Guideline: Informed consent

Purpose

The purpose of this guideline and related information is to:

- provide guidance and understanding to all staff relating to informed consent and the implications involved in their practice; and to
- enable Counties Manukau District Health Board (CMDHB) and its staff to comply with relevant legal, ethical and professional standards.

Responsibility

This guideline applies to all CMDHB employees, (full-time, part-time and casual (temporary) including contractors, visiting health professionals and students working in any CMDHB facility.

Guideline

Informed consent is a process whereby a competent patient, or an incompetent patient's legal representative, who has been given sufficient information, is able to arrive voluntarily at an unpressured, reasoned decision as to whether or not to agree to a proposed healthcare service. It is founded on ethical obligations and professional standards and is supported by legislation.

Informed consent involves four key elements:

- The person is **competent** to make the decision to undergo, or refuse, the proposed treatment;
- There must be **effective communication**;
- The person is provided with **sufficient information** to enable to them to make an informed decision about the proposed treatment; and
- The person's consent is given **voluntarily**.

Informed consent should form part of all clinical services and must be obtained from a patient before any treatment is provided, except where:

- Specific legislation allows the treatment to be provided without consent; or
- The common law allows services to be provided without consent (for example, in an emergency); or

- The patient is incompetent.

Patients must be presumed to be competent; there must be reasonable grounds for believing a patient is incompetent. Where a patient is incompetent, treatment may be given:

- According to a valid advance directive; or
- With the informed consent of a person legally entitled to give consent on behalf of the patient or
- If there is no valid advance directive and no person who is legally entitled to give consent on the patient's behalf is available, services may be provided without informed consent following the process set out in Right 7(4) of the Code of Rights or;
- Where authorisation is obtained from the Courts.

Under the Code of Rights a patient also has the right to decide about the return or disposal of any body parts or bodily substances removed or obtained in the course of a procedure; and, informed consent must be obtained if such body parts or bodily substances are to be stored, preserved, or utilised, unless an exception applies.

1. Obtaining consent

1.1 Timing and duration

Consent is not a single event but is part of a process of informing the patient in order for the patient to make an informed decision as to the healthcare services and treatment they wish to receive.

For minor procedures where a person is conscious and able to call a halt to the procedure, consent may be given verbally. In this case, it is appropriate for the patient's consent to be sought as close as possible to the intended procedure or treatment, allowing time for the patient to understand the associated information and clarify any questions, before proceeding.

For more complex procedures and where written consent is required, treatment options should be discussed well in advance of the actual procedure being carried out, where this is possible (for example with a patient undergoing elective surgery), so that the patient has enough time to absorb the information and make a voluntary and informed decision.

A patient may sign a consent form, confirming that they wish treatment to go ahead, at any appropriate point prior to the treatment. However, there is no legislative provision which sets out the **duration** for which consent is valid and this must be considered on a case by case basis, taking into account the;

- Nature of the procedure
- Progression of the patient's condition;
- Patient's health status;
- Patient's competence;
- Availability of, or a change in service or treatment options; and/or
- Perceived risks or benefits to the patient.

The following provides some guidance:

If the patient needs to **return to theatre**, then the return should be subject to a new consenting process, unless:

- there is a clinical emergency, and
- the person is unable to give consent, and
- no one is able to consent on behalf of the patient.

If there is a delay in carrying out the services for which informed consent was obtained and there is a **change** in the proposed services to be provided or a change in the risk or benefit to the patient, then a new consent should be obtained.

In the case of **on-going treatments** requiring repeated intervention, for example dialysis, repeated blood transfusions, and returns to theatre for debridement of burns, it is acceptable to obtain the informed consent for the treatment plan. Where there are changes to the treatment plan or where the risks to the patient have changed or new treatment options have become available, then it is necessary to go through a new informed consent process.

In the provision of **elective services**, there may be a delay between the patient providing consent and the procedure being carried out. It will be necessary to consider the length of time that has elapsed and any changes in the patient's clinical circumstances when deciding whether a repeat of the informed consent process is required.

1.2 Staff who have responsibility for obtaining consent

Responsibility for ensuring valid informed consent lies with the health professional that is responsible for the service/treatment being proposed.

This responsibility may be delegated provided that the person to whom it is delegated to has sufficient knowledge of the patient's condition and the treatment proposed. Where delegation occurs, the person responsible for and undertaking the proposed treatment remains responsible for ensuring sufficient information has been provided and valid consent for the treatment obtained. The person exercising such delegated responsibility must be aware of their limitations and must inform the patient who will be conducting the service/treatment. The patient should be told why the person carrying out the treatment or procedure is not imparting the information and obtaining informed consent

However, if a form is signed before a patient arrives for the actual treatment, a member of the health care team must confirm with the patient at this point whether the patient has any further concerns, whether there has been any change in condition, and whether the consent remains valid.

Before proceeding, the person undertaking the treatment or procedure must satisfy him/herself that the patient:

- has received all relevant information; and
- has given his or her informed consent to the treatment or procedure; and
- still consents to the treatment or procedure.

1.3 Provision of Information

Every patient has a right to information. The duty to provide information is independent of the duty to obtain informed

consent. Regardless of whether the patient is competent to consent, the patient must be provided with information appropriate to his or her level of competence.

1.3.1 Sufficient Information

A person entitled to give consent must be given 'sufficient' information by the person who will be responsible for the service being provided. Sufficient information is "information that a reasonable patient, in the patient's circumstances, would expect to receive and needs, to be able to make an informed choice or give informed consent" - Rights 6(1) and(2) The Code of Rights.

