Peke Waihanga
Artificial Limb Service

Orthotic Service

Informed Consent Policy

Function: Clinical
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Business Activity: Privacy & informed consent
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1. Background

1.1. It is a fundamental legal and ethical principle that valid consent must be obtained before providing any health services to a person. This reflects the right of patients to determine what happens to their own bodies. The Code of Health and Disability Services Consumers' Rights ('Code of Rights') is a key source of the law on consent, supplemented by other legislation and case law. In particular, the right to make an informed choice and give informed consent is found in:

- Right 5: The right to effective communication.
- Right 6: The right to be provided with all necessary information, including information about options, risks, and benefits.
- Right 7: The right to make informed choices and give fully informed consent to the extent of the patient's competence.

1.2. The duty to obtain informed consent applies to the provision of all health and disability services, not just health care procedures or treatment. This extends to when a patient is participating in, or it is proposed that the patient participate in, teaching or research.

2. Purpose

The purpose of this Policy is to ensure that proper processes relating to informed consent, including the provision of sufficient information to enable a patient to make an informed choice, are followed so that:

- all services provided are lawful,
- the consent process is properly documented,
- written consent is obtained where required.

3. Scope

3.1. This Policy applies to all Peke Waihanga employees, independent contractors and volunteers who provide services to Peke Waihanga patients. All persons who provide services to patients must abide by the legal requirements relating to informed consent.

3.2. For the purposes of this Policy 'services' includes procedures, service, prescriptions, fitting of prostheses and orthoses, rehabilitation and all health and disability services carried out by Peke Waihanga including the volunteer Peer Support Service.

4. Definitions

Advance directive – a legal term that means a written or oral directive by which a patient makes a choice about a possible future health care procedure; that is intended to be effective only when he or she is not competent.

Capacity/Competent – terms are used interchangeably in this Policy and refer to a patient's ability to understand the nature, purpose, effect and likely consequences of the proposed service, or refusing service.

Child – defined in the Care of Children Act as a person under 18 years of age.

Enduring Power of Attorney ('EPOA') – the holder of an enduring power of attorney granted by the patient under Part 9 of the Protection of Personal and Property Rights Act for personal care and

welfare or property. Only an EPOA for personal care and welfare can consent to service, and only when the patient is not competent to consent to the service.

Guardian – under the Care of Children Act the father and the mother of a child are usually joint guardians of the child. In some circumstances the mother may be the sole guardian. Guardianship ends when the child reaches 18 years of age. A guardian of a child has rights and responsibilities in relation to consenting to medical services for the child until the child's 18th birthday or earlier if the child is competent to make the heath care decision.

Health professional/clinician – a healthcare professional qualified in a particular area of medicine or health. In Peke Waihanga a clinician includes occupational therapists, physiotherapists, GPs, nurses, medical specialists and podiatrists (roles which are all registered under the Health Practitioners Competence Assurance (HPCA) Act 2003 as well as prosthetists and orthotists (who are not registered under the act). Whether registered or not, all health professionals are required to meet standards of practice usually set by their relevant professional bodies and ensure services they provide are in accordance with the Code of Rights. Clinicians provide direct patient prosthetic, orthotic or rehabilitative care.

Informed consent – the process whereby the patient who has the capacity to consent to a given service, (or a person legally entitled to consent on behalf of the patient who dies not have capacity) having been given sufficient information, voluntarily arrives at a decision to agree to the proposed service/treatment.

Provider – includes health professionals and other staff providing services to a patient and/or the health or disability organisation as the context requires.

Service(s) – includes procedures, service, prescriptions, fitting of prosthesis, orthoses and all health and disability services carried out by Peke Waihanga including the volunteer Peer Support Service.

Welfare guardian – a person appointed under s12 of the Protection of Personal and Property Rights Act (PPPR Act) as a welfare guardian.

5. Key principles

5.1. Patients have the right to make an informed choice about their care and, in most instances, must give permission before health and disability services can be provided.

5.2. Informed consent is not a one-off event but is an interactive and ongoing process between the clinician, the patient and sometimes those close to the patient, such as their family or whānau. It is a process of sharing information where the clinician helps the patient understand their condition and the options for treating (or not treating) that condition.

5.3. Peke Waihanga does not expect patients to sign informed consent forms (except in special circumstances, see Section 12.6) but rather records in the patient's Manaaki clinical notes the process that has taken place to communicate treatment options to the patient and their informed consent.

