

## Informed Consent

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### Purpose

These policies on informed consent provide a framework to clarify the recommended best practice in all situations that may require informed consent.

### Policy

Patients, and where appropriate a personal representative, are provided with information they need to make informed choices and give informed consent, as per the Health and Disability Services Standard 2008: 1.10. This guidance informs practice which is fundamental to New Zealand health services and practices, and core to patient centred care at CDHB.

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## Scope/Audience

All staff are to ensure that they practise within this framework with regard to informed consent. Consent must be given in writing if:

- the patient will be under general anaesthetic; or
- there is a significant risk of adverse effects on the patient; or
- when either party requests it; or
- the procedure is experimental, or
- the patient is to participate in any research, or
- the procedure is to be undertaken in the Operating Theatre.

## Definitions

### Patient

- The term 'consumer' is used in the Code of Health and Disability Services Consumers' Rights when referring to individuals who receive health services.
- The Canterbury DHB usually refers to patients, clients or residents dependent on the type of service.
- To obtain consistency, in this document, the term 'patient' has been used.

### Representative

- The term 'personal representative' is defined in two acts -
- The Health Act
- The Mental Health Compulsory Assessment and Treatment Act
- to mean:
  - Where the individual is under 16, the parent or guardian.
  - Where the individual is dead, the executor or administrator of the estate.
  - Where the individual is alive, over 16 and is unable to give consent, the person "appearing to be lawfully acting on the individual's behalf".

As to the last, this could be someone nominated by the patient, or a family member or even a friend.

## Associated documents

The table below indicates other associated documents.

Type	Title(s)
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Legislation	Code of Health and Disability Services Consumers' Rights 1996
Legislation	Health Information Privacy Code 1994
Legislation	The Mental Health Compulsory Assessment and Treatment Act 1992
Legislation	The Alcoholism and Drug Addiction Act 1996
Legislation	The Tuberculosis Act 1948
Legislation	The Health Act 1956
Legislation	The Transport Act 1962
Legislation	The Coroner's Act 1988
Legislation	The Protection of Personal and Property Rights Act 1988
Legislation	The Children's, Young Persons and Their Families Act 1989
Legislation	Criminal Investigations (Blood Samples) Act 1995
Legislation	Crimes Act 1961
Form	Agreement To Treatment Canterbury DHB Form QMR0002A

## 1 General

### Introduction

This section of the document provides the framework under which decisions on the general process for obtaining informed consent can be made.

### What is Informed Consent?

Informed consent may be defined as the process whereby someone who has the capacity/competence to consent, having been given sufficient information, arrives at a reasoned decision as to whether or not to agree to a proposed therapy or procedure.

Consent may be given orally or in writing depending upon a number of issues (see "When is written consent required" - page 7).

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 that person.

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## **Why is Informed Consent necessary?**

The patient has the right to be accurately and adequately informed about a proposed procedure or treatment and to agree or refuse to have that procedure or treatment.

All health professionals have a responsibility to inform patients about proposed procedures and to gain consent to procedures.

Where difficult situations arise, advice should be sought by the health professional from their clinical director and/or Medical Advisor.

## **When is Informed Consent required?**

Generally informed consent must be obtained for each treatment or procedure proposed (e.g. anaesthesia and surgery are separate procedures). There are, however, situations where consent for each individual treatment or procedure would be inappropriate, e.g., Composite Procedures (page 9).

There are a few situations in which individuals may be treated without consent. Acts of Parliament such as the Mental Health Compulsory Assessment and Treatment Act, control the conditions under which this may happen.

[See Laws Concerning Procedures Without Consent (page 14)].

## **What about Emergencies?**

Obviously in an emergency, the primary need is to treat the patient.

The key features of an emergency are:

- extreme urgency, or
- serious consequences of failure or delay in acting

Gaining informed consent is preferable but the circumstances may make this impossible.

In general, treatment provided in an emergency when the capacity to consent is impaired or absent should only be that which is necessary to treat the immediate problems.

After the emergency, the patient must be given information regarding the procedures carried out.

## **How long is the Consent valid?**

The length of time that consent having been given may still be considered valid is dependent on:

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- the nature of the procedure
- progression of condition
- likelihood of change in health status between consent and procedure
- change in competence

### **What and how much Information should be given?**

The amount of information given should be that which a reasonable patient, and in particular the individual patient with whom the clinician is speaking, would expect to discuss in order for a reasoned decision to be made.

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.

