STANDARDS TO BE MET

1. When Is Informed Consent Required?

1.1 Generally, informed consent must be obtained for ALL invasive procedures i.e. a medical procedure that involves entering the body, usually by cutting or puncturing the skin or by inserting instruments into the body. Where procedures are closely linked as to be considered a group of inter-related procedures then consent can be obtained grouping the procedures as a single composite procedure

1.2 Informed consent must be obtained for general anaesthesia

1.3 Informed consent must be taken for procedures performed under local anaesthesia but not for the administration of the local anaesthesia.

1.4 There are a few situations in which individuals may be treated without consent. Please refer to Protocol 2 Informed Consent - Diminished Capacity and Competence to Consent.

1.5 Where they exist, advance directives and advanced care plans should be referenced as part of the initial consent process.

1.6 Consent for the involvement of students in patient care is required by the Health & Disability Commissioner (HDC) Code of Health and Disability Services Consumers' Rights ("the Code" – see Rights 5,6,7 and 9). It is also an important aspect of building rapport with patients, and of maintaining the trust and goodwill that exists between patients and the health professionals who care for them – including medical students.

1.7 If informed consent is given by a person(s) holding an Enduring Power of Attorney (EPOA) then that document must be sighted, and a copy retained in the patient's health record.

2. Emergency Situations

2.1 In an emergency situation, procedures may be undertaken without informed consent. An emergency situation is defined as one in which there is an imminent threat of loss of life or permanent harm.

3. How Long Is Consent Valid?

3.1 Consent is only valid for up to six (6) months from date of signing.

4. Information To Be Provided To Patient

4.1 The amount of information given should be that which a reasonable patient, and in particular the individual patient with whom the clinician is speaking, needs to receive in order to make an informed decision.

4.2 The higher the probability of risk or the greater the magnitude of harm, the more care and detail in giving information is required. It is accepted that patients may refuse information however this refusal must be documented.

4.3 Every patient has the right to receive:

a) An explanation of their condition; and

b) An explanation of the procedure / investigation including information such as any potential technical positioning or safe restraint practices, if applicable, and the possibility that blood products may be required.

c) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and

d) Advice of the estimated time within which the services will be provided; and
e) Notification of any proposed participation in teaching (includes any student involvement such as observing) or research, including whether the research requires and has received ethical approval; and
f) Information regarding any further / future anticipated procedures or required interventions; and
g) Any other information required by legal, professional, ethical and other relevant standards; and
h) The results of tests; and
i) The results of procedures.

4.4 As far as reasonably possible, patients should be informed about the proposed extent and nature of student involvement. There are three ways in which students may become involved in patients' care, although in reality the distinction is blurred, as any interaction with a student contributes to a patient's care:
a) students may observe patients, or examine them, or carry out or assist with procedures on them for their educational benefit as students, or
b) bedside tutorials, when a senior medical practitioner conducts a tutorial with a group of medical students, usually focussed around examination of a patient that the medical practitioner may or may not be clinically involved with, or
c) students may contribute to the care of patients, under supervision (e.g. by taking blood, holding a retractor during a surgical procedure, or performing bag-mask ventilation under anaesthesia).

4.5 Every patient has the right to receive honest and accurate answers to questions relating to services, including:
a) The identity and the 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.

4.6 Every patient has the right to receive on request a written summary of information provided.

5. Right To Refuse

5.1 Under section 11 of the New Zealand Bill of Rights Act 1990 and Right (7) of the Code of Rights, every competent person has the right to refuse or withdraw consent to services at any time.

5.2 Patients need to know they do have a choice about the involvement of medical students, and they are entitled to change their mind at any time, about such involvement, without any negative consequences for their care. The patient's right to refuse consent or withdraw consent takes precedence over the provision of training for students.

6. How Should Information Be Given?

6.1 Privacy should be ensured for discussions of diagnosis and treatment options. Where practical, for example in outpatient clinics, patients should be encouraged to dress in their own clothes and be comfortably seated before any discussion of diagnosis and treatment options occurs.

6.2 Information should be given in a language, style and form that the patient can easily understand. Where necessary and reasonably practicable it should be translated into the patient's own language by a competent interpreter.

