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

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

Related Standard
Standard 7of the Code of Health & Disability Services Consumers Rights 1996.
Nga Paerewa Health and disability Services standard 1.7 2022??
EQuIP Standard 1.1, criterion 1.1.3

Cultural considerations
Cultural consideration is an integral part of the consent process. The person's culture should be considered as a part of the consent process. Interpretation support will be offered as needed.

NZS 8134:2021

Ngā paearu | Criteria

1.7.1 I shall have the right to make an informed choice and give informed consent.

1.7.2 I shall be empowered to actively participate in decision making.

1.7.3 I shall have a right to supported decision making.

1.7.4 My whānau shall be included in decision making with my consent and shall be enabled to do so through access to quality information, advice, and resources.

1.7.5 I shall give informed consent in accordance with the Code of Health and Disability Services Consumers' Rights and operating policies.

1.7.6 My legal representative shall only make decisions on my behalf in compliance with the law. If my legal representatives make decisions for me, I still have the right to be included.

1.7.7 My advance directives (written or oral) shall be followed wherever possible.

1.7.8 The service providers shall have processes and policies to gain my consent and respect my wishes regarding the storage, return, or disposal of my body parts, tissues, and bodily substances.

1.7.9 Service providers shall follow the appropriate best practice tikanga guidelines in relation to consent.

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.

Informed Consent

Is the result of an interactive process involving communication between a credentialed specialist or clinical team and the patient or their activated enduring power of attorney (EPOA). 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 Mercy Home page) and Return or disposal of Ngā wāhanga tinana/ Body parts, tissue and substances policy.
- Recovery and recuperation.

Advance Directives/ advanced care plan/Shared Goals of Care

- Instructions developed by a person who is considered able to make informed choices and decisions regarding how they wish their affairs to be managed if they are no longer capable of making informed decisions. Advance directives/ advanced care plan may include decisions about health and personal care, resuscitation and legal and financial affairs. Advance directives/ care plan 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 care plan given by a competent patient deemed to have been competent when the directive was formulated. If the patient becomes incompetent and is unable to decide 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.

Patient Competence / EPOA

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, dementia 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 activated or invoked Enduring Power Of Attorney for personal care and welfare 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,

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

: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 the patient's views have not been able to ascertained 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.

See appendix 3, EPOA

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, informing whanau or family is a courtesy only, as they do not have the authority to refuse or permit urgent, necessary treatment, unless there is an activated EPOA.

Verbal Consent

Verbal consent should be sought for invasive procedures not covered under operative consent that occur out of the peri operative episode. These procedures include, but are not limited to catheterisation, IV-line insertion, NGT insertion and CVL insertion. This verbal consent will be recorded in the patient notes on a highlighted sticker.
If sticker not available a nursing note of consent given or withheld must be recorded in the patient's 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. Where written consent has been completed some months prior to the procedure being undertaken consent must be reconfirmed with the patient at time of patient admission. 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.
In the event that the patient has been sedated and consent has not been signed by the patient due to oversight, 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 Gastroenterological 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.

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, and 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 appendix 2 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 Theatre Clinical Leader, Theatre Suite, if they are to be present in Theatre during the patient's procedure.

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

Consent for Students (Nursing, anaesthetic technicians, allied heath) 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/Clinical professional. This permission must be recorded on the consent form

Consent for Postmortem

Death of a Patient Policy, see SharePoint.

Consent for Do Not Resuscitate Situations

Refer to Shared Goals of Care Policy

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 Mercy Home page on the intranet.

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, the administering credentialed specialist will discuss this retrospectively with the patient.

Evaluation /Impetus for change based on:

- Patient feedback Cemplicity
- 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 (reprint 2010)
- 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 2020
- Human Tissue Act 2008
- New Zealand Bill of Rights Act 1990
- The Protection of Personal and Property Rights Act 1988
- Privacy Act 2020
- Harmful Digital Communications Act 2015
- Vulnerable Children's Act 2014, Amendment 2017.

Associated Policy

- Research Policy and appendices
- Incident and Adverse Events Policy
- CPR Policy
- Death of a Patient Policy
- Cultural Policy
- Blood and Blood Products Policy
- Return or disposal of Ngā Wāhanga tinana body parts, tissue and substances Policy
- Clinical Imaging Policy
- Site Marking Policy
- Patients rights Policy
- Privacy and release of information pPolicy.

Associated Documents

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

References

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

Appendices

1. Consent Checking process
2. Clinical Photography Form
3. Enduring Poser of attorney for health and welfare. (EPOA)