5.4. It is the clinician's responsibility to ensure informed consent is obtained and to communicate and work with patients to help them make the best decision for themselves. It is a fundamental part of good practice by clinicians.

5.5. The patient has the right to refuse treatment and withdraw consent at any time.

5.6. All patients are presumed competent to give informed consent unless established otherwise (see Section 7.2).

5.7. Without informed consent, it may be unlawful to provide the proposed services. The only exceptions for not obtaining informed consent from patients relate primarily to emergency situations (see Section 15) and incompetent patients (see Section 7). There are other statutory

exceptions to the requirement to gain informed consent which in general do not apply to Peke Waihanga in the normal course of providing services and are therefore not covered in this Policy.

6. Key elements of informed consent

6.1. There are three key elements required for informed consent. All three elements must be present for consent to be legally valid and are discussed further below. These elements are:

(a) Capacity/competence: The person must have the necessary capacity to consent to the service, or to refuse the service in question; and

(b) Sufficient information: The person must be appropriately informed in order for them to make an informed choice about the proposed service; and

(c) Voluntariness: The person's consent must be given voluntarily and without pressure from any other person.

7. Capacity/competence

Presumption of competence

7.1. Everyone is presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the person is not competent.[1] Whether or not a patient can give or refuse consent to a service depends on whether the patient is able to understand the decision that they are being asked to make. This is called the patient's capacity or competence to make the decision. It does not depend on age, intellectual ability or disability, mental illness, or any other health condition.

Assessing competence

7.2. Assessing competence is a matter of clinical judgement. Generally, a patient will have the capacity to make a particular decision if they can:

- Understand the nature, purpose, and effects of the proposed service, or of refusing the service; and
- Weigh up the service options, balancing the risks and benefits; and
- Foresee the consequences of consenting or refusing to consent; and
- Can communicate the decision.

Patients with diminished capacity

7.3. The Code of Rights applies to incompetent patients and patients with diminished competence as well as to competent patients. Patients with diminished competence have the right to make informed choices and give informed consent to the level of their understanding.[2] Where a patient can make some decisions, but not others, they retain the right to make informed choices and give informed consent to the extent appropriate to their level of competence.

7.4. If a decision is made that a patient is not competent, that should be documented in the patient's clinical file and the reasons clearly stated. Where it is unclear whether a patient has the level of

[1] Right 7(2) of the Code of Rights.

[2] Right 7(3) of the Code of Rights.

competence required for the particular decision, the clinician or other health professional responsible for the proposed service should seek a second opinion from the Regional Manager/Team Leader and if necessary, seek legal advice.

For further information on treating adult patients who are incompetent to consent refer to section 16 of this Policy.

8. Sufficient information

8.1. A competent patient, or a person legally entitled to consent on behalf of an incompetent patient, must be given sufficient information to enable them to make an informed choice and consent or to refuse consent to the proposed service.

8.2. Information needs to be provided to the patient in a form, language and manner that enables the patient to understand the information provided. Where necessary and reasonably practicable, this may involve arranging for an interpreter, or for another suitable person to be present.

8.3. Under Right 6 of the Code of Rights a patient must receive all the information that a reasonable patient in the circumstances would expect, or which is needed, to make an informed choice or give informed consent. The minimum information that must be given to the patient is set out in Right 6. This duty to provide sufficient information does not depend on the patient asking questions.[3] If a patient does ask questions, they must be given honest and accurate answers.

8.4. Under Right 6 of the Code of Rights the information to be provided at the initial consultation must include:

- An explanation of the patient's condition as it relates to the service that Peke provides (i.e. if the patient's physical condition, age or any other infirmity or condition is likely to impact on the options available).
- The available options and their expected risks and benefits, including orthosis, prosthesis and components, and costs if any, associated with each option. This would include, for example, options concerning the type of limbs available, prescription and proposed rehabilitation plan. Information on costs is particularly important for patients paying privately or where an insurance company is involved.
- An estimate of the time it will take to provide the service and begin the rehabilitation process. The patient should be told why it may be difficult to provide an accurate estimate if this is the case, and how the patient will be kept informed of progress.
- An explanation of the members of the multidisciplinary team and the role each member plays in the patient's assessment, service, and rehabilitation.
- Advice of any proposed participation in any teaching, research, or trials.
- Any other information relevant to the patient's service and rehabilitation pathway (including support services available).
- The results of any relevant tests or procedures.
- Any additional specific service information relevant to the patient, including where it is proposed to refer the patient to another health professional or provider.

