

## POLICY

INFORMED CONSENT	
Applicable to: <b>Wairarapa DHB (Provider Division)</b>	Issued by: <b>Clinical Board</b>
	Contact person: <b>Medical Advisor</b>

### POLICY STATEMENT

#### PURPOSE

To ensure:

- That prior to being asked for consent, people have sufficient information about a proposed treatment or procedure, specific to their individual situation, to enable them to evaluate the options without pressure and to agree or not agree to that treatment or procedure being carried out.
- The provision of an environment in which people have control over their own clinical decision making, accept responsibility for their health, have the opportunity to have an advocate, and in which the partnership between the health care user and the health professional is based on trust.
- Compliance with relevant legislation, and thereby minimisation of risk for Wairarapa DHB.
- Provision of principles and guidelines for Wairarapa DHB health professionals who are responsible for obtaining informed consent.

#### 1.0 SCOPE

- All Wairarapa DHB employees who provide care to patients.

#### 2.0 ROLES & RESPONSIBILITIES

- The primary responsibility for obtaining informed consent lies with the person responsible for the procedure. This will usually be the person performing the procedure. In cases where this is impractical, the information may be imparted by a health professional who is familiar with the treatment or procedure and has adequate knowledge of the risks and benefits of that treatment or procedure.

#### 3.0 DEFINITIONS

##### 4.1 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, procedure or non treatment.

Consent may be given orally or in writing.

Informed Consent is not the act of filling out forms. It is a process of the exchange of information so that a person can make an informed decision. A signature on a consent form is an indication that the process of informed consent has taken place, and is an indication that the person has understood the information provided.

There has been much debate about the extent of the information that has to be disclosed to a patient. The situation in New Zealand now appears to be that a health professional must disclose all the information that a reasonable patient in the patient's circumstances would find material to making a decision about the proposed treatment. It must be judged to be reasonable by the patient, not by the doctor.

## 4.2 Significant Risk

In considering whether a risk is "significant", health professionals must consider the particular patient's circumstances. The health professional must always err on the side of caution. Where there is any suggestion that the risk may be "significant", written consent must be obtained.

## 4.3 Patient/Client

The term 'consumer' is used in the Code of Health and Disability Services Consumers' Rights, when referring to individuals who receive health services. This policy uses the term patient/client to mean consumer, patient, client, or resident depending on the type of service being provided to them.

## 4.4 Staff

The term 'health care practitioner(s)' is used throughout the Code of Health and Disability Services Consumers' Rights to describe health and disability support service practitioners of all disciplines. It **does not** refer to medical practitioners alone. Consent is an issue relevant to every Wairarapa District Health Board employee providing health services to patients/clients in all settings.

## 4.5 Representative

The term 'personal representative' is defined in The Health Act, The Mental Health (Compulsory Assessment and Treatment) Act, and the Health Information Privacy Code to mean:

- Where the individual is under 16, the parent or guardian (except in circumstances specified in this policy)
- 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" (this could be someone nominated by the patient/client, or a family member or friend).
- Where the individual is deceased, the executor or administrator of the estate
- Enduring power of attorney for health care.

## 5.0 PROCESS OF POLICY APPLICATION

Informed consent shall be obtained prior to any procedure/treatment being carried out on a Wairarapa DHB patient/client. No undue influence or pressure is to be used to obtain consent. The only exceptions to providing care without obtaining consent related to emergency situations and specified legislative provisions.

The process of consent may be, verbal or written. There are some instances where documented consent is mandatory (*see section 6.5*).

**Any person undergoing any procedure/treatment within Wairarapa DHB (or the persons legally able to give consent on their behalf, guardian, Welfare Guardian, Power of Attorney) shall be informed of the following (verbally or in writing, as specified in the procedures attached to this policy) prior to giving their consent.**

- The nature and purpose of the procedure/treatment, including a description of the procedure proposed.
- An assessment of the expected risks, side effects, benefits and costs.
- The risks, side effects, benefits, costs and consequences of “no treatment”.
- All relevant management options with their probable effects and outcomes.
- The nature of all information being collected, the purpose for which the information is being collected and the intended recipients of that information including the persons to whom the information may or must (by law) be disclosed.
- The timeframe within which such medical treatment will occur.
- The name (where possible) of who will carry out procedure/treatment.
- The right to refuse treatment or withdraw consent at any time.
- The financial cost (if any) of the intervention to be directly borne by the person concerned.
- Any other information requested by the patient.

**The health professional is to be satisfied that they have made every endeavour to ensure that the person (and their support person) giving consent fully understands what is being proposed:**

Wairarapa DHB approves the use of four consent forms for:

- General “Consent Form”
- Blood Consent form
- Consent to Sterilization form
- Immunisation and Vaccines Consent form(s)

Any additional consent forms and amendments to the policy must be approved by the Clinical Board, see appendix 12.

## PREREQUISITES

**The patient must be informed prior to consent forms being signed.**

The five elements to the process of informed consent are:

- The Provision of information on which to base a decision
- The understanding of the treatment choices.

- The understanding of both the situation and the information.
- The competence to make a decision
- The absence of pressure or coercion.

## 6.0 REFERENCES

- 6.1 Buddle Findlay: Reference Manual Relating to Informed Consent 2002.
- 6.2 Medical Law in New Zealand; David B Collins.
- 6.3 Code of Health and Disability Services Consumer Rights.
- 6.4 MidCentral Health Informed Consent Policy 2000.
- 6.5 BOP – Informed Consent Policy 2004.
- 6.6 Auckland District Health Board Informed Consent Policy 2003.
- 6.7 Southland District Health Board Informed Consent Policy 2003.
- 6.8 Good Health Wanganui Informed Consent Policy 1995-1997.
- 6.9 Alcoholism and Drug Addiction Act, 1966.
- 6.10 Auckland Healthcare Informed Consent Policy 1998.
- 6.11 Armed Forces Discipline Act 1971
- 6.12 Children’s Young Persons and Their Families Act, 1989.
- 6.13 Code of Health and Disability Services Consumers’ Rights, 1996.
- 6.14 Consent in Child and Youth Health: Information for Practitioners, Ministry of Health 1998.
- 6.15 Contraception, Sterilisation and Abortion Act 1977
- 6.16 Coroners Act, 2006
- 6.17 Crimes Act, 1961.
- 6.18 Criminal Investigations (Blood Samples) Act, 1995.
- 6.19 Care of Children Act, 2004
- 6.20 Hauora o te Tinana me ona Tikanga: A Guide for the removal, return, and disposal of Maori body parts and organ donation, Te Puni Kokiri, 1999.
- 6.21 HDC Canterbury Report recommendation 1998
- 6.22 Health Act, 1956.
- 6.23 Health Care and the Law, ED Sue Johnson, Brookers 2000
- 6.24 Health Information Privacy Code, 1994.
- 6.25 Judicature Act 1908
- 6.26 Mental Health (Compulsory Assessment and Treatment) Act, 1992.
- 6.27 Protection of Personal and Property Rights Act, 1988.
- 6.28 Land Transport Act, 1998.
- 6.29 Treaty of Waitangi.
- 6.30 Tuberculosis Act, 1948.
- 6.31 Whanganui Informed Consent Policy 2004.
- 6.32 Health Research Policy, Whanganui District Health Board, 2002, Section E4
- 6.33 Self Discharge, Refer to Self Discharge Form

