioner, to act as the Court's agent either generally or for a particular purpose (s 31). Once a court has been appointed a guardian of the child it, or its agent (generally the child's doctor), can make decisions with respect to the health and disability services that the child receives. Generally parents retain guardianship rights to decide other matters with or for the child.
Provides limited immunity against legal and disciplinary proceedings for emergency blood transfusions without consent for persons under 18 years	Section 37 COCA provides some legal protections against criminal, civil and disciplinary proceedings for a health professional who administers a blood transfusion to a child under 18 years without consent in an emergency where the practitioner reasonably believed the transfusion was necessary to prevent death or permanent injury or prolonged pain, and had made reasonable attempts to obtain the necessary consent in the time available. The immunity can only be removed if a Judge considers that the protective circumstances in s37 of the Act were not met.
Competent female child of any age may consent to abortion or other procedure to terminate pregnancy	Section 38 COCA provides that a girl of any age is treated as an adult for the purpose of consent, or refusal of consent to, a medical or surgical procedure for the purpose of terminating her pregnancy, by a person professionally qualified to carry it out.
Contraception, Sterilisation and Abortion Act 1977	
Youth of itself is never sufficient basis for consent of a guardian to be legally effective consent to	Section 7 of the Contraception, Sterilisation and Abortion Act provides that no person is legally entitled to consent on behalf of another to a sterilisation operation where the only

sterilisation	reason that the person lacks capacity to consent is because of their age. Youth of itself is never sufficient basis for consent of another to be legally effective.
Criminal Investigations (Bodily Samples) Act 1995	
Provides Police with limited statutory regime for taking blood or bodily samples from criminal suspects for DNA profiling and for taking bodily samples from a child without consent	The Criminal Investigations (Bodily Samples) Act 1995 provides a statutory regime for obtaining blood or bodily samples for the purpose of DNA profiling from criminal suspects. The police may request a blood sample from a patient under the Act if they have reasonable grounds to believe the analysis of the sample would tend to confirm or disprove the person's involvement in an offence. The Act distinguishes between persons under the age of 14 years, children 14 to 17 years, and persons over the age of 17 years. For consent to be valid the requirements set out in the Act must be followed. The Act also sets out the limited circumstances when a bodily sample may be taken without the child's or guardian's consent.
Health Act 1956	
Certain health professionals may examine children in schools without parental consent	The Health Act (s125) permits certain health professionals to enter schools and child care centres to examine children (subject to the request of school in case of private schools). The health professional may examine any child at the school or centre. The prior consent of the parents is not required. If a child is competent to consent then a health professional must obtain the child's consent before administering treatment.
Intellectual Disability (Compulsory Care and Rehabilitation) Act 2003 (ID (CCR) Act)	
Subject to the requirements of the Act children and young persons with intellectual disabilities may be provided with compulsory assessment, care and rehabilitation	For the purposes of the ID (CCR) Act 'child and 'young person' are given the same meaning as under the Oranga Tamariki Act. The ID (CCR) Act defines the circumstances in which persons may be subjected to compulsory assessment, care and rehabilitation for intellectual disability (s37). A care recipient may be given medical treatment without the care recipient's consent only if the treatment is authorised by s62 (except emergency

	medical treatment). A guardian's consent to medical treatment is necessary if the child or young person is under 16 years and is unable to consent. The exception to this is treatment authorised under s62.
Mental Health (Compulsory Care and Treatment) Act 1992 (MH (CAT) Act)	
Parent or guardian cannot consent to compulsory treatment under the MH (CAT) Act once the child is of or over 16 years	For the purposes of consent to assessment and treatment under the MH (CAT) Act a child or young person is a patient or proposed patient who is under the age of 17 years (s85). Once a person has attained the age of 16 years, a parent or guardian cannot consent to any assessment or treatment for mental disorder on behalf of the person (s87). Therefore once a person is 16 years or older they must be treated as an adult for the purposes of consenting to assessment or treatment of any mental disorder. This means that even if the young person is incompetent it will not be sufficient for a parent or guardian to give consent. Where the person is incompetent or refuses treatment for mental disorder under the MH (CAT) Act, the young person must be managed in the same way as an adult who is incompetent or refuses assessment or treatment under the MH (CAT) Act.
Oranga Tamariki Act 1989	
There are limited exceptions to requirement for consent to medical examinations of child or young person for suspected abuse or neglect where ordered by the Family Court or requested by the chief executive of OTMC	For the purposes of the Oranga Tamariki Act a 'child' and 'young person' are defined. A child is under 14 years and a young person is 14 years or more and under 18 years (for purposes of Parts 2-3A that includes those sections concerning medical examinations. Sections 49 - 58 of the Act concern the medical examination of a child or young person). The Act provides for some very limited exceptions to the requirement for informed consent for medical examinations: The court has the power to order medical examinations and reports in respect of children and young persons (ss49 and 52 of the Act). Under s49 of the Act the court may order a medical examination of a child or young person