The Code of Rights provides some guidance as to information a patient should be given. Right 6 sets out certain information a patient has the right to (and therefore a doctor/provider has a legal duty to provide).

Information given must take into account the particular circumstances of each patient and be specific to that individual's situation. It is also important that staff demonstrate the ability to relate and respond effectively to the patient in a manner that will ensure the patient feels safe and is not being coerced.

At a minimum, every patient is to be provided with the following information:

- An explanation of his or her condition; and
- An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
- The nature and purpose of the proposed treatment the health professional is recommending and why.
- The possibility that findings made in the course of the treatment may necessitate a change of treatment; and
- The consequences of not accepting the treatment; and
- Advice of the estimated time within which the services will be provided; and
- Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval.

The patient also has the right to honest and accurate answers to questions relating to services, including questions about:

- The identify and qualifications of the provider
- The recommendation of the provider
- How to obtain an opinion from another provider
- The results of research.

They may express their preference as to who will provide treatments to them and should be informed as to the nature and purpose of any information collected in the course of the treatment and to whom it may or must be disclosed.

1.3.2 Material Risks

Providers must disclose material risks. A material risk is a risk that a reasonable person in that patient's circumstances would attach significance to if informed about. It is also prudent practice to inform patients of common minor complications and uncommon major ones. Very rare specific adverse outcomes of the proposed treatment may be material to informed consent if they represent a substantial proportion of the overall risk, or it they pertain to an area of particular concern to the patient. (Thus, for example, a patient undergoing an ophthalmic operation may need to be told both the general risks associated with surgery and anaesthesia, and the specific risk of blindness).

No consent is to be requested from individuals until the health professional is satisfied that they have made every reasonable endeavour to ensure that the patient, or the person legally entitled to consent on behalf of the patient, understands the information provided and understands the treatment being proposed.

Sometimes individuals may not wish to be fully informed about their treatment. In this circumstance, what was discussed with the patient, and the patient's wish not to be fully informed must be carefully recorded in the patient's clinical record. Care must be taken and in some situations treatment should not proceed unless the patient is willing to receive certain information.

Any staff member who believes that an individual is not adequately informed about the service they are to

receive should inform the responsible health professional as soon as practicable.

1.3.3 Effective communication

Patients have the right to effective communication in a form, language and manner that enables them to understand the information provided to them (Right 5 of the Code of Rights). Where appropriate, interpreters should be made available, and it is usually not acceptable to rely on family and friends to relay clinical information. However, when professional interpreters are not available, the risks associated with deferring investigations or treatments should be balanced against the risks associated with use of family and friends as interpreters in the individual case.

Discussions with patients should take place in an environment that enables both the patient and the provider to communicate openly, honestly and effectively. Care should be taken to ensure that the physical environment is as private as possible, taking into account the nature of the discussion. Consideration may need to be given to the involvement of support persons and whanau.

Sufficient time should be allowed for the patient to read any written information and they should have the opportunity to discuss this information.

This process should be a shared dialogue which is responsive to the needs, wishes, capabilities, culture, beliefs and concerns of the particular patient.

2. Documenting Consent

Consent, whether oral or written, should always be recorded in the patient's record.

Written consent must be obtained where:

- The procedure or treatment involves general anaesthesia or the creation of any state in which the patient is unable to communicate withdrawal of consent during the course of the treatment.
- The patient is going to theatre for a procedure.
- There is a significant risk of adverse effects.
- The patient may require blood or blood products, or may be exposed to other heterogeneous human or animal tissue.
- The procedure or treatment is experimental.
- The patient is to participate in any research.

- A section 29 of the Medicines Act medication (unregistered) is being used for experimental or clinical trial purposes and in some instances when a section 25 medication (registered medication for unregistered indications) is prescribed.
- Electro-Convulsive treatment (ECT) is being provided with the consent of the patient.
- Video or photographic recordings of the patient are being made
- Tissues, body parts or bodily substances removed or obtained in the course of a procedure are to be stored, preserved, or utilised for teaching or research
- The patient is undergoing a procedure for which written consent is specifically required under any CMDHB policy
- A bodily sample is being taken under the Criminal Investigations (Bodily Samples) Act 1995.
- Written consent has been requested by the patient or the person providing the service.
- There is any doubt about the need for written consent.

As noted above, **verbal consent** is acceptable for minor procedures not meeting the criteria for written consent and where the patient will be conscious and able to call a halt to the procedure. However the person responsible for the procedure has the discretion to obtain written consent and this should be done if the patient requests it.

Both written and verbal consent should be documented in the clinical notes and should include:

- Information provided to the patient, or legal representative, when this was provided and by whom;
- The name and designation of the person obtaining consent, and if different, the name and designation of the person who will perform the procedure or treatment (if known);
- Specific queries made by the patient;
- Any timeframe discussed with the patient
- Confirmation that the patient indicated that they understood the information provided; and
- A statement that consent was obtained (whether written or oral).

It is not uncommon that surgical, endoscopic or radiological procedures reveal unsuspected pathology or abnormal anatomy, and anaesthesia or sedation precludes rational

communication with the patient. Where the possibility of **additional treatments or procedures** can be anticipated, the patient should be fully informed in advance on these additional treatments, and their consent obtained. If an unexpected event occurs and the patient has not given their prior informed consent to any additional treatments, no further treatment can be undertaken without first pausing to obtain consent, unless those treatments are required in an emergency situation for the preservation of life.

3. Refusal of Consent

Every competent patient has the right to refuse service and withdraw consent for service/treatment: Right 7(7) of the Code of Rights and s11 of the New Zealand Bill of Rights 1990.

Where a patient refuses service/treatment and/or withdraws consent for service/treatment, the best standard of care and support possible in the circumstances is to be provided to the patient.