8.5. Since this can be a lot of information for a patient to retain, it is recommended that patients be provided with a copy of Peke Waihanga Patient Handbook which contains both generic

[3] Right 5 of the Code of Rights.

information about Peke Waihanga services and also places where information specific to each individual patient can be recorded.

8.6. The patient must be given sufficient time to consider the options and come to an informed decision. This may require repeated explanations and the patient must be made aware that they are welcome to ask any questions at any stage while they are receiving service from Peke Waihanga. This is particularly important given the long-term nature of the relationship amputee patients have with Peke Waihanga.

8.7. Under Right 7(8) a patient has the right to express a preference as to who will provide services and have that preference met where practicable. A patient can request, but not demand, a second opinion or to be seen by a different health professional. When this occurs, this should be done in consultation with the Regional Manager/Team Leader. See also the Clinician Allocation Policy Section 4.6 on Patients Seeking a Second Opinion.

9. Voluntariness

9.1. For consent to be valid it must be given freely without undue pressure or coercion. However, it is common and acceptable for patients to receive information and advice from others, and even for the patient to be influenced by the opinions of others when making their decisions, if the other person does not overbear the patient's decision.

9.2. The patient must have the opportunity to consider and discuss the information with the relevant health professional or multidisciplinary team, before consenting and should not feel coerced or rushed into deciding.

When a patient doesn't want to be informed

9.3. Care is required if a competent patient wants a service but does not want to be told all the details. Informed consent relies on the patient having the information necessary to understand the nature, options and risks associated with the proposed service. A patient may not be able to give informed consent if they have not had sufficient explanation.

9.4. If after explaining this to a patient, the patient still does not want to be informed, this should be discussed with the Regional Manager/Team Leader particularly if the proposed service is likely to significantly affect the patient's mobility, independence, or enjoyment of life, is experimental, or otherwise involves significant risk for the patient. It is very important that discussions with the patient are fully recorded in the patient's clinical file on Manaaki. If the clinician or other health professional has any doubt whether the service should proceed in this circumstance, legal advice should be sought.

10. Who should seek consent?

From new patients

10.1. The clinician who is providing the service is responsible for ensuring that the patient has received sufficient information in a way that enables the patient to understand the information, and that the patient provides informed consent to receive the service before it is commenced.

10.2. In the case of the volunteer Peer Support Service, information about the service should be provided by the referrer (referrers are sometimes a health professional from an external organisation) and for self-referrers information about the service is provided and accessed on the Peer Support Website. Referrers are reminded to obtain informed consent during electronic enrolment to the service through prompts on the website.

Ongoing service provision and research projects

10.3. The clinician responsible for providing the patient's service should explain any proposed changes to services and treatment plans to the patient concerned and the patient must consent to it before proceeding.

10.4. Researchers are responsible for gaining informed consent from participants to participate in their research projects. The rights in the Code of Rights extend to occasions when a patient is participating in, or it is proposed that a patient participate in, teaching or research.

Delegation of responsibility

10.5. In situations where it is impractical for consent to be obtained by the clinician responsible for the proposed service(s), obtaining consent may be delegated to another member of the multidisciplinary team if that person is suitably trained and qualified. The person must have sufficient knowledge of the proposed service, including the risks involved and alternative service options, to be able to provide the patient with the information required to obtain legally valid consent.

10.6. Where delegation occurs, the clinician responsible for that service remains responsible for ensuring the patient has received sufficient information to provide valid consent, and for the quality of care and service provided, regardless of how consent is obtained. If the patient's consent is obtained from a health professional, other than the health professional who will perform the service, the patient should be made aware during the process of obtaining informed consent that it will be a different health professional that will be providing the service.

11. When and where is informed consent obtained?

11.1. Obtaining informed consent is an ongoing process that takes place throughout the patient's journey with Peke Waihanga. It requires a layered and flexible approach with information being provided in a way that matches both the patient's situation and the point in their journey with Peke Waihanga.

11.2. It is important that patients receive sufficient information at each point of their journey to enable them to consent to the next step in their treatment. This means informed consent may need to begin at the hospital, during phone or video conversations, at regional clinics, and continue during a patient's first and ongoing consultations at a limb centre.

