Informed Consent

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1. Purpose of policy

The purpose of this policy is to ensure that legal obligations are met regarding informed consent and to clarify when informed consent applies to patients within Auckland District Health Board (Auckland DHB).

2. Policy statements

This document applies to all staff with direct patient contact, including technical staff, students (and their supervisors), and researchers undertaking training or research within Auckland DHB. It is the responsibility of all staff members to ensure that they work within this framework. Any variations outside this framework must be justified by the law.

3. Definitions

The following terms are used within this document:

Term	Definition
Clinical teaching	Where teaching (including assessment, or discussion or observation) occurs that is additional to normal clinical requirements, or involves someone not qualified to undertake the procedure on their own.
Code and Rights	The Code of Health and Disability Services Consumers' Rights, which are summarised as ten Rights.
Informed consent	The process that provides a patient with sufficient information to make an informed decision about accepting a service or treatment.
Observer	Someone, including students, additional to the normal medical and nursing team immediately involved in the procedure and, staff members directly concerned with the ongoing care.
Patient	The term 'consumer' is used in the Code, however Services in Auckland DHB usually refer to patients, clients or service users according to the type of service. For consistency, the term 'patient' has been used in this document.
Services/treatment	*"Health services, or disability services, or both; and includes health care procedures".* Clause 4 of the Code.

4. General informed consent information

This section of the document provides a framework for obtaining informed consent.

Where difficult situations arise you should seek advice from the Clinical Director/Professional Adviser or Auckland DHB Legal Services.

4.1 What is informed consent?

Informed consent assumes three key elements:

- Effective communication with the patient (Right 5)
- Provision of all necessary information to the patient (Right 6) and
- The patient's freely given and competent consent (Right 7)

Informed consent process applies to the provision of all health services.
Informed consent is not filling out forms, but rather the exchange of information. The patient must be able to make an informed decision about healthcare options, including the option of refusing the service.

4.2 Why is informed consent necessary?

Concerns about failure to obtain consent led to the enactment of the Health and Disability Commissioner Act 1994 (see Legislation) and the issuing of the Code. Right 7 states:

"Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or common law, or any other provision of the Code provides otherwise".

Right 7(4) sets out an alternative process that allows the provision of services, where a patient is not competent to make an informed choice and give informed consent.

There are a number of statutory exceptions to the requirement to consent. For example, s73 of the Land Transport Act 1998 (see Legislation) allows a medical practitioner to take a blood specimen without consent, where she has reasonable grounds to suspect that the person is in the hospital as a result of, or subsequent to, an accident or incident involving a motor vehicle, subject to the conditions set out in that Act.

4.3 When is consent required?

Informed consent must be obtained where a patient is competent for each treatment or procedure proposed (e.g. anaesthesia and surgery are separate procedures). There are, however, situations when a group of procedures or treatments are closely linked and consent for each individual treatment or procedure would be inappropriate (see composite procedures).

Where a series of similar treatments are to be undertaken (e.g. dialysis, counselling), provided that a full explanation/discussion is held prior to, or at commencement of care provision then on subsequent visits/appointments, agreement to proceed need only be confirmed and any new questions/issues covered. If the plan previously agreed changes significantly, a new consent process must be undertaken (including new written consent if applicable).

4.4 Provision of care pursuant to Right 7(4)

Where a patient is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the patient is available, Auckland DHB may provide services where:

- It is in the best interests of the patient; and

- Reasonable steps have been taken to ascertain the views of the patient; and either:
    - If the patient's views have been ascertained, and having regard to those views, you believe, on reasonable grounds, that the provision of the services is consistent with the informed choice the patient would make if he or she were competent; or
    - If the patient's views have not been ascertained, you take into account the views of other suitable persons who are interested in the welfare of the patient and are available to inform you

While an assessment of a patient's best interests will be based on objective clinical information, the actual test is subjective. The UK Supreme Court stated "*insofar as it is possible to ascertain the patient's wishes and feelings, his beliefs and values or the things which were important to him, it is those which should be taken into account because they are a component in making the choice which is right for him as an individual human being*". Aintree University Hospitals NHS Foundation Trust (Respondent) v James (Appellant) paragraph 45. [1]