	under the age of 17 years without the consent of either the child or young person or the child's guardian or parent. A social worker for OTMC may take custody of the child and organise this examination. The chief executive of OTMCi may request a medical examination in limited situations (where either a place of safety warrant has been taken out under s39 or where the child is in the custody of the chief executive under s40 or s42). Where consent of a guardian cannot be obtained after making reasonable efforts to obtain consent then (under s53) the chief executive can require the examination without a guardian's consent. The legal ability to require an examination without consent under s53 is not unlimited: • Section 55 of the Act sets restrictions and provides that no s53 examination may involve a general anaesthetic without consent. • Further, no medical examination carried out under s53 shall include any internal examination of the genitals or anus of any child or young person unless (a) the health practitioner carrying out the examination believes that the child or young person may have been subject to recent physical or sexual abuse involving either or both of those parts of the body and (b) the child or young person consents to such an examination of that part of the body (unless their age or level of maturity makes it impractical to consent). Every child or young person examined under s53 is entitled to have adult support (nominated by the child or the chief executive).
Where the chief executive of OTMC is made sole guardian under the Act consent to treatment must be given by the chief executive	Under s110(2)(a) Oranga Tamariki Act, where the chief executive has been appointed as a sole guardian of a child consent can only be given by the chief executive. A child 14 years and over may apply to the court to overturn a refusal of consent by the chief executive in respect of important matters that affect the child (s116).
Where the chief executive of OTMC has delegated any power or function to an OTMC social worker (or	The chief executive of OTMC has delegated a number of operational functions and powers to Ministry personnel (under s41 of the State Sector Act 1988 and s7A of the Oranga

other Ministry personnel) then the OTMC social worker (or other personnel) may exercise that delegated authority subject to any applicable restrictions or requirements of the delegation Refer: *Oranga Tamariki Delegation of operational functions and powers under the Oranga Tamariki Act* (that is published on the Ministry for Children's website in accordance with s 7F of the Act)	Tamariki Act) concerning medical examinations and consent for health and disability services to: **OTMC social workers**: • To apply to court for an order for a child or young person to undergo a medical examination (ss49(2) and 178(1)) • To arrange for a child or young person with consent of any parent/guardian to be medically examined (s53(2)) • To require a child or young person to be medically examined where, after reasonable efforts, a social worker does not obtain consent of a parent/guardian (s53(3)) • To nominate an adult who consents to be present during the child or young person's medical exam if their age or maturity makes it impracticable for the child or young person to nominate (ss54(a) and 179(4)(a)) • For the purpose of the court imposing a condition of a support order requiring a child or young person under 16 years to undergo any medical, psychiatric or psychological examination, treatment or counselling or therapy, to give consent if no parent/guardian or person acting in place of a parent capable of giving consent is able to be found in NZ (s98(a)) • To exercise the functions and powers of a sole or additional guardian for a particular purpose (such as giving consent to treatment) under an order under s110 appointing the chief executive as sole or additional guardian or for a particular purpose (ss110 and 114) • If a care agreement (under ss 139 or 140) provides for the chief executive to give consent to a medical, surgical or dental procedure, to give consent to that procedure that a guardian may give under s36(3) of the Care of Children Act 2004

	(s149) • If the chief executive of OTMC is custodian for the child (under ss 78,101 or 102) to consent to routine medical treatment (s104(1)(a)) **OTMC Team Leaders**: Where a young person is subject to supervision with residence orders, to decide whether there is any person in NZ capable of giving consent to medical treatment (s319(b)(ii)) and to consent to medical treatment (s319(b)(ii)).