## 9.0 APPENDICES

- [Appendix 1](#) Legislative Requirements relating to Mandatory Treatment and Exceptions to the Need for Consent
- [Appendix 2](#) Mentally (Intellectually) Disabled Persons
- [Appendix 3](#) Consent to Psychiatric Treatment
- [Appendix 4](#) Sterilisations, Contraception, Abortions
- [Appendix 5](#) Post-Mortem Examination / Removal of Tissue
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<a href="#">Appendix 7</a>	Involvement of Patients in Clinical Teaching
<a href="#">Appendix 8</a>	HIV Testing
<a href="#">Appendix 9</a>	Blood and Blood Products
<a href="#">Appendix 10</a>	Diminished Capacity and Competence
<a href="#">Appendix 11</a>	Criteria for Individualised Consent Forms
<a href="#">Appendix 12</a>	Approved Consent Forms
<a href="#">Appendix 13</a>	Enduring Power of Attorney [EPOA]
<a href="#">Appendix 14</a>	Age for giving consent

## LEGISLATIVE REQUIREMENTS RELATING TO MANDATORY TREATMENT AND EXCEPTION TO THE NEED FOR CONSENT

**(NOTE – Before acting upon any of the following, the person responsible for administering the treatment/process could seek advice from the Medical Advisor, and for every occasion on which a procedure to be carried out without consent is proposed, all relevant requirements of the law must be strictly complied with.)**

### 1.0 ALCOHOLISM AND DRUG ADDICTION ACT 1966

#### 1.0.1 Detention

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

### 1.1 BLOOD SAMPLES ACT 1995

#### 1.1.1 Criminal Investigations

A Police Officer may **ask** a medical practitioner (or registered nurse if the suspect agrees) to take a blood sample from a criminal suspect under this Act. The medical practitioner or registered nurse should not take the blood sample unless:

- the Police Officer provides some proof of consent by the suspect; or
- the Police Officer has an order from the High Court ordering that a blood sample be taken.

The person giving the blood sample may choose whether the blood sample is taken by way of venous sample or a finger prick sample. If the person refuses to give a sample then a finger prick sample is taken.

If the person refuses to allow a blood sample to be taken in accordance with a High Court order, then the police are entitled to use reasonable force to assist a medical practitioner to take a finger prick sample.

**A medical practitioner or registered nurse cannot be compelled to take a blood sample from any person under this Act.**

The person taking the sample is required to ask the suspect whether they wish to keep part of the sample for the purposes of having it analysed on their own behalf.

### 1.2 CARE OF CHILDREN ACT 2004

#### 1.2.1 Care of Children Act 2004 -

- Women of any age have the right to consent to a termination of pregnancy being carried out on themselves (Guardianship Act 1968, Section 25A).
- For Consent in “Children” see Appendix 14.
- Emergency Situations (see page 3).

### 1.3 CHILDREN, YOUNG PERSONS AND THEIR FAMILIES ACT 1989

#### 1.3.1 Abused or Neglected Children

1. Sections 49-52 of the Children, Young Persons and their Families Act 1989

provide that medical examinations can be ordered by the Family Court where it is satisfied that:

- a. there are reasonable grounds for suspecting the child (under 14) or young person (under 17) is suffering ill-treatment, abuse, neglect, deprivation or serious harm; and
- b. it is expedient that a medical examination be carried out for the purpose of determining whether the suspicion is well-founded.

Applications for such medical examinations can only be made by a social worker or a member of the Police. When such order is made, no parental, guardian or child's request is required.

The Act also provides for a social worker to arrange for medical examinations of persons under the age of 18 in certain circumstances. In such situations reasonable efforts should be made to obtain the consent of the parent or guardian. Section 53 provides that examinations can be made where such consent is not obtainable after reasonable efforts.

Section 55 of the Act states that where the examination includes an internal examination of the genitals or anus, the child or young person has to give consent if they are judged to be competent.

The parent/guardian of a mentally disabled minor has the power to consent on the minor's behalf to any medical treatment. Where the parent/guardian refuses to consent, the same steps should be taken as those with respect to a minor who does not have a mental disability.

However, where there is no parent/guardian an application can be made to the Family Court under section 12 of the Protection of Personal and Property Rights Act 1998 for a welfare guardian to be appointed in respect of that person.

Note: Where the mentally disabled child in question is 16 or over, a specific exception has been made regarding psychiatric treatment or assessment, so that consent of the parent or guardian is NOT sufficient consent for the purposes of the Mental Health - See Compulsory Assessment and Treatment Act 1992

### 1.3.2 Serious Risk or Harm

If the parent or guardian refuses to permit treatment for a child and this, in the view of the clinician poses a serious risk of harm to the child, then the provisions of the Children, Young Persons and their Families Act 1989 to provide care and protection to the child may be invoked. Note: It is important that the procedures laid down in the Act are followed in such circumstances. Application to the Court is required.

Where there is no parent/guardian from whom consent can be obtained, consent can be given by a District Court Judge or the Director-General of Social Welfare under section 25(3) of the Guardianship Act 1968. The Guardianship Act provides for a persona acting in "loco parentis" to give consent.

Where the parent/guardian refuses to consent to the proposed treatment then an application may be made to the District (Family) Court to remove the guardianship responsibilities of the parent and to place the child under the guardianship of the Court. Once the Family Court has been appointed a guardian of the child it, or its agent, can make decisions with respect to the medical treatment that the child receives.

An alternative to the Family Court's guardianship jurisdiction is the High Court's "parens patriae" jurisdiction. This enables the Court to make decisions regarding the welfare of the child without becoming the child's guardian.

Where the proposed treatment of the child involves **a series of decisions** to be made and not just a single incident then it is appropriate to seek an application for the Family Court to be appointed the child's guardian.

However, where the treatment in question is a one-off treatment, the High Court should consent to the treatment under its "parens patriae" jurisdiction.