No undue influence or pressure is to be brought to bear on a patient who has refused service/treatment and or withdrawn consent for service/treatment.

The following should be documented in the patient's clinical record;

- A full account of what happened (including date and time),; and
- What the patient was told, his or her response, whether any relatives/witnesses were present and an assessment of the patient's competence.

It may sometimes be appropriate, if the risks are unusually high, to ask the patient to provide a written acknowledgment of their refusal and their acceptance of the risks involved.

4. Determination of Competence to Consent

4.1 Presumption and evaluation of competence

Right 7(2) of the Code of Rights makes the presumption that every individual (including children) is competent to make an informed choice and give informed consent, unless there

are reasonable grounds for believing that the patient is not competent.

A patient is competent to consent to, or to refuse, treatment if he or she understands the nature, purpose, effects and likely consequences of consenting to, or refusing the proposed treatment. The responsible health professional is required to make a reasonable judgement as to whether an individual is competent to give informed consent to a service, depending on:

- The patient's ability to understand; and
- The patient's level of maturity; and
- The seriousness of the service being proposed.

The level of competence required depends on the nature of the decision being made: the more serious the decision, the greater the level of competence required. A patient with diminished competence retains the right to give informed consent to the extent appropriate to his or her level of competence: Right 7(3).

There is no particular age at which patients are deemed to be able to give consent. Under the Code of Rights, the actual age of the patient is not the important question, but rather their level of understanding. This fact means that all patients must be consulted in regard to consent in a manner that is relevant to their age, maturity and understanding. Consent for the child patient (defined in the Care of Children Act as less than 18 years) is addressed in paragraph 6 below.

If the patient is competent, then he or she is the only person legally entitled to give, withdraw, or refuse consent for service/treatment. This applies in all cases, including emergencies, even if the decision risks death or permanent injury to the patient. However, the more serious the decision, the greater the level of competence required so that if the decision is a matter of life or death, a high level of competence is required.

4.2 Patients with Mental Illness

The presumption of competence applies to all patients. The test for competence for patients who are mentally ill is the same as for all patients: the patient is competent to consent to, or to refuse, treatment if he or she understands the

nature, purpose, effects and likely consequences of consenting to, or refusing the proposed treatment.

In some situations a patient may be provided with treatment for mental illness without his or her consent under the Mental Health (Compulsory Assessment and Treatment) Act 1992 (MH(CAT)). However, the MH (CAT) Act authorises compulsory treatment only for the patient's mental disorder. If a patient who is subject to a compulsory treatment order is competent to consent to treatment, and treatment other than treatment for his or her mental disorder is necessary, the patient's consent must be obtained before treatment can be given. If a patient who is subject to a compulsory treatment order is incompetent, and treatment other than treatment for his or her mental disorder is necessary, then that treatment can be carried out in accordance with the general principles described elsewhere in this guideline for all patients.

4.3 Effect of Medication

Various medications may affect conscious awareness or other cognitive functions and thus competence to consent. Where practicable, discussion about treatment should take place before the administration of medication is likely to affect competence. When a patient's competence clearly has been impaired by medication and the procedure is not required for the preservation of life or prevention of serious and permanent harm, recovery should be allowed before consent to further treatment is sought.

5. Individuals Deemed Not Competent to Consent Where a patient is not competent to make an informed choice and give informed consent, treatment may be given;

- According to a valid **advance directive** that applies in the particular situation; or
- With the consent of a **person legally entitled to give consent** on the patient's behalf (a welfare guardian, or an enduring power of attorney for care and welfare); or
- According to a **personal order** made by a court; or
- Without consent, where the treatment is in the **patient's best interests** and the requirements set out in Right 7(4) of the Code of Rights are satisfied.

5.1 Advance Directives

Under Right 7 (5) of the Code of Rights every patient has the right to use an advance directive.

An advance directive is a directive made by the patient, while the patient is competent, about a possible future health care service that is intended to be used only when the patient is incompetent. An advance directive can be made orally or in writing but for evidentiary purposes a written advance directive is preferable.

A valid advance directive is binding on health professionals. For an advance directive to be valid:

- It must have been made when the patient was competent; and
- The patient must have anticipated and intended his or her decision to apply to the prevailing circumstances; and
- The patient must have been sufficiently informed to make the decision; and
- The patient's decision must have been reached without undue influence/coercion.

A valid advance directive should be followed unless there are reasonable grounds for believing it is not valid.

In situations involving refusal of treatment necessary to save a patient's life, careful scrutiny of the advance directive will be required. If there is any doubt about implementing an advance directive or the validity of an advance directive, then the patient's legal representatives should be consulted and legal advice sought.

An advance directive is distinct from Advance Care Planning (ACP) which is a process of discussion and shared planning for future health care. ACP assists the individual to identify their personal beliefs and values and incorporate them into plans for their future health care. The ACP process may result in the person writing an advance care plan and / or an advance directive. The ACP process is valuable not just because of its outcomes, but also because of the conversations and shared understanding that arise from it. As yet it is legally untested, but it is likely that a written advance care plan would constitute an advance directive for legal purposes on the proviso that the requirements of a valid advance directive (outlined above) were met.

5.2 Welfare Guardian or Enduring Power of Attorney for Personal Care and Welfare

Welfare guardians and personal care and welfare attorneys under an Enduring Power of Attorney can be appointed under the Protection of Personal and Property Rights Act 1988 ("PPPR Act") to make decisions about the care and welfare of an incompetent person.

Staff must ensure that any person claiming to be an attorney under an Enduring Power of Attorney or a welfare guardian by order of the court has documentation to prove their appointment and the authority to give/refuse/withdraw consent. If there is any doubt, legal advice should be sought.