Every patient has the right to receive:

- an explanation of their condition; and
- an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
- advice as to the estimated time within which the services will be provided; and
- any other information required by legal, professional, ethical and other relevant standards; and
- the results of tests; and
- the results of procedures

Every patient has the right to receive honest and accurate answers to questions relating to services, including:

- the identity and the qualifications of the provider; and
- the recommendation of the provider; and
- how to obtain an opinion from another provider; and
- the results of research

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

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## Right to Refuse

It must always be remembered that under section 11 of the New Zealand Bill of Rights Act 1990, everyone has the right to refuse or withdraw consent to services. This is, of course subject to any statutory negation of that right by the provisions of Acts such as those mentioned in “Laws Concerning Procedures Without Consent”. (See page 14).

It should be made clear to the patient that he or she has the right to refuse or withdraw from treatment without fear of recrimination or penalty.

## How should Information be given?

Care must be taken to reduce in all possible ways the patient's feelings of excessive dependency and vulnerability and any discomfort they may feel about asking questions or suggesting alternative points of view.

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

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

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

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.

Audio-visual material should be included where it could be helpful in providing the information needed.

## Who should give the Information?

The primary responsibility for ensuring information is imparted lies with the person who is responsible for the procedure.

In some situations it is impracticable for all information to come from the health professional conducting the procedure. In such cases an appropriate health professional familiar with the treatment or

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procedure and with adequate knowledge of the risks and benefits of the treatment or procedure may impart the information.

In situations where a team is involved in management or treatment the process of imparting information may be shared between various members of the team.

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.

### **Responsibility for Obtaining Consent**

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

The responsibility lies with the person who is responsible for the procedure.

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.

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

In situations in which a patient cannot give consent for himself/herself, it should be recorded who gave consent, and the relationship to the patient. These situations include children who are unable to exercise their rights i.e. because they are too young or too ill, and those whose mental state leaves them (temporarily or permanently) without the capacity to consent.

[See Children (Page 17) and Diminished Capacity and Competence to Consent (Page Error! Bookmark not defined.).]

### **Advance Directive**

Every patient may use an advance directive to consent to or refuse a health care procedure.

An advance directive is the patient's instructions to consent to or to refuse treatment given at a time when the patient was competent, for use when they are subsequently of diminished competency. An advance directive can be verbal or written.

Issues to consider are:

- An undocumented verbal advance directive may be difficult to substantiate. Written advance directives are preferable.

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- Whether the patient's consent/refusal was likely to be on an informed basis.
- Whether the advance directive is likely to have become out of date.
- Whether the patient is likely to have changed their mind.

### **When is Written Consent Required?**

Consent must be given in writing if:

- the patient will be under general anaesthetic; or
- there is a significant risk of adverse effects on the patient; or
- when either party requests it; or
- the procedure is experimental, or
- the patient is to participate in any research, or
- the procedure is to be undertaken in the Operating Theatre

Written consent has two main purposes:

- The protection of the patient and their rights by ensuring that health professionals do take steps to secure informed consent and to alert the patient to the fact that some procedures are more significant than others. The issue of significance must include an assessment from the patient's perspective.
- The protection of the health professional and the institution as evidence that the legal and ethical requirements for gaining informed consent have been carried out.

If there is any doubt as to whether consent should be in writing written consent must be obtained.

Regardless of whether written consent is obtained, the contents of what is discussed and the process which is completed should be documented in the patient's notes.

[See Blood and Blood Products (page 24), and Photography, Video, Audio and Related Recordings (page 26)].

It is advisable to make a special record in the patient's notes of important or contentious issues. Relevant information should also be recorded should a patient decline to undergo any procedure.

### **Teaching, Observers and Research**

Patients have a right to consent to or decline involvement in teaching (including the presence of observers during treatment or

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examination) or to take part in research. “Observers” (including students) are defined as those additional to the normal medical and nursing team immediately involved in the procedure and staff directly concerned with the on-going care.

[See Ethical Guidelines for the Involvement of Patients in Clinical Teaching (page 31).]

Patients must not be included in research without their written informed consent.

### **Further Assistance**

If the information in these policies on Informed Consent does not answer a specific issue that you are having to address, further advice can be sought from the

- Corporate Legal Advisors
- Medical Advisors
- Quality and Risk Manager

## **2 Composite Procedures**

### **Introduction**

Patients should give informed consent for each treatment or procedure before it begins. However, there are times when a group of procedures or treatments are closely linked, and should be discussed as a composite procedure for the purpose of gaining consent.

### **Interdependent Treatments**

Interdependent treatments are those where the treatments are routine and necessarily interdependent, for example, administration of general anaesthetic, endotracheal intubation and the insertion of intra-vascular lines accompanying major surgical procedures (but not the surgery itself), to be followed by a period of mechanical ventilation.

In such cases, all the component procedures should be clearly described to the patient as an integral part of the treatment for which she/he is consenting

### **Conventional Treatments for Complications**

There are conventional treatments used for the immediate management of acknowledged common potential complications related to a procedure for which consent has been obtained. In this

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case, it may not be possible to gain informed consent for the specific treatment because of the complexity or urgency of the situation.