## **1.4 CONTRACEPTION, STERILISATION AND ABORTION ACT 1977**

### **1.4.1 Contraception, Sterilisation and Abortion Act 1977**

Section 4 of the Contraception, Sterilisation and Abortion Act 1977 permits the administering of contraceptives to "mental subnormal females" without necessarily obtaining their consent.

A female is mentally subnormal if "she is suffering from subnormality of intelligence as a result of arrested or incomplete development of mind to the extent that she is incapable of living an independent life or of guarding herself against serious exploitation or common physical dangers or to the extent that she is incapable of understanding the effective use of contraceptives" (Section 4(2)). The consent of the Court should be obtained.

## **1.5 CORONERS ACT 2006**

### **1.5.1 Coroners Act 2006**

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

## **1.6 CRIMES ACT 1961**

### **1.6.1 The Crimes Act 1961**

Section 41 of the Crimes Act 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 is restricted to allow restraint of the person **but not treatment** without consent in the circumstances specified in the section (see also the Wairarapa District Health Board's Restraint Policy).

### **1.6.2 Criminal Responsibility (Section 61, 61A)**

A person performing a surgical operation with reasonable care and skill is protected from criminal responsibility if the consent of that person (or any persons lawfully entitled to consent) is obtained. Without consent the intervention may be construed to be Assault & Battery.

### **1.6.3 Duty To Provide the Necessaries of Life (Section 151)**

Any person in charge of any other person by reason of detention, age, sickness or insanity has a legal duty to supply that person with the necessaries of life. The person is criminally responsible for omitting to perform such duty if the death of that person is caused, or if his life is endangered or health permanently injured by such omission.

## **1.7 ARMED FORCES DISCIPLINE ACT 1971**



### 1.7.1 Armed Forces

Section 72 of the Armed Forces Discipline Act 1971 specified that certain persons governed by that Act may be ordered to submit to certain medical or surgical procedures.

Note: This section does not authorise treatment without consent.

## 1.8 HEALTH ACT 2009

### 1.8.1 Venereal Disease

It is mandatory for a person suffering from venereal diseases to undergo treatment under Sections 88(1) and 90 of the Health Act.

Note: These sections do not state that no informed consent is required. It is still up to the individual to consent to treatment even though a failure to do so will constitute an offence, by the patient.

### 1.8.2 School Child

Section 125 of the Health Act 1956 permits a medical officer employed in the Ministry of Health or an officer authorised by the Minister of Health or any registered nurse employed by the Royal New Zealand Society for the Health of Women and Children Inc so contracted by the Minister, to enter public schools, private schools (if the controlling authority has so requested) and child care centres and to examine any child there.

Note: Prior consent of parents is not required, but parents may be notified subsequently of any condition or disease the child is discovered to be suffering from.

### 1.8.3 Blood Transfusions to Persons under 20

Section 126B of the Health Act 1956 protects a medical practitioner/professional in respect of blood transfusion to any person under the age of 20 whose parent refuses consent, if –

- a. the transfusion is necessary to save the life of the patient or to prevent permanent injury to mental or physical health or to save the patient from prolonged and avoidable pain and suffering, and
- b. either a reasonable attempt has been made to obtain the consent of the parent or it was necessary to administer the transfusion promptly and therefore impracticable to obtain such consent, and
- c. in all the circumstances it was reasonable to administer the transfusion  
The patient must be competent to consent and give consent.

## 1.9 JUDICATURE ACT 2010

### 1.9.1 Physical or Mental Condition at Issue

Section 100 of the Judicature Act 2010 provides that, under certain circumstances, the court may order a person to submit to examination at a time and place specified in the order by one or more medical practitioners. (This provision has been employed sparingly by the court).

## 1.10 LAND TRANSPORT ACT 1998

### 1.10.1 Blood Specimens

Section 73 of this Act allows a medical practitioner at a hospital to take a blood specimen from a person without their consent where the medical practitioner:

- (1) Has reasonable grounds to suspect that the person is in the hospital as a result of an accident involving a motor vehicle; and
- (2) Has examined the person and is satisfied that the taking of a blood specimen would not be prejudicial to the person's proper care or treatment; and
- (3) Tells the person (unless the person is unconscious) that the blood specimen is being taken under this section for evidential purposes.

**Note:** There is no obligation on a medical practitioner to take a blood sample unless requested to do so by an enforcement officer. In that situation either the medical practitioner must do it or request another registered medical practitioner or medical officer to do it.

Although a blood specimen may be taken without consent under the Act, it may not be taken against the subject's will, for example using force. Where there is physical resistance from the patient a sample may not be taken.

For the purposes of the legislation an enforcement officer is a sworn or non-sworn member of the Police, or a person who has been appointed by the Commissioner of Police under the Land Transport Act 1998.

In this situation the person from whom the blood sample will be taken has a statutory obligation to permit a blood specimen to be taken. If the medical practitioner takes a blood specimen from an unconscious person, the medical practitioner must notify the person in writing as soon as practicable that a blood specimen was taken under section 73 of the Land Transport Act 1998 for evidential purposes.

## 1.11 MENTAL HEALTH (COMPULSORY ASSESSMENT & TREATMENT) ACT 1992

Refer to detailed commentary Appendix 10 pg.24

## 1.12 PROTECTION OF PERSONAL AND PROPERTY RIGHTS ACT 1988 [PPPR ACT]

### 1.12.1 Welfare Guardians

**Welfare Guardians** may be appointed to persons under 20 if no parent or guardian is living or in regular contact and such appointment is in the best interest of the minor (Section 12(3) (a) and (b) of the Protection of Personal and Property Rights Act 1988). In practice, the appointment of welfare guardians will be made in cases where the child is under the age of 16 and does not have the maturity to make decisions, or where the child is mentally disabled. Exception Contraception, Sterilisation and Abortion Act see section 1.3 & appendix 4 pg.17.

### 1.12.2 Competence (See Appendix 13)

The PPPR Act 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 electro-convulsive therapy, brain surgery designed to change a 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.

Under the Protection of Personal and Property Rights Act 1988, the patient/client may appoint someone with an enduring power of attorney to make decisions on their behalf, in the event that they become incompetent to make their own health care choices.

**The Enduring Power of Attorney for financial matters and the Enduring Power of Attorney for health matters are separate and must be specified.**

The exercise of an enduring power of attorney can become difficult when a person has some degree of competence, but insufficient competence to make important decisions.

The provider or caregiver must recognise that the assignment of an enduring power of attorney does NOT strip a person of all rights to make their own decisions.