11.3. Informed consent must be obtained:

- before any services are provided to a patient,
- when changes are proposed to prescriptions, plans or the service/treatment being provided to the patient,
- when patients are being fitted with novel adaptive devices which have been customised especially for them to enable them to carry out specific activities (such as driving, riding a bike, participating in a specific sport, hobby, work task or everyday activity),
- when patients are participating in research or trials or any experimental treatments (e.g. when testing new components),
- when patients are participating in the teaching of others (e.g. students),
- when audio or visual recordings are made of a patient.

11.4. The level of information given should match the situation and where the patient is in their journey. For example, during a visit to a patient in a hospital a Peke Waihanga staff member may provide

the patient with a high-level description of the service and what their experience is likely to be. They can answer any of the patient's questions and ensure the patient consents to being referred to Peke Waihanga and continuing with the service. This can be done at the same time as providing privacy information and providing supporting patient resources. Later, when they attend their first consultation with a clinician more detail can be provided in order for the patient to provide valid consent for the service proposed for them, e.g. provision of their primary limb.

11.5. Throughout the informed consent process, it is important that staff emphasise the importance of the patient's own role in decision-making.

11.6. The environment must be one in which the patient and the clinician or other health professional providing the service can communicate openly, honestly, and effectively. This includes a right to physical privacy,[4] and to have one or more support persons present, unless safety might be compromised, or another patient's rights might be unreasonably infringed.

12. Documenting the consent process

12.1. Regardless of legal requirements, recording the options and risks discussed with the patient in their clinical notes is good clinical practice. A contemporaneous written record of what was discussed with the patient can provide considerable protection if there is any later complaint or concern as to whether a patient's informed consent was obtained.

12.2. The consent process is normally documented in the patient's clinical record where the clinician obtaining the patient's consent records the date, what information was provided to the patient, relevant aspects of the discussion including any concerns raised, relevant aspects of the patient's social situation that may impact on the service and/or rehabilitation plan, including what devices or componentry is most applicable for the patient in his/her circumstances and any decisions made.

12.3. Normally recording well-written, descriptive clinical notes and the patient's consent is adequate documentation of informed consent. However, under the Code of Rights, a patient's signed consent must be in writing in the situations set out in Section 12.5. This is usually achieved by asking the patient to sign a consent form once the patient has had the proposed service or research sufficiently explained to them so that they can make an informed decision and they have had an opportunity to ask questions.

Subsequent service decisions, changes to service

12.4. At subsequent appointment(s)/consultations the patient should be encouraged to ask any questions and further consent should be obtained for any changes in prescription or service provision (for instance a change in componentry, a different device, a change in rehabilitation plan or the design and fitting of a customised adaptive device). Again, these discussions and changes should be well documented in the patient's clinical notes.

Requirements for written consent

12.5. Under the Code of Rights written consent is required if [5]

- The patient is to participate in any research; or
- The service is experimental; or

[4] Right 1(2) of the Code of Rights.

[5] Right 7(6) of the Code of Rights.

- The patient will be under general anesthetic; or
- There is significant risk of adverse effects to the patient.

12.6. For Peke Waihanga purposes the patient's consent must be in writing when:

- a patient is to participate in research or implementation trial (consent to be recorded on the Consent for Research/Trial Form) (see Section 13.4);
- the service/treatment to be provided to the patient is experimental (consent to be recorded on the Consent to Receive Services Form); or
- any service is delivered that could have a significant impact on the patient's health, wellbeing, mobility, or rehabilitation, as well as where there is a significant risk of adverse effects to the patient (consent to be recorded on the Consent to Receive Services Form).[6]
- the use of images, audio and video recording (consent to be recorded on the Images and Recordings Authorisation Form) (see Section 13.10).

12.7. When written consent is obtained it must be placed in the patient's clinical file on Manaaki.

13. Special informed consent situations

Fitting custom-made adaptive devices

13.1. Sometimes Peke Waihanga fabricates custom-designed adaptive devices for individual patients to enable them to carry out specific activities (such as driving, riding a bike, participating in a specific sport, hobby, work task or everyday activity). The informed consent process is particularly important for these devices since they are usually unique, novel devices unavailable in the marketplace and their use is largely untested.