5.2.1 Welfare Guardians

A welfare guardian is appointed by the court under the PPPR Act, to act in relation to specified aspects of that patient's personal care and welfare (as specified in the Court order). A welfare guardian will only be appointed when a patient is wholly incompetent.

5.2.2 Personal Care and Welfare Attorneys under an Enduring Power of Attorney

A personal care and welfare attorney (under an Enduring Power of Attorney for care and welfare) is appointed by a person, with legal advice, whilst he or she is competent. The Enduring Power of Attorney may authorise the attorney to act generally in relation to the patient's personal care and welfare (and therefore be able to consent to treatment that is in the patient's best interest), or authorise the attorney to act in relation to specific matters only.

The enduring power of attorney does not take effect until the patient becomes "mentally incapable". The PPPR Act provides that a person becomes "mentally incapable" if he or she lacks capacity to:

- make a decision about a matter relating to his or her personal care and welfare; or
- understand the nature of the decisions about matters relating to personal care and welfare; or

- foresee consequences of decisions or foresee consequences of failure to make decisions relating to personal care and welfare; or
- communicate decisions about matters relating to personal care and welfare

For matters that have a "significant effect" on health, wellbeing or enjoyment, such as a permanent change in residence, entering residential care or undergoing a major medical procedure, the attorney cannot act unless a 'relevant health practitioner' has certified (or the Court determined) that the person is mentally incapable. A certificate in the prescribed form is required for each significant matter (except where certification is indefinite or during a specified period).

The enduring power of attorney must always act in that person's best interests. The powers cease on the death of that person or if the person regains mental competence. Specific duties in relation to personal care and welfare attorneys include:

- duty to encourage the person's independence
- duty to re-integrate into community as much as possible
- duty to consider the person's money situation when making decisions
- duty to consult person and any persons identified in the Enduring Power of Attorney document
- duty to provide information on request of listed person
- duty to consult with property attorney regularly (mutual)
- may have regard to a donor's advance directive subject to limitations on actions under section 98(4) – may seek assistance of the Court.

If there is doubt as to whether one should rely on the person's own instructions, or whether due to the person's incapacity, one should rely on the attorney's instructions, legal advice should be sought and consideration given to asking the Court to make a determination (section 102 Protection of Personal and Property Rights Act 1988).

The PPPR Act only allows one person to hold an enduring power of attorney for care and welfare.

A patient may also have an Enduring Power of Attorney for property. An attorney acting under an Enduring Power of Attorney for property cannot make decisions in relation to a patient's care and welfare (unless the person is also attorney for personal care and welfare under the Enduring Power of Attorney for personal care and welfare).

5.2.3 Limitations of Powers of Welfare Guardians and Personal Care and Welfare Attorneys

A welfare guardian or an attorney under an Enduring Power of Attorney **cannot:**

- refuse consent to any standard treatment or procedure intended to save the patient's life or prevent serious damage to the patient's health
- consent to electro-convulsive therapy
- consent to brain surgery or treatment which destroys any part of the brain or brain function in order to change behaviour
- consent to experimental treatment
- make any decision that is outside the scope of the court order appointing the Welfare guardian, or that is outside the scope of the powers as set out in the deed appointing the attorney.

5.3 Personal Order Made by a Court

Under the PPPR Act, a Family Court may make a personal order in relation to an incompetent patient. A personal order may be an order that the patient be provided with medical advice or treatment of a specified kind.

A personal order may be made for a patient who is partially or wholly incompetent.

An application for a personal order may be made by a number of persons including a relative of the patient, a medical practitioner or a social worker employed by the Ministry of Social Development

5.4 Treatment without Consent

5.4.1 Best Interests

Where the patient is not competent to make an informed choice and give informed consent, and there is no valid advance directive or any person legally entitled to consent on behalf that patient (and it is not an emergency situation), treatment may be provided following the process set out in Right 7(4) of the Code of Rights.

Right 7(4) allows a health professional to 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) the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of services is consistent with the informed choice the consumer would make if he or she were competent; or
    (ii) if the consumer's view has 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.

It is important to remember that "suitable persons" such as family members, relatives and friends do not have authority to consent on behalf of an incompetent patient. However, their views should be ascertained and taken into account by the clinician(s) who will make the decisions regarding treatment in these circumstances. The overriding consideration is what is in the best interests of the patient and this is a matter of clinical judgement (but subject to possible court review).

Treatment provided in these circumstances must be clearly documented in the patient's clinical record, along with the justification for the provision of the treatment without consent. The "Treatment for Patients without Capacity to Consent" form should be completed for procedures or treatment where consent must be documented (refer point 2 above).

If there is doubt about treating an incompetent patient, (for example, there is conflict regarding the patient's best interests; or there is conflict between what is regarded as the patient's best interests and the patient's apparent wishes; or a patient's wishes cannot be ascertained and his or her best interests are not clear-cut), then in the first instance, legal advice should be sought.

For patients where incompetence is likely to be ongoing and issues of consent/refusal are likely to recur, for example because of conflicting views amongst family members, consideration should be given to applying for the appointment of a welfare guardian or a treatment order under the Protection of Personal and Property Rights Act.

5.4.2 Emergency Situations

In an emergency situation (i.e. death or permanent disability will result if treatment is not provided immediately) treatment necessary to stabilise the patient's condition may be given to the patient without consent if:

- the patient is incompetent; and
- there is no valid advance directive; and
- there is no legal representative available to give consent or no time to obtain the legal representative's consent; and
- it is in the patient's best interests to receive that service.