## 1.13 TUBERCULOSIS ACT 1948

### 1.13.1 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.

## APPENDIX 2

## 2.0 MENTALLY (INTELLECTUALLY) DISABLED PERSONS

### 2.1 Minors

See [Refer](#) to Guardianship Act

#### Adults

Where possible, informed consent should be obtained from a mentally disabled person. There is a presumption under the Code of Rights that every adult person has the capacity to consent to or refuse medical treatment.

It is not a question of the patient having capacity or no capacity to consent. An assessment must be made of the ability of the mentally disabled person to consent to or refuse consent to the medical treatment in question.

If the medical practitioner is certain that the mentally disabled person is incompetent to consent to the medical treatment in question, then the consent of that person's court appointed welfare guardian should be obtained. If the mentally disabled person does not have a court appointed welfare guardian and the treatment involves day to day standard medical treatment, including dental treatment, then the health professional may provide the treatment as long as they comply with the obligations under Right 7(4) of the Code of Rights.

The medical treatment may be provided where:

- a. it is in the best interests of the consumer; and
- b. reasonable steps have been taken to ascertain the views of the consumer; and
- c. either:
  - (i) if the consumer'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 consumer would make if he or she were competent; or
  - (ii) if the consumer'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 consumer and available to advise the provider.

Right 7(4) (c) (ii) – places an obligation on health professionals to consult with other suitable people who are interested in the welfare of the patient before deciding whether or not to provide the patient with the treatment. An appropriate written record should be maintained to demonstrate that this obligation has been fulfilled.

It is important to remember that although a patient's next of kin should be consulted under this provision, they do not have any right to consent or to refuse consent or medical treatment on the patient's behalf. Once the health professional has taken the views of others into account, he or she alone has the final decision as to whether or not to provide the medical treatment to the patient.

**Note this does not extend to the sterilisation of mentally disabled people.**

See "Diminished Capacity and Competence to Consent".

### 3.0 CONSENT TO PSYCHIATRIC TREATMENT

### APPENDIX 3

- 3.1** The Mental Health (Compulsory Assessment and Treatment) Act 1992 contains the provisions for consent in relation to psychiatric treatment. This Act also specifically incorporates a number of general rights of all mental health patients.

Note: The provisions relating to compulsory assessment and treatment as well as informed consent below do not apply in respect of any person by reason only of their “intellectual handicap”.

Where the person is undergoing compulsory assessment or subject to a Compulsory Treatment Order (CTO), the person may be subject to psychiatric treatment according to the following consent requirements:

#### **Electro-Convulsive Treatment: (Section 60)**

1. Consent in writing of patient, or
2. Treatment approved by psychiatrist appointed by Review Tribunal

#### **Other Treatment (e.g. medication)**

1. Where a patient is under assessment or within the first month of a CTO, no consent is required (Sections 58 and 59(1))
2. In other cases, the following are required:
  - i. Consent in writing of patient, or
  - ii. Treatment approved by psychiatrist appointed by Review Tribunal (Section 59(2)).

- Note:
1. Consent of the patient should be sought wherever practicable for Categories (1) and (2) under (c) above.
  2. Treatment falling within Category (2) under (c) above can be applied without satisfying requirements in (i) or (ii) where such treatment is immediately necessary to save the patients life, or prevent serious damage to the patient’s health, or prevent the patient from causing serious injury to themselves or others (Section 62).
  3. Where consent has been withdrawn, as long as treatment is approved by psychiatrists approved to do section 59 opinions, treatment can be given without the persons consent.

### **3.2 Minors**

The consent requirements above are applicable to minors subject to the following:

#### **a. Age of Consent**

A person is a minor or child at law until the age of 20 years. However, where a patient’s consent is required under the Act, treatment or assessment cannot be imposed upon the person against his/her wishes even with parental consent if the person is 16 or over (Section 87).

For the provision of psychiatric treatment to minors aged between 16 and 20, who are incapable of consenting themselves, the compulsory assessment and treatment procedures under the Act have to be utilised. Consent from a parent or guardian is not sufficient.

#### **b. Child**

The consent of a parent or guardian to the psychiatric treatment or assessment of a person under 16 years is insufficient for the purposes of the Mental Health Act 1992. Treatment given to a child under 16 under the Mental Health Act must meet the statutory requirements for treatment administered in those circumstances. Parental consent is not acceptable.

**3.3 Persons entering the Mental Health System through the Criminal Justice System**

These are “special patient” in terms of the Act (Section 2), and are to be treated as if they were subject to a CTO.

## 4.0 STERILISATIONS, CONTRACEPTIONS ABORTIONS

### 4.1 Sterilisations

#### **“Normal” Minors**

Where a person lacks the capacity to consent only by reason of their age, no other person can consent to sterilisation of that person on their behalf (Section 7 of the Contraception, Sterilisation and Abortion Act 1977).

Section 7 does not apply to the situation where the lack of ability to consent was due partly to mental disability as well as age.

#### **Mentally Disabled Minors**

The High Court decided in Re X (1990) 7 FRNZ 216 that parental consent is sufficient for sterilisation of a mentally disabled minor. In these circumstances the Medical practitioner is advised to seek legal advice.

### 4.2 Abortions

#### **Mentally Disabled Females**

In cases where a female lacks the ability to consent to an abortion because of her “mental incapacity”, a certifying consultant may determine whether or not the criteria for performing an abortion are satisfied (Section 34 of the Contraception, Serialisation and Abortion Act 1977). The consultant must consult with a registered medical practitioner or other person experienced in the field and able to make an assessment of the patient’s condition and the likely effect on that condition of the continuance of pregnancy or an abortion. In these circumstances the Medical practitioner is advised to seek legal advice.

#### **All other Females**

Any female, regardless of age, provided they are judged to be competent, may consent to or refuse to consent to an abortion performed on her (Section 25A of the Guardianship Act 1968).

## 5.0 POST-MORTEM EXAMINATION/REMOVAL OF TISSUE

### 5.1 Coroner's Post-Mortem

If a death is reported to the coroner, the decision to hold a post-mortem examination or not, rests entirely with the coroner.

### 5.2 Other Post-Mortem Situations

If the clinician wishes to undertake a post-mortem to further medical knowledge about the particular patient or disease in general, consent must be sought from the deceased's legal representative. This is the executor of the deceased's estate, who may not necessarily be a relative of the deceased's.

The clinician directly involved in the care of the patient must explain the procedure to the legal representative so that he or she can give informed consent to the procedure. The person lawfully in charge of the body (the designated Medical Advisor) can only authorise a post-mortem of the deceased's body if the legal representative consents.

Cultural and religious beliefs must be taken into consideration and respected.

### 5.3 Removal of Tissue at Post-Mortem Examination

In terms of the Human Tissue Act 1964, the removal of human tissue for therapeutic use (e.g. removal of cornea, kidney) or for the purpose of medical education and research cannot be undertaken without the prior authorisation of the person lawfully in possession of the body (designated Medical Advisor).