13.2. Although written consent does not need to be obtained under the Code of Rights unless the device is experimental or may pose a serious risk of adverse effects to the patient, it is important that the clinician working with the patient to design and fit the device ensures the patient understands the following before fitting:

- The device has been custom manufactured as a one-off device for their use only due to the unavailability of a suitable commercial one in the market.
- Peke Waihanga has taken all reasonable precautions to ensure the device is safe and fit for purpose. Patients have also been provided with instructions and training on how to use the device safely.
- The device has been designed and fitted for a specific purpose and patients have been advised the device should not be used for any other purpose.
- The device must be used in accordance with the instructions and safety information provided. No changes or modifications should be made by the patient to the device without consultation with Peke Waihanga and without Peke Waihanga approval.
- Peke Waihanga has no responsibility for the device or use of the device if it is changed or modified in any way without its approval or for any unauthorised use by any other person.

[6] Right 7(6) of the Code of Rights. Under Right 7(6) written consent is also required if the patient will be under general anaesthetic.

13.3. The clinician should ensure the information provided to, or discussed with, the patient is clearly recorded in the patient's clinical file in Manaaki.

Research and implementation trials

13.4. If the service is part of research, the researcher must ensure the patient understands the full implications of the service, especially the uncertainties associated with the research. Consent must be recorded on the Research and Trial Consent Form, and a copy must be kept in the patient's clinical file in Manaaki.

13.5. Under the Code of Rights if a patient is to be involved in research or an implementation trial, the patient must:[7]

- Be informed of the proposed participation in research or the trial, including whether the research requires and has received ethical approval.
- Be given a full explanation of the all the implications of the research or trial including any experimental aspects to the service.
- Provide consent in writing to participate in the research or trial.[8]
- Be told that if they do not wish to participate in the research or trial this will not compromise their care in anyway.

13.6. If the research or trial is changed or amended once consent has been obtained the relevant clinician must renew the patient's consent.

13.7. Sometimes Peke Waihanga carries out an implementation trial of a new component to see whether it will be added to the approved list of components. The clinician involved in trialing the new component must obtain the patient's informed consent to participating in the trial and must provide sufficient information about the trial to the patient to enable the patient to make an informed choice whether to participate in the trial and give informed consent. The consent must be recorded on the Research and Trial Consent Form, which must be recorded in the patient's clinical file in Manaaki.

Teaching and involvement of students

13.8. All the rights in the Code of Rights also apply to situations where a patient is participating, or it is proposed that the patient participate in teaching. This includes observational situations where anybody additional to the multidisciplinary team directly concerned with the ongoing care of the patient, is present, as well as where students are participating in providing care to patients.

13.9. Before a student or any other person observes a service or care provided to a patient the patient must be informed and give consent to the presence of the observer. The proposed extent of the involvement of any student or observer should be made clear to the patient. Consent can be verbal, but the discussion and patient's agreement should be documented in the patient's clinical file in Manaaki. The patient must be informed that if they do not wish to be involved in teaching or for students to observe their service this will not compromise their care in anyway.

Audio or visual recordings of patients

13.10. Consent should be obtained for any visual or audio recording taken, including for photographs or other visual images. For the consent to be valid, the purpose and intended future use of the

[7] Refer to Rights 6(1)(d), 6(3)(d), 7(6), and 9 of the Code of Rights.

[8] This should be on the Consent to Research or Consent to Implementation Trial Form as appropriate. A copy must be kept in the patient's medical file in Manaaki.

recording must be explained to the patient before their consent is obtained. All recordings should be retained in the patient's clinical file in Manaaki.

13.11. Where the recording is to be used for teaching or research the patient must be informed that if they refuse the recording this will not compromise their care in anyway. Where possible, recordings used for teaching or research should be anonymised and the patient informed of this. Where the recording cannot be anonymised, or the patient would be likely to be identified from the recording, the patient must be made aware of this and give consent to this prior to the recording being taken, or if that is not practical before the recording is used.

13.12. Further information around use of audio and visual recordings is found in the Privacy Policy. Where a photograph or recording is proposed to be used for educational or promotional use the Images and Recordings Authorisation Form which must be signed by the patient and a copy retained in the patient's clinical file on Manaaki.

14. Right to refuse service and withdraw consent

14.1. An adult patient may refuse to receive any service even if this results in that patient's death or serious consequences to their health.[9] This right is limited to patients who are competent to refuse consent, or who, if incompetent, have made a valid advance directive relevant to the service in question.[10]

14.2. If a patient refuses a service that the clinician considers is in patient's best interest, the discussion with the patient and the patient's refusal should be carefully documented in the patient's clinical file in Manaaki.

14.3. If the clinician has reasonable grounds for doubting the person's competence, or whether the refusal of consent is voluntary, further advice should be sought.