4.5 Documentation of consent

Right 7 states:

1. Every consumer may use an advance directive in accordance with the common law.
2. Where informed consent to a health care procedure is required, it must be in writing if:
    - The consumer is to participate in any research; or
    - The procedure is experimental; or
    - The consumer will be under general anaesthetic; or
    - There is a significant risk of adverse effects on the consumer.
3. Every consumer has the right to refuse services and to withdraw consent to services.
4. Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.
5. Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.

Consent must also be given in writing by the patient if:

- Body parts or tissue are to be removed other than for standard laboratory tests (information provided must cover removal, retention, return or disposal); or
- Blood or blood products are to be used; or
- A student is to perform an examination; or
- When either party requests it.

Signed consent forms are prima facie evidence that a patient was duly informed and has consented to the services described.

Explicit verbal consent is required in all other circumstances and should be documented in the patient's clinical record.

[1] *Aintree University Hospitals NHS Foundation Trust v James* [2013] UKSC 67 at [45].

For routine minor interventions e.g. taking of blood pressure or observations, while the patient must be informed of what is happening consent is implied in the absence of refusal. Consent may also be implied where the patient agrees to a package of care e.g. agreement to be admitted to hospital and monitored.

Consent for secondary purposes e.g. blood testing in case of needle stick injury, must be documented.

Whenever there is an issue or there are concerns regarding consent, or if the patient does not consent, relevant information must be clearly documented in the clinical record. Documentation of the consent discussion and decision is to be made in the clinical record including as appropriate:

- Notes of information provided (including written material)
- Specific issues of concern and/or wishes of the patient
- Important questions asked by the patient and answers given
- Who was present?
- Who gave consent?

Where a surgical procedure involves laterality the words 'left' and 'right' are used rather than abbreviations 'L' and 'R'.

4.6 Vicarious consent - children and incompetent adults

In situations in which a patient is not competent to give consent, but another person may lawfully do so that situation must be recorded, including who gave consent and their relationship to the patient.

The Care of Children Act 2004 s35 (see Legislation) provides options for consent for provision of services to children under 18:
First, the consent, or refusal to consent, to any of the following, if given by a child of or over the age of 16 years, has effect as if the child were of full age:

a) Any donation of blood by the child,
b) Any medical, surgical, or dental treatment or procedure (including a blood transfusion, which, in this section, has the meaning given to it by section 37(1) to be carried out on the child for the child's benefit by a person professionally qualified to carry it out.

Second, if the consent of any other person to any medical, surgical, or dental treatment or procedure (including a blood transfusion) to be carried out on a child is necessary or sufficient, consent may be given:

a) By a guardian of the child; or
b) If there is no guardian in New Zealand or no guardian of that kind can be found with reasonable diligence or is capable of giving consent, by a person in New Zealand who has been acting in the place of a parent; or
c) If a child has been lawfully placed for the purpose of adoption in the home of any person, then, for the purposes of subsection (3), that person must be treated as a guardian of the child.

Under the Protection of Personal & Property Rights Act 1988 (see Legislation) a competent individual may appoint an Enduring Power of Attorney for welfare (EPOA) to consent once the patient loses capacity. Before an EPOA may have lawful effect a certificate of the donor's (patient's) temporary or permanent mental incapacity must be completed by a health practitioner in the form prescribed in the Act.

If an EPOA has been formally activated then the attorney may consent to any service and must consent to the administering to that patient of any standard medical treatment or procedure intended to save that patient's life or to prevent serious damage to that patient's health. An EPOA may not consent to Electro Convulsive Therapy (ECT), brain surgery designed to change the patient's behaviour, and participation by the patient in any medical experiment other than for the purpose of saving the patient's life or of preventing serious damage to the patient's health.

The Family Court may also make an order appointing a welfare guardian, who may then provide consent.