### **Potential Pathology confirmed during Surgery**

Appropriate further action may be consented to by a patient in the event of potential pathology being confirmed during the procedure for which he/she actually consented. For example, the surgeon may proceed to a more extensive operation following a biopsy that is confirmed as malignancy during frozen section analysis.

The patient should be informed as to the possible nature of the additional surgery, and the consequences of non-consent; for example, further surgery. If the patient is unable to make an informed decision without a confirmed diagnosis, consent to a composite procedure should not be sought.

### **Limitations on Composite**

This should never be used to imply prior consent to treatment or procedures which are not routinely used in the clinical procedure for which the patient has consented, and/or are unproven in the situation, even in an emergency.

### **Unforeseen Pathology during Surgery**

In the event of unforeseen pathology being discovered during the procedure for which the patient actually consented, the surgeon should not perform a definitive procedure for that pathology during that procedure. It is preferable that the diagnosis should be considered separately and separate consent to treatment gained from the patient.

## **3 Post Mortem Examination (Autopsy)**

### **Introduction**

Post-mortem examinations may be required under the Coroner's Act or may be requested by the clinician responsible for the care and treatment of a patient.

### **Coronial Autopsy**

If a death is reported to the Coroner, the decision whether or not to order a post-mortem examination, rests entirely with the Coroner.

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The categories of death which are required to be reported to the Coroner are in Part II, section 4 of the Coroners Act 1988.

They are summarised as follows:

- where death is natural but the cause is unknown
- suicide
- where a death is unnatural or violent
- where death may be seen to be due to a medical, surgical, dental, or anaesthetic procedure
- deaths of persons who are:
  - in custody of the Police
  - an inmate of a jail
  - in foster care
  - in an institution or residence established under the Children's, Young Persons and their Families Act
  - an inmate of a 'mental institution'

Canterbury DHB has an established reporting framework developed in conjunction with the District Coroner. The forms to be used for all hospital deaths are available on every ward and should be completed by the attending doctors and where appropriate faxed to the Coroner. The Mortality Co-ordinator at Christchurch Hospital can assist in this regard. In cases of doubt, discuss the matter with senior staff, and/or the Coroner and/or the Forensic Pathologist.

In coronial post-mortems, the family has the right to request and receive a copy of the post-mortem report from the Coroner. In day-to-day practice in Canterbury DHB, they are free to discuss the findings with the pathologist.

### **Non-Coronial Autopsy**

It is not permissible to request a non-coronial autopsy to determine cause of death for the purpose of completing the Medical Certificate of Cause of Death. In general a non-coronial autopsy can be requested only to further elucidate the known cause of death, for educational purposes and for audit /research purposes.

It is necessary that requests for non-coronial post-mortem examinations come from the doctors directly involved in the care of the patient and that they be made by direct discussion with the family.

The Chief Executive, as the person lawfully in charge of the body, delegates this authority to the clinician in charge of the cases.

Only with the informed consent of the family, may the autopsy be performed.

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Telephone requests are acceptable provided that adequate discussion takes place. Consent should be confirmed utilising the “Consent for Post mortem Examination” form. The “Requisition for Hospital Post mortem Examination” form also has to be completed. The Mortality Coordinator Christchurch Hospital, (ext. 81019), can advise on this process.

It is recommended that the doctor directly involved in the case and/or the pathologist who performs the autopsy discuss the findings with the family, provided the family wants to be advised of the findings, both at the preliminary stage, and at the final report stage.

### **Removal of Tissue at Post Mortem Examination**

A person may request in writing or orally before two or more witnesses during his/her last illness, that his/her body (or some part of his/her body) be used for therapeutic purposes, research, or education after his/her death, in terms of the Human Tissue Act 1964.

The clinician in charge of the case may authorise removal from the body, any body part or as the case may be the specified body part, provided he/she has reason to believe that the request has not been withdrawn, and that the family consent.

In practical terms, no tissue is removed for therapy, research or education without the consent of the family, even where the deceased has indicated prior permission, e.g. indicated on the deceased’s Driver’s License.

In coronial autopsies, consent may be given by the deceased’s family, but the Coroner needs to agree. In practice, the Forensic Pathologist will have the final say as to whether or not the body/body parts are to be used for therapeutic purposes, research or education. In coronial autopsy requests must be made of the family even in cases where the deceased may have indicated prior permission (e.g. Driver’s License).

### **Requests for Consent for Organs for Transplant.**

In general, the doctors requesting consent should not be from the “transplant team”. Rather, they should be from the medical team caring for the patient. Agreement needs to be reached with the family. In addition, if the death is in a category reportable to the Coroner, the consent of the Coroner will be required prior to any removal. In practical terms, discuss the case with the Duty Forensic Pathologist.