The responsibility for determining what treatment is immediately necessary and in the patient's best interests rests with the attending clinician (who administers the treatment). Consultation with another member of the senior medical staff not involved in the patient's care and adherence to practice guidelines, if available, will support the determination of what constitutes good medical practice.

The following guidelines are offered for medical staff when consent cannot be obtained in emergency situations:

- The consultant under whom the patient is admitted should be notified and should confirm that a

situation exists requiring intervention without consent.

- Either the consultant, or another medical member of the team, should consult with another consultant not involved in the care of the patient, to determine whether the proposed treatment constitutes good practice.
- Should the consultant decline to offer an opinion, or express the opinion that the proposed treatment falls outside the bounds of good medical practice, the attending clinician is advised to seek further advice.
- Responsibility for justifying intervention ultimately rests with the attending clinician.

Treatment provided in an emergency situation must be clearly documented in the patient's clinical record, along with the justification for the provision of the treatment.

The patient or their legal representative must be informed of the service that has been provided at an appropriate time after the emergency.

5.4.3 Statutory Exceptions Where Consent Is Not Required

There are a number of statutory provisions which allow treatment to be provided without consent. These statutory exceptions are summarised in **Appendix 1.**

5.4.4 Suicide

The law relating to suicide and whether to treat without consent even though a patient may be conscious and refusing treatment is not clear cut.

The first question should still always be "is this patient competent?" The fact that a patient is attempting to take their life does call into question their competence and most will be deemed incompetent, at least temporarily. Nonetheless, if the patient is considered competent, then his or her wishes must be respected.

If the patient is considered incompetent, then he or she can be treated with the consent of his or her legal representative or without consent following the procedure as set out in Right 7 (4). Reasonable force can be used if necessary: the Crimes Act 1961, section 41 provides that

everyone is justified in using such force reasonably necessary to prevent the commission of suicide.

6. The Child Patient

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

6.1 Children 16 Years and Over

Under the Care of Children Act 2004, a child who is 16 years or over, or is or has been married, in a civil union, or living in a de facto relationship can consent, assuming he or she is competent, to any medical procedure (including blood donation and surgical and dental procedures). Consent to medical treatment and procedures expressly includes the right to refuse consent.

6.2 Children Under 16 Years

It is generally agreed that children under 16 years of age can consent to their own treatment if they are competent to make a decision about the particular treatment. The assessment of competence is a question of fact for the health professional to determine in each case. The health professional must assess whether a child has the maturity and capacity to understand and to make a decision in relation to the particular treatment.

6.3 The Test for Competence

The test for competence is the same as for an adult: a child is competent to consent to, or to refuse, treatment if he or she understands the nature, purpose, effects and likely consequences of consenting to, or refusing the proposed treatment. The child must have sufficient maturity to understand the nature of the proposed treatment, its purpose, and consequences (including intended and possible side-effects and anticipated consequences of treatment).

As with an adult, the level of competence required will vary according to the seriousness of the service/treatment proposed.

When determining the competence of a child, health professionals are to make an individual assessment in every case. Questions that can be asked to assist in the determination of competence include assessing if the child understands:

- Why the service is needed; and
- What the service involves and what it is for; and
- The benefits, risks and alternatives.

Where a child is competent to consent to a particular treatment, the child's consent is likely to be sufficient. However, involvement of the parents should be encouraged. If a competent child refuses to involve their parents, or the parents disagree with the competent child's decision, the child's decision must be respected. But, if the responsible health professional does not consider the competent child's decision to be in his or her best interest, legal guidance should be sought.

6.4 Incompetent Children

If a child is incompetent to make an informed choice and give informed consent, services may be provided;

- with the consent of the child's legal representative; or
- in an **emergency**, treatment can be given to save the child's life or prevent serious risk to his or her health; (see: **Emergency Situations**)
- without consent, provided the treatment is in the child's best interests and the requirements set out in Right 7 (4) of the Code of Rights have been satisfied. (see: **Best Interests**)

6.5 Legal Representatives: Who can legally consent on behalf of a child?

Where the child is under 16 years of age consent may be given by;

- A legal guardian. This will usually, but not always, be the child's parents. It may also include;
    - a testamentary guardian;
    - a court appointed guardian;
    - a welfare guardian.

- 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, consent may be given by;
    - a person in New Zealand who has been acting in the place of the parent; or
    - a Court; or
    - the Chief Executive of the Ministry of Social Development under section 36 of the Care of Children Act 2004

6.6 Legal Guardians

Generally a child's parents will be the child's legal guardians and therefore will be legally entitled to consent on behalf of an incompetent child.

Under the Care of Children Act 2004, if the father of the child was married to, or in a civil relationship with, or living with the mother at any time during the period beginning at conception and ending with the birth of the child, he will share automatic guardianship of the child with the mother.

6.6.1 Testamentary Guardians

A testamentary guardian who is appointed by deed or will by the child's parents to be a guardian after the parents' death.

6.6.2 Court Appointed Guardians

On application (under section 31, Care of Children Act 2004) the court can place a child under the guardianship of the court and appoint a person to be the court's agent (with authority to make decisions regarding the child's care/treatment). Or, under section 39 of the Children, Young Persons and Their Families Act 1989, an application can be made for a place of safety warrant (such a warrant includes the power to direct a child be detained in hospital).

6.6.3 Person Acting in the Place of a Parent

If there is no guardian in New Zealand, or no such guardian can be found with reasonable diligence or is capable of giving consent, a person who has been acting in the place of a parent can consent to any medical, surgical, or dental treatment or procedure (under section 36(2)(b), Care of Children Act 2004).