4.7 What and how much information

Right 6 states that in informing a patient you provide the information a reasonable patient, in that patient's circumstances, would expect to receive" in order to make an informed choice or give informed consent. This includes:

- An explanation of their condition; and
- An explanation of the options available, including an assessment of the expected risks (including likely consequences if the treatment is not provided) and side effects, benefits, and costs of each option (options include alternative treatments and/or a second opinion); and
- Advice of the estimated time within which the services will be provided; and
- Who will be providing those services; and
- Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; 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 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 the information provided. The higher the probability of risk or the greater the magnitude of harm, the more care and detail in giving information is required. There is no fixed threshold (e.g. occurs in >1% of cases) for defining what must be discussed. For example, a 1 in 1000 chance of death should be discussed but not necessarily a 1 in 50 chance of minor discomfort.

The patient must be informed of rare risks that are more likely because of their particular circumstances, or which would have greater significance for that particular patient, e.g. risk of bleeding in someone taking anticoagulants or the consequences of arm nerve damage for a carpenter.

Enabling informed consent involves some level of checking that the patient has understood what they have been told. No consent should be requested until the health professional is satisfied that the patient has demonstrated an adequate understanding of what is proposed.
It is accepted that the patient may refuse information or will not want detailed information about complications. The clinician still has an obligation to ensure the patient has had core information on the procedure and its implications.

4.8 Primary responsibility for information and consent, and delegation

The primary responsibility for ensuring information is imparted and for obtaining consent lies with the person who is to carry out the treatment or procedure.

In some situations it is impracticable for all information to come from the health professional conducting the treatment or procedure. In such cases an appropriate health professional familiar with the treatment or procedure and with adequate knowledge of the risks and benefits of the treatment or procedure should impart the information.

Where it is impracticable for consent to be obtained by the health professional conducting the procedure, an appropriate health professional may be delegated this responsibility.
The health professional doing the procedure must ensure that this is only delegated to another health professional who is familiar with the issues noted above and who also fully understands the associated risks and benefits for that particular patient.

Regardless of who is taking consent, the name of the health professional performing the procedure must be documented on the consent form. If this is unknown at the time of taking consent, then the patient, or person giving consent, must be advised verbally prior to the procedure and this must be documented. Where the procedure will be performed by a trainee then the name of the trainee and the supervisor should be documented.

4.9 How should information be given?

Clinicians should try to reduce in all possible ways, any feelings of excessive dependency, vulnerability or discomfort the patient may have about asking questions or suggesting alternative points of view.
There should be privacy for discussions of diagnosis and treatment options. Where practical, for example in outpatient clinics, the patient must be encouraged to dress in their own clothes and be comfortably seated before discussion of diagnosis or treatment options is held.

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

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The patient 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 health advocate may attend at the request of the patient.

Any available written or audio-visual material should be included where it could be helpful in providing the information needed and supporting the discussion. The patient should also be referred to any other relevant and reliable resources e.g. websites.

Sufficient time should be allowed for the patient to read the written information, and discuss this and any verbal information with whomever they wish.

The patient should be advised of how any further questions can be addressed and who to contact.

4.10 Team approach to providing 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. Each team member must document the information/discussion covered so that their colleagues may be assured that sufficient information to enable informed consent has been given.

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

4.11 Team approach to obtaining consent

Where the situation arises where obtaining consent is delegated, the patient must be told the reason why the person carrying out the treatment or procedure could not personally obtain consent. The person carrying out the procedure must assure himself that consent has been obtained before commencing the procedure.

Any clinician delegated the task of obtaining informed consent who does not have the knowledge of the procedure/treatment and risks and benefits has a responsibility to inform their consultant/supervisor so that alternative arrangements to get consent can be made.

4.12 Right to refuse

Under section 11 of the New Zealand Bill of Rights Act 1990 (see Legislation) and Right 7 (7) of the Code, every competent person has the right to refuse or withdraw consent to services.
It must be made clear to the patient that he/she has the right to refuse or withdraw from treatment without fear of recrimination or penalty.

