

Purpose

To ensure all patients at Mercy Hospital are fully informed about their operation procedure prior to its occurrence.

Related Standard

Standard 1.8 of the Code of Health & Disability Services Consumers Rights 1996.
Standard 1.1, criterion 1.1.3 of the EQuIP programme.

Applies To

All Mercy Hospital clinical staff and credentialed staff working within Mercy Hospital.

Definition

Consent may be defined as 'granting permission to do something they would not have the right to do without permission' (H & D Sector Standards).

Informed consent implies that enough relevant information is provided to enable a reasoned decision to be made, and that the information is understood. Without understanding what is involved no one can make a reasoned decision. The consent must be voluntary. There must be no pressure on the person to give their consent. No undue influence or duress should be present. Patients shall be advised that they have a right to an Advocate present. Should the patient require an interpreter please refer to the Interpreter services available in the Cultural policy.

Informed Consent

Is the result of an interactive process involving communication between a credentialed specialist or clinical team and the patient. Informed Consent is not the act of filling out forms, but rather a process of exchange of information so that an informed decision can be made by the patient.

Right 7 of the Code sets in place the provision to make an informed choice and give informed consent.

- The communication must occur in an environment that enables the parties to communicate openly, honestly and effectively.
- Credentialed Specialists and staff must provide information in relation to a proposed procedure in a form, language and manner that the patient can understand.
- The patient has the right to consider fully the information given and seek further opinion.
- The patient, free from coercion, then consents to the procedure.

- Under section 11 of the New Zealand Bill of Rights Act 1990 the patient has the right to refuse or withdraw consent at any time. It should be made clear to the patient that he/she has the right to refuse or withdraw without fear of recrimination or penalty. Where the Credentialed Specialist is concerned that refusal of treatment may have a detrimental effect on patient outcomes then this should be documented in writing.

The Right to be fully informed (Right 6 of the Code of Rights)

Before making a choice or giving consent, every patient has the right to the information that a reasonable person, in that patient's circumstances, would expect to receive, including:

- An explanation of his or her condition including the results of any relevant tests and investigations.
- An explanation of the options available, including an assessment of the expected risks, side effects, and costs and benefits of each option.
- Notification of any proposed participation in teaching or research and that it has received ethical approval.
- The consequences of not accepting treatment.
- Implications of existing advance directives.
- Issues related to body parts - (refer to Tikaka Best Practice Guidelines on Sharepoint).
- Recovery and recuperation.

Patient Competence

Every patient must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the patient is not competent. It is the Credentialed Specialist's responsibility to ascertain whether the patient is competent to give informed consent. Medication, intellectual disability, mental illness, inebriation, or physical injuries may affect the informed consent process. Where a patient has diminished competence, that patient retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

Where a patient is deemed not competent to consent and has a welfare guardian and/or person with enduring Power Of Attorney this authority needs to be supplied and a copy put into the patients notes.

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

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

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

- a) It is in the best interests of the patient; and
- b) Reasonable steps have been taken to ascertain the views of the patient; and
- c) Either,
 - i. If the patient'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 patient would make if he or she were competent; or
 - ii. If the patient'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 patient and available to advise the provider. Other suitable persons to advise the provider may include:

* The Patient's permanent caregivers, the patient's General Practitioner, next of kin

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

Children

The Code of Rights does not specify an age for consent. A provider must assess a child's competency to decide whether he or she is able to give informed consent. Under Right 7 (2) there is a presumption that a person of any age is competent to give consent unless there are reasonable grounds to believe otherwise. A person is competent if they;

- Can comprehend and retain the necessary information about the procedure or treatment
- Is able to believe it
- Is able to weigh the information, balance risks and needs and so arrive at a choice.

Equally as important is that the person is able to communicate a decision.

Accordingly, Credentialed Specialists are legally obliged to inform children about operation and treatments in a manner relevant to their level of competence and, if appropriate given that level of competence, to obtain their informed consent. Generally

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

At Mercy Hospital for those children under 16 years of age who are able to consent we require a parent/whanau or guardian to countersign.

Emergency Operation/Treatment

If a person is unconscious or otherwise unfit to express an opinion, then the operation or treatment may be carried out at the instigation of the Credentialed Specialist in charge. Although it is customary to obtain the consent of the next of kin whanau or nearest relative available in such cases, it is doubtful whether consent of a relative is of any value since an adult cannot consent to treatment being carried out on another, nor have they authority to refuse to permit urgent, necessary treatment.

Verbal Consent

If verbal consent is given, it should be documented in the health record. Although informed consent for a health care procedure may be given verbally, it should be given in writing in the following circumstances:

- If it assists the informed consent process.
- If the patient or the clinician requests a written consent.

Written Consent

Written consent should be on an approved Mercy Consent form and must be completed before the health care procedure is undertaken. Informed consent to a health care procedure must be in writing in the following circumstances;

- The patient is participating in research
- The procedure is experimental
- The procedure is in an operating theatre
- The procedure will be carried out while under a general anaesthetic
- The procedure involves a significant risk to the patient.

The responsibility for ensuring that consent has been obtained lies with the person who will carry out the procedure, i.e. the patient's Credentialed Specialist and Anaesthetist. Mercy Hospital staff are responsible for checking that consent has been obtained. The procedure for checking that the consent has been obtained can be found on Appendix 1 of this policy.