The person lawfully in charge of the body may only authorise the removal of tissue if he or she has no reason to believe (having made reasonable enquiry) that the deceased had not expressed an objection, or that the surviving spouse or any surviving relative of the deceased person does not object to the body being so dealt with.

The person lawfully in charge of the body cannot permit the removal of tissue if he or she has reason to believe that an inquest may be held on the body or that a post-mortem examination may be required by the Coroner.

In Coroner's cases, the authorising person can inform the Coroner that valid consent has been received for tissue removal, and this can proceed if the Coroner agrees.

### 5.4 Requests for Consent for Organs for Transplant

The Senior Medical Officer (Wairarapa District Health Board would refer to a Neurologist) is to gain permission from the legal representative, and any other family deemed appropriate by the legal representative, and then seek the approval of the Coroner before proceeding.

### 5.5 Removal of Tissue for Research Purposes

If tissue is to be obtained and used for research purposes, appropriate approval for the research project must have been obtained. Note changes proposed to the Health & Disability Commissioner Code may alter this in 2004/05.

A request for removal of tissue for a specific purpose may be sought as described under "Other Post-Mortem Situations" above.

### 5.6 Removal of Tissue for Education Purposes

Consent must be sought from the legal representative as above.



*6.0 FILMS, PHOTOGRAPHS AND TAPE-RECORDINGS*

Written consent from the patient is required if the films/photographs and tapes are not part of the clinical record, and/or will be used for teaching purposes if the patient is identified.

## 7.0 INVOLVEMENT OF PATIENTS IN CLINICAL TEACHING

While all fully qualified staff have an obligation to facilitate the teaching of students in their own and related disciplines, such teaching relies heavily upon the willingness of patients to be involved in this process.

The following principles will apply:

- Every patient has the right to decide whether they wish to agree to an interview, examination or other specific procedure carried out by a student, and to withdraw from the teaching situation at any stage.
- Special care is to be taken to ensure the patient understands what is involved, and cultural sensitivities must be respected.
- Any patient declining such involvement must receive a clear prior assurance that refusal will not jeopardise their medical care in any way.
- Students must seek the agreement of patients allocated to them, and must explain clearly what is involved.
- Teachers must seek the agreement of patients to be involved in group teaching or clinical demonstration sessions, and explain clearly what is involved and how many students and/or other staff will be present.
- If the teaching involves patients disabled by confusion, an altered state of consciousness or mental incompetence, agreement should be sought from another person who can speak for the patient.
- Children who can understand what is involved have the right to consent to or decline involvement themselves. For young children, consent must be sought from parents or guardians.
- Students are responsible for ensuring that personal information acquired by them about patient's remains strictly confidential, and that health information collected is used only for the purposes for which it is collected, in accordance with the Health Information Privacy Code 1994.

## 8.0 HIV TESTING

In accordance with this policy, written information is to be provided as part of the process of informing the patient, and written consent is to be obtained prior to the patient undergoing HIV testing.

### **Counselling**

Pre and post counselling is to be provided, appropriate to the situation as follows:

**If a positive result is unlikely** (if testing is done to rule out HIV early in investigations or for a needle stick injury), a brief explanation with the assistance of an information sheet (available from the Infection Control Department) which also contains information about Hepatitis B and C.

**If a positive result may be expected**, either from symptoms or the presence of high risk behaviours, full pre and post counselling must be carried out by an appropriately qualified person. (Contact Social Work Services to arrange referral.)

## 9.0 BLOOD AND BLOOD PRODUCTS

Blood products must be prescribed and ordered by a Registered Medical Practitioner through completion of the specific form produced by the New Zealand Blood Service. This must be recorded in the patient's notes.

As with any other treatment/procedure, the patient must receive information in accordance with this policy prior to giving consent. Written consent is required for all blood products.

Transfusions of all blood and blood products including:

- Albumex 4% and 20%
- CSL anti-D
- Factor VIII (AHF)
- Factor IX (prothrombinex)
- Fibrogammin.
- Fresh frozen plasma
- Hepatitis B immunoglobulin 100 and 400 IU
- Intragam, (Ivimmunoglobulin) 50ml, and 200ml.
- Normal immunoglobulin 2ml and 5ml
- Platelets
- Red cells
- Rhogam anti-D
- Tetanus immunoglobulin.
- Winrho anti-D
- Zoster immunoglobulin.

All require written consent.

It is therefore necessary that the New Zealand Blood Service be responsible for producing up-to-date written information (including risk factors) for Registered Medical Practitioners and clients on all blood and blood products.

A record of administered blood and blood products is to be available to the recipient if requested.

If samples of donated blood or blood tests from patients are to be used for testing, teaching and research, donors and patients should have the opportunity to consent or not to their donation being used in this way.

When blood samples are taken from a patient, it is the responsibility of the attending medical practitioner to ensure that the patient is informed about what the blood samples are being taken for and what treatment will follow, depending upon the laboratory result. Any question directed to the laboratory staff must be redirected to the doctor concerned. All research, including that using blood in storage, must be approved in accordance with the Wairarapa DHB Health Research Policy.

## 10.0 DIMINISHED CAPACITY AND COMPETENCE

For consent to be valid it must be **voluntary, informed and competently given**. Influence of medication and therapeutic substances, intellectual disability, mental illness, inebriation, or physical injuries may all compromise the informed consent process.

### 10.1 Capacity to Give Consent

- Every individual is presumed to be competent to consent unless proved otherwise. The Code of Health and Disability Services Consumers' Rights states that "where the consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence" (Right 7(3)).
- In each case staff must assess the patient to decide whether the patient's capacity to consent is so reduced that he or she does not sufficiently understand the nature, purpose and effects of the proposed treatment.
- If the patient/client has been assessed by the clinician/psychiatrist as lacking the capacity to understand the nature of the treatment, and to foresee the consequences of decisions in respect of matters relating to his/her personal care, and they do not have an appointed representative; then the following action can be taken:
  - Treatment may be able to be undertaken if it is necessary and in the patients best interests; or
  - The Protection of Personal and Property Rights Act may be invoked. A Welfare Guardian or an Enduring Power of Attorney (EPOA) appointed under the Protection of Personal and Property Rights Act will exercise the rights of the patient/client under the code including the rights to give written consent; or
  - An application can be made to the court under section 10 (1) (f) of the Protection of Personal and Property Rights Act 1988.
- In practice, staff seeking consent from a patient/client who is willing but who has diminished capacity must impart information to the patient/client and to **suitable persons including** the spouse, next of kin or appointed representative. While next of kin do not have the right to consent to or refuse medical treatment, staff must take their views into account when deciding whether to administer treatment. (Right 7(4) (c) (ii)).