4.13 How long is consent valid?

Verbal consent should be reaffirmed immediately prior to a procedure or intervention.

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Where written consent has been obtained in advance of a procedure the consent may need to be revisited dependent on:

- The period since consent was given - months earlier rather than days
- The nature of the procedure
- Likelihood of change in health status between consent and procedure
- Progression of condition
- Change in competence
- Significant change in the patient's personal circumstances
- A change to the clinician who will be undertaking the procedure.

Services may set a period consent is considered valid. The above factors need to be considered in establishing such a timeframe, which should also be reconsidered on an individual patient basis. Services should continue to engage with a patient awaiting a service to ensure that any changes in circumstances, clinical and personal, may be discussed and addressed.

4.14 Advance directive

Every patient may use an advance directive to consent to, or refuse, a healthcare procedure.
An advance directive is a 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. While an advance directive may be verbal or written, a patient making an advance directive should always be asked to document that directive. If that is not possible it must be documented in the patient's clinical record and where practicable signed by the patient.
Issues to consider when contemplating effecting an advance directive are:

- Whether the advance directive is likely to have become out of date
- Whether the patient is likely to have changed their mind
- Did the patient intend the directive to apply to the present circumstances?

4.15 Effective communication - special requirements

Clinicians must exercise special care when the patient may have difficulties in understanding what is proposed or in making their own views known. Patients who may have such difficulties include:

- Those from a different cultural background: Cultural differences in decision-making must be respected. This process may require involvement of family members in the information giving and decision making.
- Those not proficient in English: The patient must have an adequate understanding of what is proposed in order to give informed consent. The involvement of a recognised interpreter may be necessary, particularly for situations involving written consent.
- Those disabled by confusion, an altered state of consciousness, mental incompetence, speech or understanding difficulties or hearing problems: Information may need to be presented in a facilitated way or by alternative means e.g. non-verbally. Clinicians should seek and take into account the views and advice of families and/or paid caregivers who are familiar with the patient's means of expression and communication.

Some patients will require a formal assessment of their communication (receptive or expressive) so that the clinician gaining consent can be confident the patient understands the information or

expresses their requests adequately. Any such assessment by e.g. Speech Language Therapist, Occupational Therapist is to be clearly documented.

5. Children and young persons

The Code applies to children as it does to adults. The general provisions outlined in this policy apply to children and young people.

In addition to imparting information in order for parents/guardians to make a decision on a child's behalf, information must, where practicable, be given to the child in a way that the child can understand and, where possible, the child's agreement must also be sought. Of course this will vary with the age of the child, but the general principle is to involve the child as much as possible.

The Care of Children Act 2004 s36 (see Legislation) provides options for consent for provision of services to children under 18:
First, the consent, or refusal to consent, to any of the following, if given by a child of or over the age of 16 years, has effect as if the child were of full age:

a) Any donation of blood by the child:
b) Any medical, surgical, or dental treatment or procedure (including a blood transfusion, which, in this section, has the meaning given to it by section 37(1)) to be carried out on the child for the child's benefit by a person professionally qualified to carry it out.

Second, if the consent of any other person to any medical, surgical, or dental treatment or procedure (including a blood transfusion) to be carried out on a child is necessary or sufficient, consent may be given:

a) By a guardian of the child; or
b) If there is no guardian in New Zealand or no guardian of that kind can be found with reasonable diligence or is capable of giving consent, by a person in New Zealand who has been acting in the place of a parent; or
c) If a child has been lawfully placed for the purpose of adoption in the home of any person, then, for the purposes of subsection (3), that person must be treated as a guardian of the child.

6. Teaching and observers

This section applies to:

- Students in training;
- Staff members in recognised training programmes
- Registered and employed clinicians undertaking on the job training and further education
- All teaching staff.

All healthcare settings should be learning environments where clinical teaching and learning occur as part of day to day practice. Additionally, as a teaching institution, formal teaching occurs. This includes further education for registered and employed clinicians and training for unqualified students.