6.6.4 District Court Judge or the Chief Executive of the Ministry of Social Development

If there is no guardian, and no person acting in the place of a guardian is available or capable of giving consent, a District Court Judge or the Chief Executive of the Ministry of Social Development can give consent (under section 36(2)(c), Care of Children Act 2004).

6.6.5 Doubt of Guardianship

If there is doubt about an incompetent child's guardians and it is not an emergency situation, legal advice should be sought.

6.6.6 Disputes between Guardians

If a child has two or more guardians, they should consult and cooperate with each other. If there is a dispute between guardians that cannot be resolved informally, legal advice should be sought.

6.6.7 Limitations on Guardians' Rights to Consent.

A guardian's right to consent/refuse consent on behalf of an incompetent child is not absolute. The welfare and best interests of the child is the first and paramount consideration (section 4, Care of the Children Act 2004). Parents/guardians do not have the right to refuse treatment that is in the child's best interests.

If the parents/guardians refuse consent or insist on withdrawal of treatment and the provider believes that treatment is in the child's best interests then:

- In an **emergency**, treatment can be given to save the child's life or prevent serious risk to his or her health; (see: **Emergency Situations**)
- If not an emergency, the provider should consider if there are adequate alternatives that would accommodate the parents' and/or guardians' preferences or beliefs. As a last resort, the direction of the court may be sought.

6.7. Blood Transfusions

Section 37 of the Care of Children Act 2004 may protect a registered health professional who has administered certain blood transfusions to any person under the age of 18 without consent, if 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 his or her physical or mental health, or to save him or her from prolonged and avoidable pain and suffering; **and either**
    - reasonable attempts were made to obtain the consent of the person appearing to be legally entitled to consent to the transfusion; **or**
    - the circumstances were such that it was necessary to administer the transfusion promptly and it was impracticable, in the time available, to attempt to obtain the consent of the person appearing to be legally entitled to consent; **and**
- In all the circumstances, it was reasonable to administer the transfusion.

In considering the reasonableness of the medical practitioner's opinion, a judge will take into account the condition of the patient before transfusion (i.e. was the transfusion really necessary) and whether it was reasonably practicable for the medical practitioner to consult any other medical practitioner and, if this was done, their opinion.

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

7. Abortion and Sterilisation

In the case of abortions, a female of any age is legally entitled to consent or refuse consent provided that she is competent (section 38, Care of Children Act 2004).

If a patient is incompetent because of any 'mental incapacity', section 34 of the Contraception, Sterilisation, and Abortion Act 1977 provides that the certifying consultants must, before determining whether or not to authorise an abortion, consult with a registered medical practitioner (or other qualified and experienced person) regarding an assessment of the patient's condition and the likely effect of the continuance of the pregnancy or an abortion on the patient's condition.

Mental incapacity in this context means 'severely mentally subnormal to the extent that she is incapable of living an independent life or of guarding herself against serious exploitation or common physical dangers'.

No person can consent to the sterilisation of another person if that other person lacks the capacity to consent by reason only of age (section 7, Contraception, Sterilisation, and Abortion Act 1977). If sterilisation of an incompetent adult or child is proposed, legal advice should be sought as it may be necessary to obtain a Court order to ensure that the proposed sterilisation is lawful.

If there is any doubt in relation to contraception, sterilisation abortion or the life of an unborn child, legal advice should be sought.

8. The Unborn Child

If a health professional is concerned that a pregnant patient's treatment decision is not in the unborn child's best interests, legal advice should be sought.

9. Post-Mortem Examination and Removal of Body Parts of Tissue and Bodily Substances

9.1 Coroner's Post-Mortem

Where the cause of death is unknown or unexpected, the death must be reported to the Coroner. It is for the Coroner to decide whether or not a post-mortem examination is required, and it is the Coroner's responsibility to discuss and arrange for the removal, retention and storage of body parts/tissue/bodily substances. It is the Coroner's role to determine whether to open an inquiry and whether an inquest should be held.

9.2 Non-Coronial Post-Mortem

A non-coronial post-mortem is a post-mortem performed for a primary purpose other than determining cause of death, eg, gathering further information about a known cause or for medical research.

For a non-coronial post-mortem, informed consent must be obtained from the necessary parties as specified in the Human Tissue Act – see below. Specific information requirements apply for non-coronial post-mortems – see below.

9.3 Removal of Body Parts or Bodily Substances During the Course of a Health Care Procedure

The Code of Rights specifies that a patient has the right to decide about the return or disposal of any body parts or bodily substances removed or obtained in the course of a procedure; **and**, informed consent must be obtained if such body parts or bodily substances are to be stored, preserved, or utilised - right 7(9) and 7(10) – except for the storage, preservation or utilisation for the purposes of;

- research that has received the approval of an ethics committee
- one or more of the following activities, being activities that are each undertaken to assure or improve the quality of services,
- a professionally recognised quality assurance programme
- an external audit of services
- an external evaluation of services.

9.4 The Human Tissue Act

9.4.1 The Human Tissue Act 2008 regulates the collection and use of tissue, primarily from deceased persons, and sets up a framework for informed consent for human tissue collection and use. The Act considers the recognition, respect, autonomy and dignity of the individual, cultural and spiritual needs, values and beliefs of the immediate family and cultural, and ethical and spiritual implications. The Act also regulates the use of tissue for non-therapeutic purposes (eg audit, anatomical examination, research and post mortem).

The Act makes informed consent the fundamental principle underpinning the lawful collection and use of human tissue and is consistent with the Code of Health and Disability Services Consumers' Rights.