### Mental Health Assessment and Treatment

- Informal patients/clients – shall be requested to provide written consent to treatment.
- An application under the Mental Health (Compulsory Assessment and Treatment) Act 1992 for a Compulsory Treatment Order should be considered when there is a clinical judgment that there is an abnormal state of mind, whether of a continuous or intermittent

nature, which is characterised by delusions or by disorders of mood, volition, cognition, or perception AND that abnormal state of mind must be of such a degree that it;

- poses a serious danger to the health or safety of the person or others; or
  - seriously diminishes the capacity of the person to take care of himself or herself.
- Responsibility for the treatment of a compulsory patient/client under the Act is vested in the Responsible Clinician in terms of the Act. A patient's consent is not required for the first month of treatment under a Compulsory Treatment Order. However, consent should always be sought for compulsory treatment even though it may be authorised under the Act. A patient may withdraw consent at any time and treatment thereafter is done without the patient's consent.
    - Following the first month of treatment no patient is required to accept treatment unless he or she consents or the treatment is considered to be in his or her best interests by two psychiatrists (one of whom is approved by the Mental Health Review Tribunal). The exception to the need to obtain consent is where treatment is immediately necessary to save the patients life; or
    - to prevent serious damage to the health of the patient; or
    - to prevent the patient from causing serious injury to himself or others.  
(Mental Health Compulsory Assessment and Treatment Act, Part V (62)).
  - Although the patient/client is subject to a compulsory treatment process under the Act, he/she and/or their representative should continue to be fully informed at all stages.

## 10.2 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. Although consciousness may be sometimes impaired, there is often an improvement in concentration and thinking ability with the relief of such symptoms as pain, anxiety, and depression. Unrelieved pain, anxiety or depression may impair competence in itself.
- Where practicable, discussion about treatment should take place before the administration of the medication liable to affect consciousness. The treatment of moderate or severe acute pain should not be delayed because informed consent has not yet been obtained.
- When a patient/client's competence has clearly been impaired by medication, and the procedure is not urgent, recovery should be allowed before consent to further treatment.

## 10.4 Further Information and Flow Chart

Diminished Competence to Consent in the Non-Life Threatening Situation

### **Background**

In medicine and law respect for individual autonomy is generally regarded as the first ethical principle. Competence can be defined as the ability to make an autonomous informed decision that is consistent with the person's lifestyle and attitudes and to take the necessary action to put this decision into effect.

All persons are presumed under the New Zealand Bill of Rights Act 1990, Right 7 (2) to be competent to give informed consent, unless there are reasonable grounds for believing that this is not the case.

Right 7 (3) of the code states a patient with diminished competence retains the right to give informed consent appropriate to that patient's level of competence. If the patient is both legally (not under PPPR Act - see later) and clinically competent, the usual guidelines for informed consent apply.

### **Previous Competence Decisions and Enduring Power of Attorney for Property and/or Welfare**

Competence may already have been previously decided under the Protection of Personal and Property Rights Act (PPPR) 1988 where property and welfare choices may have been given to another person (an enduring power of attorney (EPOA) or court appointed welfare guardian). The PPPR Act still requires that the patient should be involved in making decisions where possible.

An EPOA becomes effective when a person is "mentally incapable" in relation to personal care and welfare. Even if an EPOA exists, clinicians still needs to assess the competence for themselves before relying on an EPOA consent in relation to any significant personal care or welfare matter e.g. a rest home placement or major medical procedure. Note that an EPOA for property does not give rights over welfare. Clinicians should sight and copy the Enduring Power of Attorney form and ensure it does relate to welfare and file it in the patient record.

Although an EPOA for welfare or welfare guardian can make decisions in relation to consent of treatment, an EPOA cannot refuse consent to any standard treatment or procedure intended to save the person's life or prevent

serious damage. They also cannot consent to clinical trials, or electroconvulsive therapy (ECT).

The medical opinion is relevant as impairment is usually caused by inebriation, medication, and medical conditions such as head injury, dementia or severe psychiatric disorders. In some cases of disability it is an acquired state, which may be brief or prolonged or it can be a permanent state where individuals with permanent conditions may lack the capacity to fully give or withhold consent. If any doubt exists seek advice if competence is questioned.

By finding a patient incompetent, the patient's very important right to autonomy is removed. It is therefore incumbent on the practitioner to justify such an action.

### **Deciding the Degree of Competence Required**

Competence is a relative concept, and people can be more or less competent in different areas of their lives - for example someone with moderate dementia may be able to decide what to have for breakfast but may not be able to manage their investments. The test for competence must vary according to the potential consequences of the decision as shown in the table below.

If a procedure has a low risk and a high benefit i.e. favourable odds, then for a patient to consent to the treatment we only need a low test of competence because we are acting in the patient's best interests and as long as the patient has some basic understanding then we would be happy to proceed. However for the same procedure we would expect the patient to have a high test of competence if they were refusing consent i.e. we need a rigorous test of competence so that we can be satisfied that the person has good insight and can justify their refusal of a very favourable treatment.



<b>Patient's decision</b>	<b>Low Risk / high benefits Treatment 'favourable'</b>	<b>High risks and low benefits 'unfavourable'</b>
<b>To Consent</b>	<b>Low test of competence</b>	<b>High test of competence</b>
<b>To Refuse</b>	<b>High test of competence</b>	<b>Low test of competence</b>

Kennedy I et al<sup>1</sup>

### **Patient explanations**

When explaining a procedure, communication needs to be in a form and language that can be understood by that person. The onus is on the health professional (HP) to take reasonable steps to ensure the person understands the information given. The HP must allow time for digestion of information and the opportunity to ask questions. There needs to be privacy and an environment that is conducive to effective discussions.

### **How to assess Competence (see attached form)**

When assessing competence a clinician must ask the following eight questions:

**1. *Why does the issue of competence arise at this stage?***

One must presume the patient was competent at some stage and one needs to know what has changed to cause concern and medically to explain the impairment

**2. *Does the patient know what their current circumstances are i.e. the history of the presenting complaint?***

Does the patient know what others are concerned about and why the treatment is being considered?