Some teaching occurs within the clinical team as part of the optimal provision of care for that patient e.g. case discussion or assistance with a procedure. Teaching is simply a secondary element of sound care provision. While the basic provisions of common courtesy and respect apply, specific patient consent is not required.

A patient has the right to be treated with respect and must consent to or decline involvement in teaching, including the presence of observers during treatment or examination. The patient must be provided with sufficient information to give or withhold consent. This includes being informed of the identity and qualifications of the provider.

6.1 Principles for clinical teaching

Where teaching (including assessment, or discussion or observation) occurs that is additional to normal clinical requirements for that patient in that patient's circumstances, or involves someone not qualified to undertake the procedure on their own, an explanation is to be given to the patient and their explicit permission sought.

A patient who is not competent to give consent should not generally be involved in teaching without vicarious consent.

Common courtesy applies. This means there must be an appropriate introduction of the staff member/student and identification of their role. An explanation of what is occurring and why must be given as part of the usual interaction with the patient. It is appropriate to explain the staff member's intention prior to discussing the patient in the third person with team members/students.

Where practicable the request to the patient must be made without the trainee staff member/student present so the patient is able to freely decide whether or not to be involved in the teaching situation. However where the trainee/student attends on their own they must obtain the patient's agreement.

Every patient has the right to withdraw from the teaching session at any stage and must receive a clear prior assurance that refusal to participate in teaching or withdrawing from teaching will not jeopardise their care in any way.
The patient has the right to have a support person present including during intimate examinations such as rectal or vaginal examinations.

Verbal discussion about involvement in teaching should be recorded in the clinical record for reference.

6.2 Consent for involvement of students

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

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

It is generally not necessary for students to get written consent for their participation in specific interventions however, students must get written consent to perform all sensitive examinations. The patient has the right to know the name and professional status of any person who wishes to interview them for teaching purposes and/or examine them, or to carry out specific treatment or investigation procedures. Students must introduce themselves to the patient and must, on each occasion, explain clearly their role (e.g. observing, assisting under supervision).

Teachers must obtain a patient's permission to involve them in group teaching or clinical demonstration sessions and explain exactly what will be involved and how many students will be present.

Physical examination or specific procedures undertaken by students must not be repeated unreasonably on any one patient, or to the patient's detriment and must not produce or prolong unreasonably any distress, embarrassment or pain. Students must comply with any other policy requirements including the presence of a chaperone where indicated.

In operating rooms, supervising consultants and registrars must inform the patient that a medical student is assisting or observing as part of the anaesthetic or surgical team, but that any practical task undertaken by that student is directly and closely supervised. Verbal consent must be obtained. The consent and student role must be documented by the clinician responsible. The consent must be obtained before pre-medication is given.

Where prior consent could not be obtained e.g. opportunity to observe an unusual or unexpected finding, with clear teaching purpose; the patient or their representative must be notified as soon as practicable.

Students are entitled to question or challenge their supervisor if they believe these provisions are not being met appropriately.

6.3 Observers not involved in clinical care

On occasion an observer may be present who is not directly involved in the patient's immediate clinical care team e.g. company representative on introduction of new equipment or visiting clinician.

The clinician responsible for the patient must explain the observer's role and seek the patient's permission for the observer to be present. The consent must be documented in the clinical record. The Observer must confirm that they aware of their obligations under the Health Information Privacy Code, including not disclosing any personal health information.

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7. Research

The Code extends to when consumer patient is participating in, or it is proposed that a patient participate in research.

Any research involving a patient must have prior ethics committee, research office and management approval to ensure that appropriate mechanisms are in place for identifying the patient and gaining informed consent. All research involving human participants must comply with ICH-Good Clinical Practice.

A parent or guardian may consent to participation of a child in research.
Every patient has the right to withdraw from the research at any stage and should receive prior assurance that refusal to participate in research or withdrawing will not jeopardise their care in any way.

8. Composite procedures

The patient must 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.

8.1 Interdependent treatments

Interdependent treatments are when 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, to be followed by a period of mechanical ventilation.