Appendix 3: Health & Disability Commissioner/ HPDT / MPDT Decisions

(On the outcome of complaints investigated concerning informed consent) illustrative of this Policy

Code of Rights	HDC/HPDT/MPDT Case
R (5) - to effective communication	14HDC00307 Consent for surgery obtained while on operating table, 15 June 2015 Discussion in theatre did not meet requirement for effective communication with result that consent given was not effective: Clinician breached Rights 5 and 7(1). Held that the manner in which the woman's consent was obtained for the removal of her ovaries was not appropriate. Theatre was not an appropriate environment for the informed consent process to occur, and did not allow for effective communication. Furthermore, the woman was not given sufficient time to consider whether she wished to have the procedure, and was not in a position to give informed consent to the removal of her ovaries.
	16HDC00083 Laser eye surgery and informed consent for change of treatment plan, 9 Mar 2018 Discussion in theatre with patient under sedation did not meet requirement for effective communication: Clinician breached R 5 and R7(1). Where the change in procedure was not due to an emergency, mid-surgical procedure was not an appropriate environment for the surgeon to seek the woman's informed consent for the change in procedure. Because the ophthalmologist discussed the change in procedure with the woman during the surgery, while she was sedated, she was not able to give adequate consideration to the change and was not in a position to give her consent to the change in procedure freely.

	01HDC01835 Lack of informed consent prior to abdominoplasty, June 2003 Discussion in theatre corridor with patient under sedation was not effective communication: Clinician breached Rights 5, 6 and 7(1). HDC referred to Director of Proceedings who laid charges with MPDT 04/118D MPDT Finding of Conduct Unbecoming (on appeal to District Court) The consent which the patient purportedly gave to the Doctor for the surgical procedure was not valid. The patient was unable to consent because of the effects of midazolam which had been administered approximately one hour earlier. The MPDT also considered it was not appropriate for the surgeon to attempt to obtain consent for a significant procedure in the corridor of the theatre giving no time for the patient to consider and reflect on the information in the short time before going into theatre.
Right 6(1) - to information that a reasonable consumer, in that consumer's circumstances would expect to receive	15HDC01847 Removal of fallopian tube without informed consent, 12 March 2018 Proceeding with an additional surgical procedure without having obtained consent deprived the patient of the right to give informed consent to treatment: Clinician breached Rights 6 and 7(1). The Commissioner considered that although the woman may have required further surgery or intensive care treatment in the near future, it was plainly unacceptable that the gynaecologist removed the right fallopian tube without the woman's consent. The right to decide was the woman's, and she was deprived of it. It was found that the gynaecologist failed to provide the woman with the information that a reasonable consumer would need in order to give informed consent. It follows that the woman was not in a position to give informed consent to the surgery.
	15HDC00369 Advice from midwife during labour, 3 May 2018 Failure to discuss Ministry Referral Guidelines with the woman in the circumstances deprived the woman of information a reasonable consumer would expect to receive: Midwife breached R 6. The LMC midwife failed to discuss the requirements of the MOH Referral Guidelines with the woman when her blood pressure increased antenatally. The LMC midwife also did not discuss the