The Act **requires** informed consent for the following:

- Collection or use of human tissue that is, or is collected from, a body (this includes a non-coronial post mortem):
- Collection of non-health-care tissue (human tissue that is, or is derived from, human tissue that is collected from a living individual, but is neither collected from a living individual in the course of a health care procedure; nor derived from human tissue collected in that way) for donor analysis:

- Donor analysis of non-health-care tissue:
- Use for a secondary purpose, after the donor's death, of human tissue collected from a living individual.

9.4.2 Consent Required under the Human Tissue Act

Under the Act, the primary consent or objection will be that of the deceased, if formally recorded before he or she died, or of someone nominated by the person to make the decision on his or her behalf. If there is no nominee, consent or objection may be given collectively by the deceased's immediate family, or by a specified member of the immediate family.

The Act specifies who may give consent or raise an objection for the collection and use of human tissue (including for a purpose not covered by the original consent).

Any informed consent must be:
- in writing (including a will); or
- made orally and in the presence of two or more witnesses.

The existence of informed consent would be sufficient for organ or tissue donation to be lawful. However, in practice, there can be a number of reasons why donation should not proceed – organs and tissue may be unsuitable for donation, the family may be aware that the person had changed their mind since recording their consent, or the immediate family may be distressed by a decision to proceed with donation. The Act allows for collection and use not to proceed in these circumstances.

9.5 Information required to be provided in a non-coronial post-mortem

Appropriate information must be available to the nominee(s), and/or immediate family and/or close available relatives and should include;

- An explanation about the nature of the examination, including advice about the need to open the body, remove, weigh and examine organs, and examine tissue under the microscope and advice that body parts/tissue removed will be returned to the body at the end of post-mortem unless they are to be retained for a specific, approved purpose;

- Advice as to whether or not the examination will involve the whole body, a specified part of the body, access through a surgical incision, samples from specified organ;
- Advice as to whether photographs or x-rays may be taken;
- Advice as to the need for samples and potential retention of organs, including the identity of each organ and the proposed purpose(s) for which they will be used; and
- Advice that the findings will be made available.

The person obtaining approval should ask about and discuss any special requests concerning the procedures to be followed, particularly for cultural or religious reasons.

Sufficient time must be allowed for the nominee(s), and/or immediate family and/or close available relatives to consult and reach a decision. It is recommended that the clinician in charge offers to discuss the findings of the post-mortem with the nominee(s), and/or immediate family and/or close available relatives and, when accepted, does so at the preliminary and final report states as appropriate.

Associated Documents

Other documents relevant to this guideline are listed below:

NZ Legislation	CareofChildrenAct2004 Children,YoungPersonsandTheirFamilies Act1989 Contraception,Sterilisation,andAbortion Act1977 CoronersAct2006 CrimesAct1961 TheCodeofHealthandDisabilityServices Consumers'RightsRegulation1996 HealthInformationPrivacyCode1994 HealthAct1956 HumanRightsAct1993 HumanTissueAct2008 LandTransportAct1998 MentalHealth(CompulsoryAssessment andTreatment)Act1992 NewZealandBillofRights1990 PrivacyAct1993 ProtectionofPersonalandPropertyand RightsAct1988
CMDHB Clinical Board Policies	Documentationintheclinicalrecord Providingserviceswithoutinformed consenttoanadultpatientwith diminishedcompetency AdvancedDirectives CulturalSafety– LinguisticInterpreters Summaryof statutoryexceptionstothe needforinformedconsent Guidancenotes:Enduringpowerof attorneyandWelfareGuardian Donotattemptresuscitation Informed Consent:ChildrenandYouth Clinical Photography TikangaBestPractice
Forms	Treatment for Patients without Capacity to Consent form: http://mmhiis04/docsdir/opendocument.aspx?id=A7348
Organisational Procedures	HRPolicies–CodeofConduct

Other related documents	SouthNET – LegalandPrivacywebsite

Acknowledgements

- *Informed Consent Policy and Related Information* (October 2010) Taranaki District Health Board.
- *Informed Consent Policy* (January 2011) Northland District Health Board.

APPENDIX 1

Summary of Statutory Exceptions to Requirement for Informed Consent

Definition / treatment of alcoholics	**S9 Alcoholism and Drug Addictions Act 1966**: a District Court Judge can order a person believed to be an alcoholic (as defined in the Act), who has been arrested under this section, to be examined by two doctors for the purposes of confirming or denying the alcoholic condition.
Treatment of armed forces personnel	**S72 Armed Forces Discipline Act 1971** provides that certain persons governed by that Act may be ordered to submit to certain medical or surgical procedures. However this section does not authorise treatment without consent.
Taking blood samples to detect drink driving offences	**S72, 73 and 74 of the Land Transport Act 1998** allow the taking of blood samples from persons attending hospital or doctors surgery suffering injury as a result of a motor vehicle accident in certain situations. There is no obligation to take a blood sample unless requested by an enforcement officer. If requested by an enforcement officer the medical practitioner must take the sample, or cause another medical practitioner or medical officer to do so. A medical practitioner may also take a blood specimen for alcohol testing from a person if the medical practitioner; o Has reasonable grounds to suspect that the person is in the hospital as a result of an accident involving a motor vehicle; and o Has examined the person and is satisfied that the taking of a blood specimen would not be prejudicial to the person's proper care or treatment; and o Tells the person (unless the person is unconscious) that the blood specimen is being taken under section 73 of the Land Transport Act 1998 for evidential purposes. In this situation the person who the blood sample will be taken from has a statutory obligation to permit a blood specimen to be taken. If the person is unconscious, the medical practitioner must notify the person in writing as soon as practicable that a blood specimen was taken under section 73 of the Land Transport Act 1998 for evidential purposes. Although a blood sample may be taken without consent force may not be used.
Blood Transfusions for persons under 18 years	**Section 37 of the Care of Children Act 2004** may protect a registered health professional who has administered a blood transfusion to a person less than 18 years of age without consent. For further information see **Blood transfusions**.
Civil proceedings	**Section 100 Judicature Act 1908** (as at 01 August 2008),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
Examinations of children in public and private schools	**S125 Health Act 1956** permits the Medical Officer of Health or person authorised by the Minister of Health to enter public schools and child care