6.3 Sufficient time should be allowed for the patient to read the written information, and discuss this and any verbal information with whomever he / she wishes.

6.4 Patients should be advised that they have a right to have another person or persons present during the discussion related to the proposed treatment or procedure. A patient advocate may attend at the request of the patient.

6.5 Any available audio-visual material should be included where it could be helpful in providing the information needed.

7. Responsibility For Giving Information And Obtaining Consent

7.1 The primary responsibility for ensuring adequate information is given and fully informed consent is obtained sits with the person who is responsible for the procedure, or who is the prescriber of the treatment or procedure.

7.2 It is permissible for the responsible person to delegate this responsibility to another suitably qualified medical professional.

7.3 Where the situation arises where obtaining consent is delegated, the patient should be told the reason why the person carrying out the treatment or procedure could not personally obtain consent.

7.4 No consent should be requested until the health professional is satisfied that the patient has demonstrated adequate understanding of what is proposed.

7.5 Anyone involved in the care or treatment of a patient who believes the patient is not being kept adequately informed should convey this to the person responsible either directly or through another member of the team.

7.6 The primary responsibility for ensuring that consent is obtained for the involvement of a medical student in a patient's care lies with the registered health professionals responsible for that patient at the time or their delegate.

7.7 Any information given to the patient, (in the process of obtaining consent), should be documented in the patient's health record by the health professional obtaining the consent.

8. Responsibility For Obtaining Consent

8.1 The principles for responsibility for obtaining consent are the same as those for imparting information.

8.2 The responsibility lies with the person who is responsible for, and / or prescribing the procedure or treatment.

9. Advance Directive

9.1 Every patient may use an advance directive to give informed consent to, or refuse, a healthcare procedure - refer to Protocol 2 Informed Consent - Diminished Capacity and Competence to Consent.

10. Teaching, Observers And Research

10.1 Patients have a right to consent to or decline involvement in teaching (including the presence of observers during treatment or examination) or to take part in research. This includes students being present or involved in the patient treatment.

10.2 Patients must be advised that a refusal to have any students present does not impact on the delivery of the service for patient care.

10.3 It is essential that there is no possibility for the consent to have any element of coercion. Without such consent a student cannot undertake such activity.

10.4 Explicit consent is required in any sensitive examinations (includes breast, rectal, vaginal examinations and those of the external genitalia). Includes such examinations under anaesthesia which require formal written consent obtained in advance and signed by the patient.

10.5 It is reasonable to construe consent for a student to be involved in a patient's care as including consent for that student to read relevant patient records, but it would usually be courteous to mention this point to patients. Patients' medical records are confidential and medical students should only access such records in line with a purpose that has been notified to the patient at the point of collection. There must be a genuine educational reason to do so, and with the permission of the health professionals responsible for the patient's care.

ASSOCIATED DOCUMENTS

- Te Whatu Ora Hauora a Toi Bay of Plenty policy 1.1.1 Informed Consent
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 1.1.1 protocol 2 Informed Consent – Diminished Capacity and Competence to Consent
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 1.1.1 protocol 3 Informed Consent – Children
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 1.1.1 protocol 5 Informed Consent – Nurse Facilitation of Process
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 1.5.1 Interpreter Services
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 2.5.2 Health Records Management
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 6.1.4 Advanced Directives
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 6.3.9 Body Parts, Tissues and Substances
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 6.6.1 Death of a Patient
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 2.1.4 protocol 3 Incident Management – Open Disclosures
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 2.4.2 External Enquiries, Investigations, Inquests and Hearings
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 2.5.1 Health Information Privacy
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 1.2.5 Jehovah's Witness Patients – Providing Care
- Te Whatu Ora Hauora a Toi Bay of Plenty policy 1.2.6 Refusal of Blood Products
- Te Whatu Ora Hauora a Toi Bay of Plenty Informed Consent form (7752) – *viewable only. Order from Design & Print Centre*
- Te Whatu Ora Hauora a Toi Bay of Plenty Form FM.T7.1 Treatment / Non Treatment of the Incompetent Adult Patient
- Te Whatu Ora Hauora a Toi Bay of Plenty Form FM.B2.1 Blood Products – Refusal - Understanding Regarding Refusal for Minors