In such cases, all the component procedures must be outlined to the patient as part of the explanation of the treatment for which they are being asked to consent to.

8.2 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 case, it may not be possible to gain the patient's informed consent or that of their representative for the specific treatment because of the complexity or urgency of the situation.

8.3 Potential pathology confirmed during surgery

Consent can be given by the patient for appropriate further action in the event of potential pathology being confirmed during the procedure for which they have given consent. 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 must 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 must not be sought.

8.4 Limitations on composite procedures consent

Consent to composite procedures must never be used to imply prior consent to treatment or procedures that 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.

Informed consent from the patient or their representative must always be sought for the use of extreme measures or unconventional treatment.

8.5 Unforeseen pathology during surgery

In the event of unforeseen pathology being discovered during the procedure for which the patient consented, the surgeon should not perform a definitive procedure for that pathology during that procedure. The diagnosis should be considered separately and separate consent to treatment gained from the patient, except where this approach significantly increases procedural risk to the patient.

9. Blood and blood products

9.1 Prescribing

Blood and blood products are registered medicines in New Zealand. They must be prescribed by a registered medical practitioner, or where appropriate a registered midwife, and this must be recorded in the patient's clinical record.

9.2 Information

The patient brochures on blood and blood products prepared by the New Zealand Blood Service should be widely available, particularly in areas where blood and blood products are regularly given. All patients must receive the relevant brochure on the blood product or blood component prior to giving informed consent. This must be documented in the patient's clinical record.
As with any other prescribed drug, the patient must receive adequate information on the reasons for the transfusion, the risks, the benefits and the adverse sequelae that may result if the transfusion is not received.

9.3 Consent

Written consent should be obtained for the use of blood and blood products. 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.

In circumstances where the patient cannot give informed consent e.g. under anaesthesia, blood products may be given if required unless there is knowledge that the patient would not agree. Section 37 of the Care of Children Act 2004 (see Legislation) permits the administration by a health practitioner of a blood transfusion to a patient under 18 without consent where in the circumstances it was reasonable to administer the transfusion and:

a) The transfusion was, in the reasonable opinion of the health practitioner who administered it, necessary to save the life of the patient or to prevent permanent injury to the patient's physical or mental health, or to save the patient from prolonged and avoidable pain and suffering; and
b) Reasonable attempts were made to obtain consent or the circumstances were such that it was necessary to administer the transfusion promptly and it was impracticable, in the time available, to attempt to obtain consent.

Legal Services may be contacted when use of s37 is contemplated.

9.4 Refusal of blood products

A patient's decision to refuse blood or blood products must be clearly documented in the patient's clinical record. This documentation should include details of the advice given to the patient, including discussion of alternative courses of action e.g. not performing surgery and their implications.

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 parents refuse to consent to blood products for their child, there may be a legal basis to challenge that position. When situations such as this occur, advice must be sought from Legal Services.

In both situations it is recommended discussions be held with the Service Clinical Director/Medical Director of the unit/hospital, exercising the 'one up' authority principle.

10. Diminished capacity and competence to consent

10.1 Capacity and medication

While the principles in this section apply to all patients, specific provisions for children and young people are covered in the Legal Issues Relating to Children Board policy (see Associated document).

Deciding whether someone is legally competent to make decisions regarding their own treatment requires an assessment of their mental capacity.

Right 7 (2) of the Code provides that everyone must be presumed competent to give informed consent, unless there are reasonable grounds for believing that the person is not competent.

Medication, intellectual disability, mental illness, inebriation, or physical injuries all may affect the informed consent process.

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 other cases it is an acquired state which may be brief or prolonged.

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, unrelieved pain, anxiety or depression may impair competence.

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

In principle, consent must not be sought when a patient is drowsy or unable to concentrate, but in practice consent for further treatment will sometimes be necessary for a patient, who has, for instance, received medication for pain relief. In no circumstances must written consent be obtained once sedation or pre anaesthetic medication has been administered.