15. Emergencies

15.1. Even in an emergency a patient who is competent to consent has the right to consent to, or refuse, to receive services. If an adult patient is competent and refuses to consent to a service, the benefits and risks associated with consenting or refusing to consent must be explained to the patient. However, the decision must remain the patients. If the patient is not competent to consent, services necessary to save the patient's life or prevent serious damage to the patient's health, should be provided.[11]

16. When a patient is not competent to give informed consent

16.1. When a patient is not competent to consent to a service, a legal basis must be found for providing that service. In New Zealand service can be provided to incompetent adult patients in the following circumstances:

[9] This right to refuse health care service and services is found in the New Zealand Bill of Rights Act, Right 7(7) of the Code of Rights, and the common law.

[10] Right 7(5) of the Code of Rights.

[11] The only exception to this is where the patient has made a valid advance directive refusing the service and the directive applies in the current situation. In an emergency situation, if there is any reason to doubt the validity of an advance directive, the health professional should provide services necessary to preserve the patient's life and health.

- In reliance on the patient's advance directive;[12] or
- If consent is given by a person legally entitled to consent on behalf of the incompetent patient (refer to Section 16.2 - 16.3); or
- If there is no other person legally entitled to consent on behalf of the patient available after following the steps in Right 7(4) of the Code of Rights (refer to Section 16.9); or
- Under authorisation from the Courts.

Who can legally consent for an incompetent adult?

16.2. The only persons able to consent on behalf of an incompetent adult are:

- A welfare guardian; or
- A person who holds an enduring power of attorney ('EPOA') for personal care and welfare under the Protection of Personal and Property Rights Act (PPPR Act).

16.3. While both welfare guardians and an EPOA for personal care and welfare can consent to services on behalf of the patient they represent (unless such power has been specifically excluded), they cannot refuse to grant consent to the administration of 'standard medical treatment' or procedures intended to save the patient's life or to prevent serious damage to the patient's health.

Role of next of kin and family

16.4. A person cannot consent on behalf of an incompetent adult simply because they are that patient's next of kin, a family member, or a close friend. They can only provide legally valid consent if they hold an EPOA for personal care and welfare or have been appointed a welfare guardian for the patient concerned.

Role of EPOAs for personal care and welfare or welfare guardian

16.5. Where an adult patient does not have capacity to make a particular service decision, the patient's EPOA for personal care and welfare or welfare guardian must consent to a service and make personal care and welfare decisions for the patient. In such circumstances:

- The consent of the welfare guardian or EPOA for personal care and welfare must be obtained before providing a service to the patient (except where the patient him/herself has the capacity to consent to a minor service, and does consent, to the service, or in an emergency situation).
- The welfare guardian or EPOA for personal care and welfare should be provided with all the information necessary to give informed consent.

16.6. The document empowering the EPOA or order appointing the welfare guardian must be checked to ensure that the EPOA or welfare guardian has the authority to act in the current situation, and a copy must be kept in the patient's clinical record.

16.7. There are limits placed on EPOAs for personal care and welfare and welfare guardians' powers. An EPOA for personal care and welfare and a welfare guardian:

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[12] Under the Right 7(5) of the Code of Rights every person has the right to use an advance directive by which the person has made a choice about a possible future health care procedure that is effective when he or she is not competent to make that decision. If there is any doubt as to the validity of an advance directive or whether the directive applies in the particular situation, legal advice should be sought.

- Cannot consent in respect of a 'significant matter,' including a major medical procedure or treatment, unless a relevant health practitioner registered under the Health Practitioners Competence Assurance Act has certified, or the Court has determined, that the person is mentally incapable;[13]
- Can consent for a service that does not meet the 'significant matter' threshold in the PPPR Act, as long as the EPOA believes on reasonable grounds that the patient is mentally incapable;
- Cannot refuse consent to standard medical treatment/procedure intended to save the patient's life or prevent serious damage to their health; consent to a patient taking part in medical experimentation (unless it is to save the patient's life or prevent serious damage to their health); or make decisions outside the scope of the Welfare Guardian Order or the EPOA document.[14]

16.8. Under the Code of Rights, a patient with diminished competence retains the right to make informed choices and consent to the extent appropriate to his/her level of competence. Patients with diminished competence (i.e. who are mentally incapable in relation to some decisions, but capable in relation to other every-day matters of personal care and welfare) and who have an EPOA in place should be encouraged to be involved in service decisions to the extent of their capacity.