**3. *Does the patient know what his or her realistic options are i.e. what treatment choices are available to them?***

**Does the patient understand the medical procedure and the risks and benefits of doing / not doing the procedure?**

4. Does the patient know the consequences of each of the available choices?

5. What is the patient's reason for making a particular choice?

6. Is the patient consistent in their decision or can change their mind frequently and easily?

**Is there a consistent approach rather than chopping and changing of ideas?**

7. Is there any particular pressure on the patient to make one choice?

**Ensuring that there isn't an overenthusiastic doctor or family member. Need to give people time to think about decisions**

8. Is the patient able to take the appropriate action to execute the choice he or she has named?

PLAY SOCCUR EXCELLENTLY

**Mnemonic<sup>2</sup> to remember these 8 points is 'play soccur excellently'**

Play	<b>Presenting situation, getting the patient to write that down</b>
<u>S</u> ituation	<b>Does the patient know what the situation is, e.g. the facts of the procedure?</b>
<u>O</u> ptions	<b>What are realistic options available to that patient?</b>

<u>C</u> onsequence	Of each of these options
<u>C</u> onsistency	Looking for a consistency of response rather than chopping and changing of ideas
<u>U</u> ndue Influence	Ensuring that there isn't an overenthusiastic doctor or family member and giving people time to think about decisions
<u>R</u> eason	For the decision
<u>E</u> xcellently	Executive function

### ***When a patient lacks capacity to give or withhold consent***

Under Right 7(4), if someone lacks competence to consent, a proposed treatment that is in the best interests of the patient can still be provided even if no person (such as an EPOA for welfare) can consent on the patient's behalf, as long as

- reasonable steps have been taken to ascertain the patient's views for
  - example expressed in an advance directive
- or after discussion with family or other interested parties.

The clinician must believe on reasonable grounds that the treatment is consistent with the informed choice the patient would make if competent.

**In the absence of any of the above avenues then the clinician should consult with a clinical head of department / director of surgery / or professional advisor - Chief Medical Officer / Director of Nursing / Director of Allied Health. A two doctor signed consent form is not valid.**

### **Documentation**

All discussions should be well documented so it is clear that the process has been followed and attempts to gain this information have occurred.

Documentation should include

- day/time of discussions
- people discussed with
- outcome of discussion
- medications and plan
- statement on risks and benefits of proposed treatment i.e. favourable / unfavourable odds.

The SOCCUR form attached should be filed in patient record with name / designation of those asking questions and dated.

### **Emergency Situations**

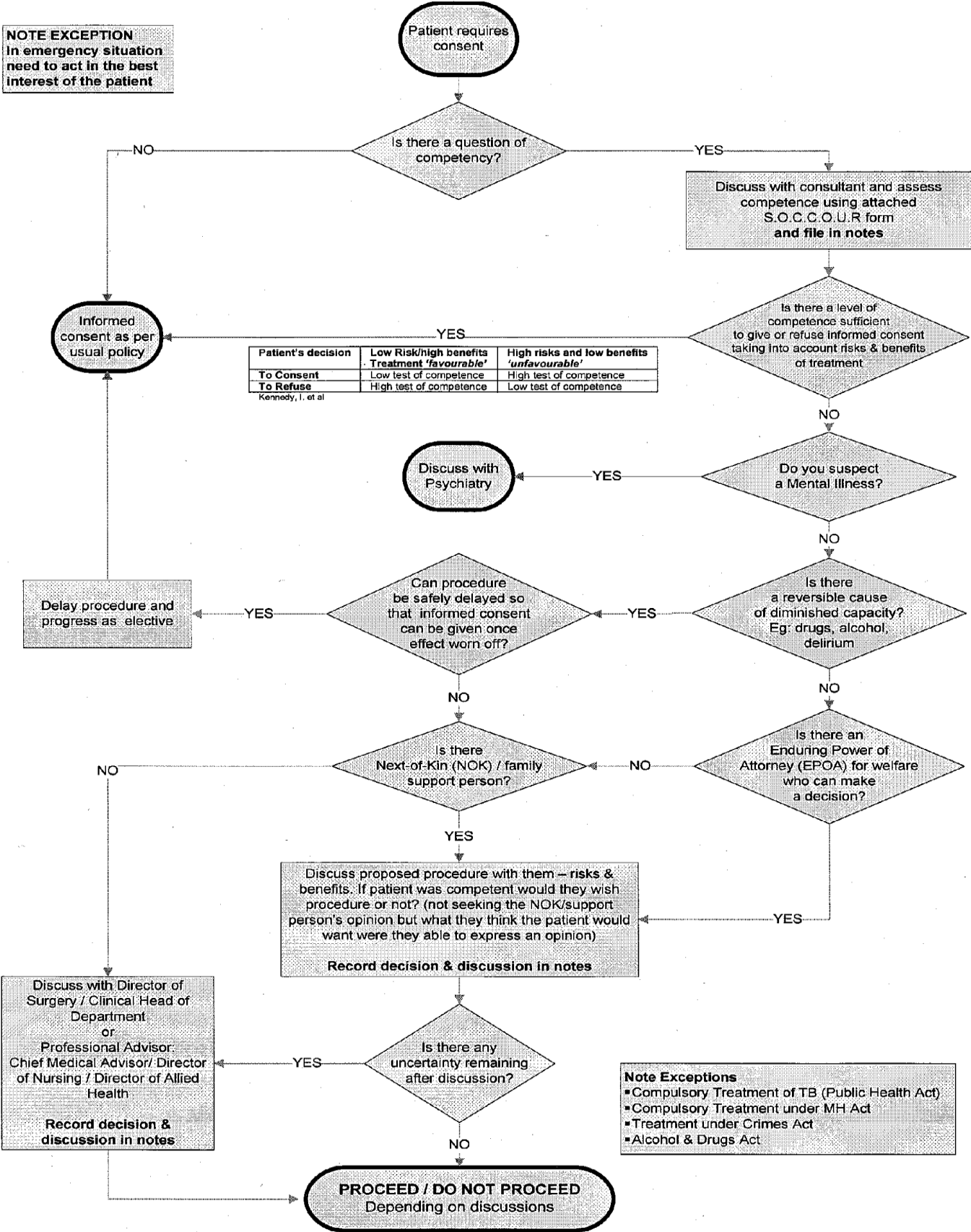
Treatment can be provided in the absence of consent in an emergency situation if such treatment is necessary to preserve life, health and well-being and is in the best interests of the person. However –

- treatment will not be justified if it is contrary to the known wishes of a competent person
- the treatment must not be inconsistent with a valid Advance Directive given by a person
- the treatment must be, and be no more than, what a reasonable person would expect to receive in the circumstances

### **References:**

- 1: Kennedy, I, Grubb A. Medical Law. London: Butterworths, 1989: 196
- 2: Young, Greg, “How to assess a patient’s competence”, New Ethicals Journal, February 2004: 41-45
- 3: The HDC Code of Health and Disability Services Consumers' Rights Regulation 1996