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

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

10.2 Determining competence

Deciding that a patient is not competent to make an informed choice is a significant step and requires careful consideration and consultation (see Diminished capacity and competence to consent and associated documents for Caring for patients with diminished competence).

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. Relevant factors to determining competence are the patient's ability to:

- Understand and retain relevant information
- Believe it
- Understand the nature and consequences of options
- Weigh the information, balance the risks and arrive at a choice

- To communicate a choice.

See Caring for patients with diminished competence guideline.
Note: an imprudent decision is not the same as an incompetent decision.

10.3 When a patient lacks capacity to give or withhold consent

Where a patient is not competent to give consent and no person entitled to consent of behalf of the patient is available, Auckland DHB may provide services where:

- It is in the best interests of the patient; and
- Reasonable steps have been taken to ascertain the views of the patient; and
- Either:
  - If the patient's views have been ascertained, and having regard to those views, you believe, on reasonable grounds, that the provision of the services is consistent with the informed choice the patient would make if he or she were competent; or
  - If the patient's views have not been ascertained, you take into account the views of other suitable persons who are interested in the welfare of the patient and available to inform you, such as their spouse, whanau, caregivers or supporters.

The senior clinician responsible is to make appropriate documentation of what steps were undertaken to establish capacity, to seek the patient's views and the clinical decision made. This must be recorded on the CR0114 Authority to treat without consent (see Clinical forms).

If an incompetent patient declines treatment despite discussion and involvement of significant others, and is considered a danger to themselves or others, an application to the Family Court for a treatment order under the Protection of Personal and Property Rights Act 1988 (see Legislation) might be considered. Legal Services must be advised.

10.4 Compulsory assessment and treatment - Mental Health

If the treatment is for a mental disorder an application under the Mental Health (Compulsory Assessment and Treatment) Act 1992 (see Legislation) may be considered. Mental Health services are responsible for all such applications.

11. Declining services and withdrawing consent

Should a competent adult patient decline an option of services for themselves or withdraw consent, that choice cannot be overruled and must be respected, with no change in the standard of care provided.

Appropriate risk assessment must be carried out and case review with senior colleagues or notifying referrer.

If there are concerns that the mental health of a patient in a general clinical area has an effect on their competence, the Liaison Psychiatry team must be asked to assess the patient.

Where there may be language difficulties, an official interpreter must be utilised as part of the process to assess competence.

11.1 Clinician responsibilities and documentation

The clinician's responsibilities are to:

- Clarify competence
- Document assessment of competence
- Provide the patient with a full explanation of, and information on the proposed treatment; risks and likely consequences if the treatment is not provided; and options including alternative treatments and/or a second opinion
- Document the patient's decision
- Involve family/support persons as appropriate
- Seek advice from Clinical Director/Professional Adviser/Legal Counsel where required.

The documentation in the patient's clinical record must include an assessment of the patient's competence to make an informed decision to refuse treatment; advice given to the patient and concerns of the clinician, including a full explanation of consequences, risks and options.

This is to be completed by the person with prime responsibility for care/or who has given the advice. The advice provided must be documented in detail.

If relevant, CR2683 Discharge at Own Risk (see Clinical forms) is also used in adult (non-mental health) inpatient services.

If an interpreter is used to assist with communicating with the patient, they must sign the clinical record detailing what was told to the patient.

If the patient's condition is serious and persists and resolution is not imminent, the patient must be asked to sign a formal statement in the clinical record.

This statement must state that the patient:

- Understands the concerns of their clinicians, and
- Understands the advice given (in particular the nature of the proposed treatment/intervention and the risks if those risks are not detailed)
- Has received all the information that they require, and
- Accepts responsibility for the consequences of their decision.

If the patient refuses to sign the statement, two staff members must sign confirming that they heard the information the patient was given.

11.2 Ongoing care

Where possible, an agreed plan must be developed while maintaining communication with the patient, and with their family/whānau as appropriate. Detailed entries must be made in the patient's clinical record as the situation progresses.

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A high standard of care should continue. In some circumstances a change of clinician may be indicated. Care must be handed over to the subsequent clinician and an explanation given to the patient.