	centres and examine children. Medical Officers may enter and examine children at private schools if an application has been made in writing.
Children suffering from ill treatment, abuse or neglect (the Children Young Persons and Their Families Act 1989)	**Sections 49-52 of the Children Young Persons and Their Families Act 1989** provide that the Court may require a child/young person to attend a medical examination by a registered medical practitioner if there are reasonable grounds for suspecting that the child/young person is suffering ill treatment, abuse, neglect, deprivation, or serious harm. The medical practitioner must prepare and supply to the court a written report of the results of the examination. **Section 53(3):** a social worker can require a child/young person to whom the section applies, to be medically examined by a registered medical practitioner without the informed consent of a parent/guardian after making reasonable efforts to do obtain the parent/guardian's consent. **Sections 178 & 333:** the Court can order a child/young person subject to the Act to attend a medical, psychiatric or psychological examination for the purpose of the Court's proceedings.
Treatment of infectious / venereal disease	**Infectious disease** For the purpose of precenting the outbreak or spread of any infectious disease, the Medical Officer of Health may, if authorised to do so by the Minister, or if a state of emergency has been declared under the **Civil Defence Emergency Management Act 2002**, or while an epidemic notice is in force: - require a person to report or submit themselves for a medical examination at specified times and places (section 70(1)(e), Health Act 1956); - forbid a person to leave the health district or the place in which he or she is isolated or quarantined until the person has been medically examined and found to be free of infectious disease, and until the person has undergone such preventive treatment as prescribed by the Medical Officer of Health (section 70(1)(h), Health Act 1956) **S77 Health Act 1956** also empowers Medical Officer of Health in certain circumstances to enter any premises and examine any person believed to be suffering from or recently exposed to an infectious disease. **Venereal disease** **S88(1) Health Act 1956** makes it mandatory for persons suffering from venereal diseases to undergo treatment and S90 (1) requires parents or guardians of children suffering from venereal disease to make them available for treatment. However, these sections do not preclude the requirement for informed consent, even though a failure to undergo treatment may constitute an offence.
Mentally Ill persons	**The Mental Health (Compulsory Assessment and Treatment) Act 1992** allows treatment without consent in certain situations. *Compulsory assessment* Under section 9 a patient may be required to undergo an assessment examination.

	Compulsory treatment - first and second periods of assessment A patient is required, for the first (section 11) or second (section 13) periods of assessment, to accept treatment for mental disorder as directed by the responsible clinician. *Compulsory treatment when subject to a compulsory treatment order* Under section 59 a patient subject to a compulsory treatment order is required to accept treatment for mental disorder as directed by the responsible clinician for the first month of the order. Thereafter, the patient is required to accept treatment for mental disorder if it is considered to be in the patient's interests by a Review Tribunal appointed psychiatrist. *Electroconvulsive treatment* Section 60 a patient may be required to undergo ECT if it is considered to be in his/her interests by a Review Tribunal appointed psychiatrist. *Urgent treatment* Under section 62 treatment may be given to a patient subject to a compulsory treatment order without the patient's consent or the authority of a Review Tribunal appointed psychiatrist if the treatment is immediately necessary to save the patient's life, prevent serious damage to the health of the patient, or to prevent the patient from causing serious injury to himself or herself or others.
Blood samples from Police suspects	**Criminal Investigations (Bodily Samples) Act 1995.** DNA testing A Police Officer may ask a medical practitioner (or a registered nurse if the suspect agrees) to take a bodily sample from a criminal suspect under this Act. The medical practitioner or registered nurse should not take the bodily sample unless: The suspect is over 14 years of age and consents to taking of the blood sample (and if the suspect is under the age of 17 years, the suspect's parents have also consented to the taking of the bodily sample); or The Police Officer has an order from the High Court ordering that a bodily sample be taken. The person giving the bodily sample may choose whether the sample is taken by way of venous sample, finger prick sample, or buccal sample. A suspect may refuse or withdraw consent at any time before the sample is taken. However, if the person refuses to allow a bodily sample to be taken in accordance with a High Court order, the police are entitled to use reasonable force to assist a medical practitioner to take a finger prick sample, or a buccal sample if ordered by the Court. The person taking the sample is required to ask the suspect whether they wish to keep part of the sample for the purposes of having it analysed on their own behalf.
Offence likely to cause immediate / serious injury	**S41 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 person / property	to the person or property of anyone.
Examination and treatment of persons with Tuberculosis	**Sections 7 and 9 of the Tuberculosis Act 1948** empower a Medical Officer of Health to require a person refusing / failing to undergo an examination to do so. S16 of the Tuberculosis Act 1948, A District Court Judge may make an order detaining a TB patient in hospital for specified time to undergo treatment.
Psychiatric report without consent	**Criminal Procedure (Mentally Impaired Persons) Act 2003** Section 38 a person may be subject to a psychiatric report without giving consent if ordered by the Court. This applies when a person is charged with, or convicted of, certain offences and a psychiatric report would assist the Court in determining: if the person is "under disability"; if the person is insane under section 23 of the Crimes Act 1961; the appropriate type and length of sentence; or, the nature of any requirement or condition the Court may impose as part of any sentence or order.