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## 4 Storage of Body Parts

If a request is made by a patient for storage of his/her body parts, then contact should be made with the Business Manager of Mortuary Services to arrange storage.

## 5 Laws Concerning Procedures without Consent

### Introduction

A number of Acts of Parliament provide for overriding the individual's right to decide whether or not to consent to procedures, in cases where that right is seen to work against the public good. The following Acts apply:

### **Mental Health Compulsory Assessment and Treatment Act 1992**

- Every "proposed patient" and patient under this Act is "entitled to receive an explanation of the expected effects of any treatments offered to the patient, including the expected benefits and the likely side effects, before the treatment is commenced".
- A "proposed patient" may be urgently sedated, by injection if necessary, without their consent being given when the medical practitioner issuing a Section 8B Medical Certificate has reasonable grounds to believe this is necessary to maintain that person or another person's safety.
- A patient *undergoing assessment* under sections 11 and 13 of this Act must accept treatment for mental disorder as directed by the Responsible Clinician and is not required to give consent.
- A patient who is subject to a Compulsory Treatment Order under this Act must accept treatment as directed for a mental disorder during the first month in which the order is in place, but written (informed) consent is required after this period has expired *unless* the treatment is considered to be in the best interests of the patient by an independent psychiatrist. (This also applies to consent for Electro-Convulsive therapy).
- Brain Surgery cannot be performed without the written informed consent of the patient.
- Under this Act consent is dispensed with only for services provided in relation to the mental disorder. Provision of all services other than for the mental disorder, require the provider to give effect to the consumer's right to make an informed choice and give informed consent about the proposed service. Consent for these must therefore be obtained in accordance with this policy.

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### **Alcoholism and Drug Addiction Act 1996**

A judge may issue orders for detention and treatment of alcoholics and drug addicts, which have to be complied with.

### **Tuberculosis Act 1948**

A District Court Judge may, under s16, order a person to be detained in an institution (i.e. a hospital) or other suitable place for treatment for a period of three months, though the period can, if necessary be extended by the judge for a further three months. Again, there is no option but to comply.

### **The Health Act 1956**

This Act provides for the compulsory carrying out of procedures in several different situations including infectious diseases, most of which are within the domain of Medical Officers of Health and are well known to them. Of considerable importance in hospitals is s126B, which safeguards doctors who administer blood transfusions to persons under the age of 20 years in emergencies when consent to the procedure has been refused.

### **The Transport Act 1962**

Section 58D of this Act authorises the hospital doctor who has charge of the patient to take a blood specimen whether or not the person being tested has consented or is even capable of giving consent.

The conditions to be complied with are:

- that the doctor is requested by an enforcement officer to take the blood specimen;
- that the doctor believes that the person is there as the result of a motor vehicle accident;
- that the doctor is satisfied that taking the sample would not prejudice the person's care and treatment
- the hospital doctor may direct another doctor, nurse or medical laboratory technologist or any employee whose duties include the taking of blood specimens to take the specimen

### **Coroner's Act**

This statute empowers coroners to require post-mortems, which the deceased's family has no right to refuse.

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### **Protection of Personal and Property Rights Act 1988**

This empowers the Court to appoint a welfare guardian to make decisions on behalf of a person who wholly lacks capacity to make or communicate decisions about any particular aspect or aspects of that person's personal care and welfare - including medical and surgical procedures.

Expressly excluded, however, are consents to ECT, brain surgery designed to change the person's behaviour, and participation in any medical experiment other than for the purpose of saving the person's life or of preventing serious damage to the person's health. Section 18 of the Act obliges a welfare guardian to have as the paramount consideration the promotion and protection of the welfare and best interests of the person for whom that guardian is acting.

This Act also allows people to appoint welfare attorneys to act in relation to personal care and welfare.

See CDHB Manual, Volume 2 – Legal and Quality  
Power of Attorney

### **Children's Young Persons and Their Families Act 1989 (sections 49 & 53)**

Family Court Judges have the power to order medical examinations and reports in respect of children and young persons. The report must be provided immediately following the examination. In limited circumstances social workers have the power to require medical examinations.

### **The Criminal Investigations (Blood Samples) Act 1995**

This Act provides for a High Court Judge to make orders for the taking of blood samples from suspects in police investigations when the suspects decline consent.

### **The Crimes Act 1961**

Section 41 expressly authorises the use of "such force as may be reasonably necessary" to prevent the commission of suicide, or of an offence likely to cause immediate and serious injury to the person or property of anyone. This allows restraint without consent in the circumstances specified in the section.

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## 6 Children

### Introduction

This document provides a framework under which decisions on the process for obtaining informed consent for children can be made.