Consent Guidelines

- Mercy Hospital requires that written consent is obtained for all procedures carried out in the Mercy Hospital operating rooms, Manaaki operating rooms, Mercy Cancer Care(MCC) and Mercy Heart Centre(MHC)

- Consent is gained using the information as outlined in this document.
- The Patient, the Credentialed Specialist and the Anaesthetist are all required to sign a consent form. The exceptions to this are MCC and MHC where an anaesthetist may not be involved
- A patient will not receive any form of sedation until the patient has signed a consent form.
- In the event that the patient has been sedated and consent has in error not been signed by the patient, the Credentialed Specialist and anaesthetist must confirm they had obtained verbal consent prior to the sedation being given and this must be documented by the Credentialed Specialist /anaesthetist confirming he/she has obtained verbal consent.

Specific Requirements

MCC

Consent for treatment and the consent form is individualised to the particular type of cancer and cancer treatment relevant to the individual patient as explained by the Oncologist.

MHC

Consent for treatment is incorporated into the MHC documentation

Manaaki

Consent for treatment for endoscopy patients is incorporated into Gastro-Enterological Endoscopic Procedures form

Ward Procedures

- For invasive procedures patients should receive adequate verbal explanation of what is proposed and verbal consent should be obtained. Details of the information given to obtain this verbal consent should be documented in the clinical records.
- Where the risk to the patient of the invasive procedure is thought to be significant written consent should be gained.
- Where the patient has declined to give their consent, and the patient is competent to do so this shall be documented in the clinical records and the procedure will not be carried out.

Blood and Blood Products

Refer to Blood & Blood Products Policy See Sharepoint

- Informed consent is required for the transfusion of any blood product. Blood and blood products are prescribed drugs (Medicines Act 1981) under schedule A. They must therefore be prescribed by a Credentialed Specialist.

- Where it can reasonably be expected that the patient may receive a blood product or tissue, Mercy Hospital requires that the blood consent section on a consent form be fully explained to the patient in terms of risks and benefits.
- The blood section on the consent shall be completed by the patient.

Advance Directives

- Instructions developed by a person who is considered able to make informed choices and decisions regarding how they wish their affairs to be managed in the event that they are no longer capable of making informed decisions. Advance directives may include decisions about health and personal care, resuscitation and legal and financial affairs. Advance directives may also designate substitute decision makers, who will assume responsibility for ensuring that a person's wishes are respected and supported. Such directives are intended to be effective only when the individual is no longer competent.
- Mercy Hospital policy is to comply with Advanced Directives given by a competent patient deemed to have been competent when the directive was formulated. If the patient becomes incompetent and is unable to make a decision regarding treatment, the following guidelines will be followed:
 - The attending Credentialed Specialist will determine a patient's incompetence according to the standards of medical practice. The Credentialed Specialist should seek corroboration of his/her conclusions from at least one other Credentialed Specialist.

Any Credentialed Specialist or staff member in a clinical role who is not prepared to comply with an Advanced Directive should remove themselves from the patient's care.

Photography, video, audio and related recordings

Photographs and any digital images illustrating a patient's condition or aspect of treatment form part of the patient's health record.

Informed Consent must be obtained prior to the taking of any recordings (photos, audio, video) that do not form part of the clinical record. Consent will be documented on the Consent Form, including how images are stored and destroyed. Where images are taken in the ward a clinical photography form will be completed, with Consent noted.

Consent for Presence in Theatre

Students and any visitors to theatre, who do not constitute part of the theatre team, must obtain prior consent from the Credentialed Specialist, Patient and Clinical Co-

ordinator, Theatre Suite, if they are to be present in Theatre during the patient's procedure.

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

Consent for Student Nurses being involved in Patient Care

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

Consent for Post Mortem

Death of a Patient Policy, see SharePoint.

Consent for Do Not Resuscitate Situations

Refer to Resuscitation/Not for Resuscitation Policy, See SharePoint.

Consent for Research - See Research Policy and appendices

Any research involving patients must have Ethics Committee approval to ensure that appropriate mechanisms are in place for identifying patients and gaining informed consent.

Consent for Storage Disposal and Return of Body Parts/Tissues

Return or Disposal of Body Parts Policy see SharePoint.

Consent for Section 29 medicines

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

Evaluation /Impetus for change based on:

- Patient Questionnaire feedback
- Incident reports
- Complaints feedback
- Informed Consent for Health Care Procedures – Audit and Patient Survey
- Staff training education records
- Medical Advisory Meetings.

Associated Legislation

- Care of Children Act 2004
- Health Act 1956
- Health & Disability Commissioners Act 1994
- Health & Disability Commissioner (Code of Health & Disability Services Patients' Rights) Regulations 1996 www.hdc.org.nz
- The Human Rights Act, 1993
- Health Information Privacy Code 1994
- Human Tissue Act 2008
- New Zealand Bill of Rights Act 1990
- The Protection of Personal and Property Rights Act 1988
- Privacy Act 1993
- Harmful Digital Communications Act 2015
- Vulnerable Children's Amendment Act 2017.

Associated Policy

- Research Policy and appendices
- Incident Policy
- Resuscitation/Not for Resuscitation Policy
- Death of a Patient Policy
- Cultural Policy
- Blood and Blood Products Policy
- Return or Disposal of Body Parts - Human Tissue Policy
- Clinical Imaging Policy
- Site Marking Policy.

Associated Documents

- Mercy Hospital By-Laws for Credentialed Specialists
- Ethics Directives
- Mercy Hospital/MHC/MCC/Manaaki Consent Forms
- Patient Information Booklet
- Takaka Best Practice Guidelines.

References

- Johnson, Sue **Healthcare and Law** 3rd New Zealand edition
Thomson/Brookers

Appendices

1. Consent Checking process
2. Clinical Photography Form