ASSESSING COMPETENCY for INFORMED CONSENT for NON-EMERGENCY SITUATIONS



**'SOCCUR' Assessment of Mental Competence for treatment or procedure consent**

Attach Patient Sticky Label here

Date of interview: \_\_\_/\_\_\_/\_\_\_\_\_

Carried out by: \_\_\_\_\_

**1. Why does the issue of competence arise at this stage?**

Comment:

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**2. Does the patient know what their current circumstances are? i.e. their presenting complaint?**

Yes       No

Comment:

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**3. Does the patient know what his or her realistic options are i.e. what treatment choices are available to them?**

Yes       No

Comment:

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**4. Does the patient know the consequences of each of the available choices?**

Yes       No

Comment:

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**5. What is the patient's reason for making a particular choice?**

Comment:

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**6. Is the patient consistent in their decision or can change their mind frequently and easily?**

Yes       No

Comment:

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**7. Is there any particular pressure on the patient to make one choice?**

Yes       No

Comment:

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**8. Is the patient able to take the appropriate action to execute the choice he or she has named?**

Yes       No

Comment:

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**9. Please circle the risk benefit of the proposed treatment**

<b>Patient's decision</b>	<b>Low risk / high benefits Treatment 'favourable'</b>	<b>High risks and low benefits 'unfavourable'</b>
<b>To Consent</b>	<b>Low test of competence</b>	<b>High test of competence</b>
<b>To Refuse</b>	<b>High test of competence</b>	<b>Low test of competence</b>

Kennedy I et al<sup>1</sup>

**10. Does the patient meet the criteria on level of competence required?**

Yes       No

Comment:

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### 11.0 CRITERIA FOR INDIVIDUALISED CONSENT FORMS

These must be approved for use by the Clinical Board. The following information must be included:

- Date
- Wairarapa DHB Letterhead
- Name and status of person/professional group carrying out the procedure
- The right to withdraw consent or refuse treatment at any time • A privacy statement which outlines:
  - who may receive this information, e.g. General Practitioner, Ministry of Health
  - what information is collected and what it is used for, e.g. statistic

Other information must also be given (but not on the consent form) as required in this policy (refer to the policy statement):

- The nature and purpose of the procedure/treatment
- Risks/side effects
- Relevant options
- Financial cost (if any) to the person concerned
- The consequences of not accepting the proposed treatment
- The time frame within which treatment will occur
- The right to refuse treatment or withdraw consent at anytime.
- Any other information requested by the patient/client.
- Discussion of alternate treatments

## **12.0 APPROVED CONSENT FORMS**

- General Consent Form
- Blood Consent Form
- Consent to Sterilisation Form
- Immunisation and Vaccine Consent Form(s)

## **GUIDELINES ON ENDURING POWER OF ATTORNEY [EPOA]**

### **Background:**

There are two types of EPOA as determined by the Protection of Personal and Property Rights Act 1988 and an amendment in 2007.

1. An EPOA in relation to personal care and welfare
2. An EPOA in relation to property
  - This power is effective only when a person is unable to handle their own affairs due to mental incapacity.
  - A patient's mental capacity needs to be determined at the time of any decision making.

### **Definition of “Mentally Incapable”**

Who decides an individual is no longer “mentally capable”?

This must be a medical professional whose scope of practice includes the assessment of mental capacity.

There is no prescribed method of assessing mental capacity for the purpose of enacting an existing EPOA for personal care and welfare. The practitioner must record the reasons in anticipation of the decision being challenged.

### **EPOA**

The need to enact an EPOA may result from an acute event e.g. major stroke, head injury, or from gradual change in a clinical condition e.g. dementia.

The assessment of mental capacity in a patient with a slow, degenerative process of dementia possibly complicated by variable delirium can be difficult. This assessment should be performed by a medical practitioner who is qualified to assess mental capacity and whose routine practice includes the assessment of mental capacity.

For the purposes of accessing funded services which depend on an enactment of an EPOA, and where time allows for instances of “informed consent” the DHB considers that assessment for mental capacity which relates to dementia ideally requires the opinion of a psychogeriatrician.

The recommendation to enact an EPOA should occur in consultation with two vocationally registered medical practitioners, one of whom should be involved in the care of the elderly. Ideally one practitioner would be a psychogeriatrician. It is understood this cannot always be achieved.

The level of understanding required will vary according to the particular service being proposed.

Ultimately, assessment of a particular child's competency to make an informed choice about a particular procedure or treatment will depend on the understanding, maturity, and interest of the child and the type and gravity of the proposed procedure or treatment.

A parent can only make an informed choice on a child's behalf if the child is not competent to do so themselves.

The Code provides that a child retains the right to make an informed choice and give informed consent to the level of his or her competence.

Under the Code parents do not have an automatic right to consent or refuse treatment for their child, but are entitled to do so if their child cannot.

Where a child is able to understand and make an informed choice and is interested enough to want to do so, that child can consent for themselves even without their parent's knowledge.

*Stated 1985 House of Lords [England]*

"Providing the child is capable of understanding what is proposed, and of expressing his or her own wishes I see no good reason for holding that he or she lacks the capacity to express them validly and effectively to make the examination and give the treatment that [the doctor] advises".

The rights of parents to control their child are for the child's benefit and are recognised only as long as they are needed for the protection of the child.

Parental rights dwindle proportionately with the child's maturity.

There may be occasions when the child's interest indicates that a parent's rights should be disregarded. The child should always be encouraged to discuss their care with their parents.

#### Charging for a service:

Under Contracts Law a person under 20 years of age is a minor. Even if the parent pays they are not entitled to health information about the child. The Code is subject to Common Law. The right to refuse medical treatment is not an absolute right and can be overridden in the child's best interest.

Parents patriae jurisdiction can override the wishes of a person under 18 years. Although children can agree to treatment this does not mean an absolute right of refusal of treatment. There must be "informed" refusal. The health professionals should seek directions from a Court under the "Guardianship Act 1968".

**Informed Refusal:**

If a child refuses and a competent parent refuses, but medically determined to be in the child's best interests –can apply to make the child a ward of the court. Should an individual able to as a Loco-Parentis cannot be found, a District Court Judge or Director General of Social Welfare can give consent.

Parents do not have the power to consent to the sterilisation of their intellectually disabled children and welfare guardians should obtain a specific order from the Court before consenting to sterilisation of an adult whom they act.

Reference: Health Care and the Law, ED Sue Johnson. 2<sup>nd</sup> Edition, Brookers Ltd 2000.

**10.0 KEY WORDS (maximum of 4)**

- **Informed consent**

**Link:**

<http://www.mcnz.org.nz/portals/0/publications/2011%20-%20Information%20and%20Consent.pdf>