### Code of Rights

Subject to the following, the Code of Rights applies to children as it does to adults.

### Age of Consent

The age of consent is not defined under the code. The code simply requires a person to consent provided they are competent to do so. As a general rule it is assumed that the nearer to 16 a child is, the more likely they can consent to a procedure. However this will depend on the nature of the procedure, the risks involved and the maturity of the child.

Treatment or investigation involving children under 16 years should not take place unless

- the child has capacity to consent and does so
- or
- the informed consent of the child's parent or guardian has been obtained, with two exceptions set out below

### Guardian

Under the Guardianship Act 1968 a guardian is a person who has custody of a child and custody is defined as "the right to possession and care of a child". Normally this will be the parents, or a parent of the child but this may not always be the case. If a guardian is not available the code requires the clinician to consult other suitable persons interested in the welfare of the child.

### Information Giving

There is the same requirement for information to be given to parents and for consent to be obtained from parents as in all other cases.

In addition to the need for parents to consent, information should, where practicable, be given to the child in a way that the child can understand and, where possible, the child's agreement should also be sought. Of course this will vary with the age of the child, but the general principle should be to involve the child as much as possible.

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## Declining Consent

If, despite information on the consequences of non-treatment, the parent or guardian continues to decline treatment, then the child may not be treated at that time.

Where a child with understanding of proposed treatment disagrees with parent, the role of the clinician is to identify a mediator who is acceptable to the child and parents, to facilitate a resolution. Mediators may include other family members, chaplains, kai awhina, child psychologists, social workers, etc. The same process should occur where parents disagree between themselves.

## Consent to Non-therapeutic Procedure

If any procedure is contemplated which is not for the child's personal benefit, e.g. transplant donor, the interests of the child must be carefully considered. It is unclear legally whether the guardian's consent is effective in this situation.

## Dissent between Parent and Clinician

If the parent refuses to permit treatment for a child which refusal to permit treatment in the view of the clinician, poses a risk of harm to the child and the parents refuse to consent to the treatment despite reasonable efforts having been made to obtain their informed consent; then an application to the High Court under the Guardianship Act 1968 may be necessary. Such circumstances would include if a child needs urgent treatment to:

- save the child's life; or
- prevent permanent injury to the child's physical or mental health; or
- save the child from prolonged and avoidable pain and suffering;

The Corporate Legal Advisor should be contacted to provide advice.

Social workers will provide a central co-ordination role which will be ongoing following the court order.

Outside court hours a judge may need to be contacted at home to obtain a court order. Follow the procedures set out below in these circumstances.

The following procedure is to be followed when the Corporate Legal Advisor is unavailable:

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Step	Action
1.	The doctor will contact first the specialist responsible for the child's care or the appropriate clinical director.
2.	The specialist/clinical director responsible for the child's care shall first seek an opinion from a colleague to check validity of proposed treatment.
3.	The Specialist Clinician contacts the General Manager for approval.
4.	The General Manager will contact the Duty Inspector at the Control Centre, Christchurch Central Police Station.
5.	The General Manager gives the Police all relevant information including prognosis if treatment withheld, timeframes, and steps already taken to obtain the guardian's consent and their reasons for refusal.
6.	The Police obtain an order from the High Court authorising the treatment/procedure to be provided.

This procedure does not apply in the case of blood transfusions in acute emergency situations on persons under 20 years when reliance may be placed on s126B of the Health Act 1956.

Nor does it apply in other cases in which emergency, rather than urgent, treatment is required.

### **Treatment without Parental Consent**

The exceptions to the general rule that the consent of parents is required are:

- Women of any age have the right to consent to a termination of pregnancy being carried out on themselves. (Guardianship Act 1968, S25A).
- A child may be given a blood transfusion without the consent of a parent if the medical practitioner believes that a transfusion is necessary to save the child's life, or to prevent permanent injury or prolonged and avoidable pain and suffering, provided a reasonable attempt has been made to obtain consent from the parent. (See Health Act 1956 s126B). The legal requirements must be fully observed. In particular, this section cannot be relied upon as protection if the need for a transfusion can reasonably be foreseen. In such a case an application to the Court under the Guardianship Act is necessary
- The exceptions outlined in Laws Concerning Procedures without Consent (page 16) also apply to children.

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- Certain medical officers have rights to enter schools or childcare centres to examine children when there is concern about the health or welfare of the child. There is no requirement for parental consent or the consent of the child. (section 125 Health Act 1956)
- Compulsory medical examinations can also be ordered by the Family Court under the Children's, Young Persons and Their Families Act, 1989 where abuse, neglect, etc. is suspected.
- No parents/guardian available and the medical practitioner believe that a treatment is necessary to save the child's life, or to prevent permanent injury or prolonged and avoidable pain and suffering.