	recommendation in the Referral Guidelines for an obstetric consultation in light of the woman's slow progress in labour and the risks that the slow progress could pose to her and her baby. This was information a reasonable consumer would expect to receive.
Right 6(1) - to information that a reasonable consumer, in that consumer's circumstances would expect to receive	13HDC00538 Provision of insufficient information to obtain informed consent, 16 December 2014 Failing to adequately inform the patient of the individual risks for that patient of surgery where there was undue reliance on an information sheet or to inform of other options meant the patient didn't have sufficient information to give informed consent: Clinician breached Rights 6 and 7(1). The surgeon concluded that the best option was surgery and did not inform the patient of other options or of the risks of surgery for him in his circumstances. Held that the man had the right to the information that a reasonable consumer in his circumstances would expect to receive, including an explanation of the treatment options available and an assessment of the expected risks, side effects, benefits and costs of each option. Without this information, the man was not in a position to give informed consent to the surgery. Regarding the use of information sheets in obtaining informed consent the HDC stated: "…information given to a patient must be specific to the particular patient, and take into account the particular circumstances and requirements of the patient. I do not consider that standard information forms are a substitute for providing specific information to an individual patient."
Right 6(1) - to information that a reasonable consumer, in that consumer's circumstances would expect to receive	03HDC05435 Complications following bilateral breast reduction, abdominoplasty, and liposuction, 28 October 2005 Failure to advise patient of the "gory details" meant consent was not informed, regardless of whether the patient wished to hear such details. Clinician breached Right 6. HDC referred to Director of Proceedings who laid charges with HPDT 107/Med06/37D where charge of inadequate informed consent upheld. Prior to patient's arranged surgery for combined surgical procedures, failed to adequately inform Mrs T of all the risks involved in the procedures and therefore failed to obtain informed consent. HDC stated:

	"*a patient's signature on a form is not in itself proof that all necessary information has been provided in a way that enables the patient to understand it. The nature of the proposed surgery (though not all the technical details) must be explained)*".. HPDT stated: "*When Dr H wished to discuss the incisions he would make, the patient did not want to know what the "gory details" were. She was not pressed on this issue and should have been. This is because unless the surgeon could properly describe the procedures to be carried out, the patient could not fully understand what was involved. [This case] involved significant procedures, and the patient needed to have a full understanding of what was involved. [A] statement by a patient that they do not want to hear the details does not obviate the obligation that the surgeon has to properly inform.*"
Right 6(1) - to information that a reasonable consumer, in that consumer's circumstances would expect to receive	12HDC01488 Failure to provide full information; postoperative bleeding and delay in re-operating, 10 March 2015 Information about restrictions on surgical practice was information that a reasonable consumer undergoing surgery would expect to receive: Clinician breached Right 6. Surgeon explained to the man that he required removal of his gallbladder and a hernia repair operation. At the time, the surgeon was subject to voluntary restrictions on his surgical practice, which the man was not informed of. Held that information about the voluntary restrictions on the surgeon's practice may have influenced the man's decision to undergo the surgery at that time and place, and to have had it performed by that surgeon. By not providing that information, the surgeon breached Right 6(1).
	13HDC01345 Complication during eye surgery, 16 June 2015 Information about trainee status was information a reasonable consumer undergoing delicate surgery would expect to receive: Senior ophthalmology trainee breached Rights 6 and 7(1). Held that in the particular circumstances that the senior ophthalmology trainee did not explain to the woman sufficiently that he was a trainee and that he would be carrying out the surgery on her, and did

	not inform her of any increased risks resultant from having such delicate surgery performed by a trainee. It followed that the woman was not in a position to give informed consent.
Right (7)(1) - Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent	15HDC101925 Insertion of intrauterine device without consent, 19 December 2016 Proceeding with an alternative procedure without having obtained consent deprived the patient of the right to give informed consent to treatment: Clinician breached Right 7(1). An attempt to perform the consented endometrial ablation procedure had to be abandoned. The gynaecologist then decided to insert a Mirena intrauterine device despite the woman having declined to have a Mirena inserted on a previous occasion, and not having given consent to have a Mirena on this occasion. The gynaecologist considered the Mirena to be the safest and most easily reversible treatment option. The right to decide was the woman's, and she was deprived of it.
Right 7(9) - right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure	00HDC08358 Written consent to hysterectomy considered conditional on surgical finding of ovarian cancer not severe endometriosis, 9 May 2002 Proceeding with an additional surgical procedure without having obtained consent deprived the patient of the right to give informed consent to treatment: Clinician breached Right 7(1) and also Right 7(9) in failing to advise right to have tissue returned. The HDC held that the consultant did not state that ovarian cancer was anything more than a possibility to be confirmed during surgery. The key issue was whether the patient consented to a hysterectomy in the event endometriosis, and not cancer, was confirmed during her operation. She had indicated she would consider radical surgery if cancer was confirmed but she had not consented to the radical procedure to treat severe endometriosis alone (in the absence of cancer). The Consent Form included the radical procedure but "a signature on a consent form is not necessarily determinative that valid and effective consent has been given".