The Duty Manager/Team Leader or other appropriate manager/senior colleague must be informed.

11.3 If a pregnant woman or fetus is at risk

Special consideration is to be made in the situation where a pregnant woman refuses treatment. If the life of the woman or the fetus, or both are at risk, because of the woman's refusal of treatment, the Board's Legal Counsel must be consulted.

11.4 Legal advice

In any situation where clinicians have ongoing concerns about a patient's refusal of treatment, the Board's Legal Counsel may be consulted.

12. Procedure specific consent forms

12.1 Auckland DHB policy on forms

Auckland DHB does not encourage the use of procedure specific consent forms.

It is recommended services use the generic CR0111 Agreement to Treatment (see Clinical forms) and include specific information in patient information leaflets and, document in the clinical record specific issues of concern discussed.

In limited and specific areas it may be more appropriate to have procedure specific consent forms; however this must be approved by the Director of Operations Information Management and the Legal Counsel. These situations could include e.g. courses of treatment such as chemotherapy and haemodialysis and where other specific legal requirements apply. (Section 29 form is to be used for unregistered medicine).

The critical part of the process is the information imparted to the patient and the documentation in the clinical record. Information sheets and service protocols can be developed to cover common complications and risks that are to be routinely covered with patients.

13. Supporting evidence

- Auckland District Health Board. 2002. Report of the Auckland District Health Board Body Parts, Tissues and Substances Review Panel. Auckland: Auckland District Health Board.
- *Aintree University Hospitals NHS Foundation Trust v James* [2013] UKSC 67 at [45].
- New Zealand Blood Service blood and blood products consent information. Available from: https://www.clinicaldata.nzblood.co.nz/resourcefolder/consent.php?dhbid=1

Patient information
All New Zealand Blood Service information brochures

14. Legislation

- Alcoholism and Drug Addiction Act 1996
- Care of Children Act 2004
- Children, Young Persons, and their Families Act 1989
- Contraception, Sterilisation and Abortion Act 1977
- Coroners Act 2006
- Crimes Act 1961
- Criminal Investigations (Bodily Samples) Act 1995
- Health Act 1956
- Health and Disability Commissioner Act 1994
- Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996
- Health Information Privacy Code 2020
- Human Tissue Act 2008
- Land Transport Act 1998
- Mental Health (Compulsory Assessment &Treatment) Act 1992
- New Zealand Bill of Rights Act 1990
- Privacy Act 2020
- Protection of Personal and Property Rights Act 1988

(All Acts of Parliament available from http://www.legislation.govt.nz)

15. Associated documents

- Blood Product Administration in Adults & Children
- Body Parts - Autopsy
- Body Parts / Tissue Storage, Cremation & Return
- Caring for patients with diminished competence
- Deceased (Tupapaku) +/- Referrals to the Coroner for an Adult, Child, Infant, Neonate or Stillbirth
- Discharge - Self Discharging Patients
- Holding a Child in Hospital Against Parent/Guardian's Wishes - Emergency Protocol
- Interpreters
- Legal Issues Relating to Children
- Media
- Medications - Prescribing
- Research - Principles
- Research - Risk Management
- Resuscitation of Adults

Clinical forms

- CR0025: Post Mortem Consent (Non Coroners)
- CR0111: Agreement to Treatment
- CR0114: Authority to Treat Without Consent
- CR2205: Consent to Disclosure/Use of Photographic or Recorded Information
- CR2683 Discharge at Own Risk

16. Disclaimer

No guideline can cover all variations required for specific circumstances. It is the responsibility of the health care practitioners using this Auckland DHB guideline to adapt it for safe use within their own institution, recognise the need for specialist help, and call for it without delay, when an individual patient falls outside of the boundaries of this guideline.

17. Corrections and amendments

The next scheduled review of this document is as per the document classification table (page 1). However, if the reader notices any errors or believes that the document should be reviewed ***before*** the scheduled date, they should contact the owner or Document Control without delay.