### **Clinical Teaching, Research**

See separate section of this Policy for informed consent requirements as they relate to children.

## **7 Diminished Capacity and Competence to Consent**

### **Introduction**

For consent to be valid it must be voluntary, knowing or informed, and competently given. Medication, intellectual disability, mental illness, inebriation, or physical injuries all may affect the informed consent process.

As stated in Right 7(3) of the Code of Rights a patient with diminished competence retains the right to give informed consent appropriate to that patient's level of competence.

### **Capacity to Consent**

Individuals with the above conditions may lack the capacity to fully give or withhold consent. In the case of intellectual disability this is a permanent state. In the other cases it is an acquired state which may be brief or prolonged.

A person may be competent in some respects (e.g. to manage their financial affairs) and incompetent in others (e.g. to understand the effect of illness upon them, to assess the value of treatment). Medication can alter mental state, and may either improve or impair competence.

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## **Determining Competency**

Clinicians are often concerned to determine competence, i.e. to form an opinion as to whether a patient has the capacity to give informed consent.

There are reasonably well established guidelines as to what criteria to use in the assessment, but clinical opinion and practice may vary. The law is vague, using such terms as “*mental capacity*” and “*sound mind*”, but not specifying exactly what is meant by competence or its absence. Courts usually defer to clinical judgment.

## **The Legally and Clinically Competent patient**

If the patient is both legally and clinically competent, the usual guidelines for informed consent apply.

## **When a Patient lacks Capacity to give or Withhold Consent**

The Decision to undertake a procedure or administer blood or blood product to a patient who is unable to provide consent due to diminished consciousness and for whom there is no legal representative is ultimately the responsibility of the doctors caring for the patient.

In these situations medical staff can undertake those measures which are in their opinion necessary to save a life or prevent permanent physical and mental injury, or prolonged unavoidable pain and suffering, provided that:

- reasonable attempts have been made to obtain consent, or the time to do so was not available in terms of the patient’s interests;
- they are in a position to document justification for proceeding without obtaining consent;
- where time permits the specialist having overall responsibility for the patient is aware of the proposed action;
- where appropriate and time permits the specialist in charge has sought an alternative opinion from another senior staff member not involved in the patient’s care

In non-urgent situations reasonable steps must be taken to ascertain what the patient’s informed choice might be in the given circumstances. This may necessitate seeking opinion from others having an interest in the welfare of the patient. In this regard Right 7(4) of the Code of Health and Disability Services Consumers’ Rights applies.

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Where the situation is ongoing consideration should be given to approaching the Courts for the purpose of appointing a Welfare Guardian (see Section on Legislation below).

## **Legislation**

Where a patient lacks, wholly or partly, the capacity to understand the nature, and to foresee the consequences, of decisions in respect of matters relating to his/her personal care and welfare, the Protection of Personal and Property Rights Act may be invoked.

A welfare guardian appointed under the Protection of Personal and Property Rights Act will exercise the rights of the patient under the Code including the rights to give written consent.

If a clinically incompetent patient continues to decline treatment despite discussion and involvement of significant others, and is considered a danger to himself, herself or others, an application under the Protection of Personal and Property Rights Act 1988 should be considered.

Corporate/Legal should be contacted if this is seriously contemplated.

## **Compulsory Assessment and Treatment**

If the treatment is for a mental disorder an application under the Mental Health Compulsory Assessment and Treatment Act should be considered.

Responsibility for the treatment of a compulsory patient under the Mental Health Compulsory Assessment and Treatment Act is vested in the Responsible Clinician in terms of the Act. Such patients are the subject of a compulsory treatment order under the Act. This authorises compulsory psychiatric treatment only.

If a patient under the Mental Health Act requires medical treatment and lacks capacity to give or withhold consent, the Protection of Personal and Property Rights Act procedure applies as above.

## **Medication and Competence to Consent**

Medication given for pain relief, in anaesthesia, or to treat psychiatric illness may affect conscious awareness and thus competence to consent. This is a complex issue.

Although consciousness may sometimes be impaired, there is often an improvement in concentration and thinking ability with the relief of symptoms such as pain, anxiety and depression. Conversely,

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unrelieved pain, anxiety or depression may of themselves impair competence.

Where practicable, discussion about treatment should take place before the administration of medications liable to affect consciousness. When a patient's competence clearly has been impaired by medication, and the procedure is not urgent, recovery should be allowed before consent to further treatment is sought.

In principle, consent should not be sought when a patient is drowsy or unable to concentrate, but in practice consent for further treatment will sometimes be necessary from patients who have, for instance, received medication for pain relief.

It would be impractical to suggest that consent should never be sought from patients on any medication with the potential to affect concentration and thinking. Sound clinical judgment and common-sense should always be exercised.