	The consultant and the hospital also breached Right 7(9) in failing to inform the patient of her right to have her uterus returned to her.
	15HDC01258 Misdiagnosis of ectopic pregnancy and communication about return of tissue, 31 March 2017 Failure to provide information about the right to have tissue removed during a health care procedure returned to the patient was a failure to provide information that a reasonable consumer would expect to receive: DHB breached Right 6. The DHB did not provide the woman with information that a reasonable consumer would expect to receive regarding the process for the return of tissue, including information relating to the timeframe, and consequences of any decision relating to the return of tissue. The patient stated: "*I am Māori with strong connections to my tikanga … no one asked me if I wanted my tissue returned. … for a week after the surgery I believed that my removed fallopian tube contained a baby and I wanted to have it returned to me so that I could dispose of it in line with tikanga*."
Adult patients with diminished competence	
Right 7(1) – Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code of Rights provides otherwise.	16HDC00720 Use of canvas belt without consent and failure to ascertain competency, 11 January 2018 The consent of the legal representative (EPA) was not valid when the patient was competent to consent and had not given informed consent. Rest Home breached Right 7(1) and also breached Right 4(1) by failing to verify the man's legal status and competency. The man had appointed his sister with enduring power of attorney (EPA) for personal care and welfare. Despite the man being competent and the EPA for personal care and welfare not having been activated, the rest home consulted the EPA for personal care and welfare about use of an enabler/restraint and obtained her consent for its use. There were no grounds to believe that Mr A was mentally incapable and unable to make decisions for himself. The EPAs consent was not legally valid and there was no

	evidence that the man had given informed consent to its use. The rest home had a responsibility to verify Mr A's legal status, and to be clear about the legal basis on which it was to provide services.
Right 7(4) – 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 he or she were competent; or (ii) if the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in	13HDC01252 Informed consent for use of haloperidol, 23 June 2015 No informed consent was obtained for treatment as the patient was not competent to consent and no consent was sought from the legal representative (EPA) or within the terms of R7(4). DHB breached Right 7(1). The woman had a complex medical history including dementia. She had previously appointed her daughter with enduring power of attorney (EPA). Hospital clinicians failed to be clear as to the legal basis on which haloperidol was being administered to the woman, either by consent from the woman or of her EPA or within the terms of Right 7(4). The HDC stated: "Mrs A should not have been administered haloperidol without her consent to that treatment, or there being clarity as to the alternative basis on which it was being provided. There was a lack of consideration as to who was able to provide informed consent to the administration of haloperidol to Mrs A."

the welfare of the consumer and available to advise the provider.	
Children and young persons	
Right (7)(1) - Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent. Right 7(2) – Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.	01HDC02915 Child consent to a vaccine, 6 March 2002 GP did not breach the Code when he administered the tetanus vaccine with consent of the child. In these circumstances it was held the boy had given a valid consent to the vaccination. Two questions required consideration: did the locum and the practice nurse adequately inform the boy about his condition and treatment options, and was he "competent" to consent to treatment? It was held that at age 14, this boy was well able to understand basic medical information and give consent to the tetanus vaccination after having presented with an open wound. There was no evidence the boy did not understand the information. He did not indicate that he felt unable to make a decision without his mother's approval where his mother was out of town and not contactable.

Appendix 4: Referral to Whānau Care Services

Referral to Whānau Care Services

Appendix 5: Request for Treatment/Procedure Form

Request for Treatment /Procedure(s) Form

Appendix 6: Treatment/Procedure without consent Form

Treatment /Procedure(s) without Consent Form

Appendix 7: Prescribing unregistered medicines

Prescribing unregistered medicines and use of medicines for unapproved indications

Appendix 8: Mental incapacity for EPA

HP certificate of mental incapacity for EPA in relation to personal...

Appendix 9: Medical examination: child Form

Request for medical examination: child Form