## **8 Blood and Blood Products**

### **Prescribing**

Blood and blood products are prescribed drugs (Medicines Act 1981 under Schedule A). As such they must therefore be prescribed and ordered by a Registered Medical Practitioner and this entry must be made in the clinical records.

### **Information**

As with any other prescribed drug, the patient must receive adequate information as to the reasons for the transfusion, the risks, the benefits and the adverse sequelae that may result if the transfusion is not received.

### **Consent**

The patient or their parent/guardian must agree to the transfusion before it is carried out. Written consent must be obtained for the use of blood and blood products.

In circumstances where the patient cannot give informed consent (e.g. under anaesthesia) blood products may be given if deemed to be in the patient's best interests unless there is knowledge that the patient would not agree.

As a general rule, when consent is being obtained for an anaesthetic, consent would also be obtained for the use of blood products if, in the particular circumstances, there is a significant risk, of 1% or more, of these products being required.

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The New Zealand Blood Service is responsible for producing up-to-date information on all blood and blood products for the purpose of fully educating Registered Medical Practitioners and Nursing staff, etc.

### **Refusal of Blood Products**

Where blood or blood products are refused by an adult for any reason (e.g. religious beliefs), this decision must be respected, ensuring that those making the decision fully understand the implications this may have on the clinical outcome.

When this decision is made by one or more people on behalf of another who is not capable of making the decision, such as in the case of a minor, there is provision for the decision to be legally challenged. When situations such as this occur, advice should be sought from Corporate/Legal.

In both situations it is recommended discussions be held with the Clinical Director of the Department involved and/or one of the Medical Advisors.

### **Information Leaflet**

The patient information sheet on blood and blood products should be widely available, particularly in areas where blood and blood products are frequently given.

## **9 Photography, Video, Audio and Related Recordings**

### **Introduction**

Recordings of patients or staff occur in three situations.

1. Clinical Recordings.

As part of patient diagnosis and management.

For education and/or research.

**(Note:** These do not include radiology and related procedures.)

2. Recordings by external agencies.

3. Private Recordings (made by patients or their relatives)

### **Principles**

The two fundamental principles are:

1. Making a recording of any patient without informed consent is not permitted.

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2. The requirements of the Privacy Act 1993 and the Health Information Privacy Code 1994 must be observed.

**Any recordings must be made with consent, the major requirement being to protect the interests of the patient.**

## 10 Clinical Casenote Recordings

### For Diagnosis and Management

Where recordings are made as an integral and necessary part of patient treatment or management, written consent is required.

The recordings must be used purely for patient management and must be part of the patient's records or stored in a locked indexed filing system.

**In no circumstances may these recordings be used for education or research purposes unless appropriate consent is given.**

### For Education and Research

Recordings made for purposes of clinical teaching or research require informed consent and compliance with storage requirements.

### Consent

The prior written consent of the patient or patients who are to figure in the recording must be obtained.

Retrospective consent must be sought in cases where prior consent was impossible to obtain. If retrospective consent is denied, the recording must be destroyed.

In the case of any patient who is incapable of consenting personally, consent must be obtained from that patient's representative.

No patient who has declined consent may be included in a recording.

Where staff or relatives are to be included in the recordings their verbal consent must be obtained for recordings.

### Medical Illustration

The Medical Illustrations Department should be contacted for the appropriate consent documentation.

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## Publication Consent

Where recordings are to be used for reproduction in a journal or textbook, inclusion in a display presentation or any other form of publication, or distributed or transmitted by electronic or digital media, consent using the appropriate consent form is required.

## Consent to be “Informed” Consent

A consent is ineffective unless it is given following a disclosure of all the relevant information surrounding the recording, including:

- who is to make the recording
- why it is being made
- the audience for whom it is to be made

These matters must be specified in the written consent obtained.

The patient must not be subject to any pressure to give consent.

## Ownership of Recordings

All recordings made in Canterbury DHB's institutions by health care staff must at all times be and remain the property of Canterbury DHB. Recordings should be identified by a Canterbury DHB label if feasible.

## Storage

All recordings should be stored either in the clinical notes, or in locked indexed departmental storage areas suitable for the containment of clinical recordings.

Recordings may be transported outside the organisation only for a specific educational or research activity following which they must be returned to their usual storage place.

Recordings are to be identified by the patient's hospital number, rather than by use of the patient's name. There shall be no information on any recording which specifically identifies the patient.

## Use of Recordings

No recordings may be used for any purpose other than the purpose or purposes specified in the consents obtained.

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## Who May Make Clinical Recordings?

In most situations clinical recordings will be made by the Company's medical illustration professionals. When registered health professional staff make clinical recordings because the medical illustration professional is not available, or there is urgency, the guidelines apply, including the obtaining of written informed consent.

## 11 Recording by External Agencies for Research Educational Purposes

### Approval

Any person or organisation requires approval for filming or photography within Canterbury DHB premises.

Proposals for recordings must be submitted verbally or in writing to the General Manager or delegate and include:

- the proposal for the recording and the benefit it will generate
- the audience
- how long the recording will be in circulation
- statement that the proposed recording will fill a unique need and that there is no other suitable material available
- where appropriate the script is to be submitted for approval

Approval is given for the stated purpose only.

### Consent

This must be obtained before any recording is made.

Consent forms are available from the Medical Illustrations Department.

Consent must be obtained from visitors and staff members to be filmed or photographed. They have the right to refuse.

## 12 Private Recordings

### Introduction

Private recordings include any photographs, video and audio recordings made in any Canterbury DHB premises by patients or their families/whanau or support persons.

Patients, their families or support persons are entitled to make a recording except in the following circumstances:

- when making the recording might jeopardise patient safety

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- when the staff involved in caring for the patient have not given consent to be recorded, and need to continue the caregiving
- Patients, visitors and staff member's rights to privacy of identification are to be respected. The person wishing to make the recording must seek the verbal consent of all those likely to be included.
- Specific unit policies may be developed (e.g. obstetrics).

## **13 Ethical Guidelines for the Involvement of Patients in Clinical Teaching and Research**

### **Introduction**

Ethical guidelines for the involvement of patients in clinical teaching and research are essential in order to consider the welfare and interest of the patient.

### **Scope**

Applies to all teaching staff, other qualified staff and students working in all settings in Canterbury DHB where patient/student interactions are organised primarily for teaching and research purposes.

### **Principles**

In the partnership between patient, teaching and research staff and student, the paramount consideration must always be the welfare and interests of the patient.

An effective health care setting needs a continuing supply of qualified staff. An essential requirement for training health professionals is access to practical experience that is well planned and properly supervised.

Good quality experience for students is based on a three-way partnership between the patient who agrees to be part of the teaching/learning process; teaching staff, and the student. This process involves co-operation between the teacher and other qualified staff.

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

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## Supervision of Experience

The quality of patient care is the responsibility of the clinical team. Students providing aspects of the clinical treatment are supervised by their clinical team and supported by the teaching staff.

Physical examination or specific procedures undertaken by students must not be repeated unreasonably on any one patient and must not produce or prolong significantly any distress, embarrassment or pain.

Students involved in research activities must have received authorisation to proceed and do so under supervision of the teaching staff.

## Effective Communication

Special care must be exercised by teachers when there may be difficulties for patients in understanding what is proposed or in making their own views known. Patients who may have such difficulties include:

### **Children**

Consent must be sought by an appropriate means from a parent or guardian for children under 16. Children who can understand what is involved should participate in the decision. Verbal discussion about involvement in teaching must be recorded in the clinical record in the patient notes for reference.

### **Those from a different cultural background**

Cultural differences in decision-making should be respected; this process may include involvement of family members.

### **Those not proficient in English**

Patients must have an adequate prior understanding of what is proposed; the involvement of family members or a recognised interpreter may be necessary, before, during or after teaching.

### **Those disabled by confusion, an altered state of consciousness, mental incompetence, speech understanding difficulties or hearing problems.**

Agreement should be sought from another person who can speak for the patient, e.g. family member, or friend.

## Consent

Every patient has the right to decide whether he or she wishes to agree to an interview, examination or other specific procedure carried out by a student.

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Every patient has the right to withdraw from the teaching session or research project at any stage and must receive a clear prior assurance that refusal to participate in teaching and research or withdrawing from teaching and research will not jeopardise his or her care in any way.

Students must seek the agreement of patients allocated to them to be interviewed and examined, or to be the subject of specific learning procedures, and must explain clearly what is involved.

Written consent must be obtained from the patient for a student to undertake any procedure or examination to be performed by them while the patient is under general anaesthesia or sedation.

Students must obtain the patient's verbal consent to observe procedures in theatre if they are part of the care giving team. The consent should be obtained before pre-medication is given.

Patients have the right to know the name and professional status of any person who wishes to interview them for teaching or research purposes and/or examine them, or to carry out specific treatment or investigation procedures.

Teachers must ask a patient's permission to involve him or her in group teaching or clinical demonstration sessions and explain precisely what will be involved and how many students will be present.

### **Support**

Patients have the right to have a support person present including during intimate examination such as rectal or vaginal examinations.

### **Confidentiality**

Students and researchers are responsible for ensuring that personal information acquired by them about a patient remains confidential.

<b>Policy Owner</b>	Clinical Board
<b>Policy Authoriser</b>	CEO
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