16.9. Right 7(4) of the Code of Rights provides a framework for decision-making for persons without capacity in non-emergency situations but only where there is no one legally entitled to consent available. Right 7(4) is not a means of obtaining consent from the next of kin or any other person interested in the person's welfare.[15]

16.10. The steps that must be followed to provide service under Right 7(4) are:

- The patient must be incompetent to make an informed choice and give informed consent to the proposed service; and
- There is no person entitled to consent on behalf of the patient available; and
- The service 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, the provider believes, on reasonable grounds, that the service is consistent with the informed choice the patient would make if he or she were competent; or
    - If the patient's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the patient's welfare and available to advise the provider.[16]

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[13] 'Significant matter' is defined in the PPPR Act as a matter that has, or is likely to have, a significant effect on the health, wellbeing, or enjoyment of life of the donor. It includes a major medical procedure. Any service proposed to be provided by Peke Waihanga - Artificial Limb Service that is likely to have a major impact on the patient's life, rehabilitation or health, is also likely to come within the definition of a 'significant matter'.

[14] Refer to ss98(4) and 18 (1) of the PPPR Act for other situations that an EPOA or welfare guardian cannot consent to that would not apply to Peke Waihanga - Artificial Limb Service.

[15] Care should be taken in relying on Right 7(4) if the service is experimental or carries significant risks, or there is disagreement amongst family or health professionals as to what is in the patient's best interests.

[16] The prosthetist or other health professional does not have to provide service in accordance with these views, but the proposed service must be in the patient's best interests.

16.11. Right 7(4) does not apply if the patient:

- Is competent to consent to the service; or
- Has a valid advance directive relevant to the situation; or
- Has a welfare guardian or EPOA for personal care and welfare in place, and that person is available.

17. Providing service to children

17.1. A child is a person under 18 years of age.[17] A child's guardians have rights and responsibilities until the child turns 18.[18] The elements required to obtain legally effective consent from a child are effectively the same as for an adult. In particular:

- The presumption of competence applies regardless of a person's age. Whether or not a child can give or refuse consent to a service does not depend on the child's age, but on whether the child understands the decision about their health care that they are being asked to make.
- If the child cannot understand the information provided or balance the risks and benefits of the proposed service and alternative services, and the possible consequences based on the information provided, then he or she will not be competent to give informed consent.
- If the child is competent to make the decision, he/she must make the decision voluntarily, having received sufficient information to make an informed decision.
- If the child is competent to consent to the service, and written consent is required, the child's written consent is sufficient. While there is no need to also obtain the written consent of the child's guardian if the child is competent, there is no problem in doing so, and if the child and/or guardian wants the guardian to sign the form this should be allowed.
- Under the Code consent must be in writing in the same situations as for an adult (see Section 12.5 - 12.6).

17.2. If a child who appears to be competent is refusing service that will prevent further harm to their health, further advice should be sought.

When can a guardian consent for a child

1. A guardian or parent cannot consent on behalf of a person 18 years of age and over.
2. A child who is 16 or 17 years old with the capacity to give informed consent has the right to consent or refuse consent to medical treatment (including services provided by Peke Waihanga), and their decision cannot be overturned by a guardian. However, a guardian can still make decisions for, and with, an incompetent or partially competent child who is 16 and 17 years of age.
3. A child under 16 years of age, if they are competent to make a decision, can make that decision themselves. The child's guardian can also consent on the child's behalf.
4. Where a child (under 18 years of age) does not have capacity to make a particular decision, consent must be obtained from the child's guardian. The guardian should be provided with all the information that is necessary to make an informed decision.

[17] Section 8 Care of Children Act.

[18] In most circumstances, a child's parent will be his or her guardian. Guardians can also be appointed by the court.

5. Consent is only required from one guardian. If there is conflict between guardians, the child's wishes conflict with the guardian(s) wishes, and/or where the guardians' wishes conflict with what the multidisciplinary team feel is in the best interests of the child, further advice should be sought.

What if there is no guardian?

17.3. If a child under 18 years of age is not competent to make a particular decision, and does not have a guardian in New Zealand, or their guardian cannot be found with reasonable effort, or is not capable of consenting, a person who is acting in the place of a parent may consent on behalf of the child.[19]

17.4. If the child does not have a guardian, or a guardian cannot be found, services may be provided if it is in the best interests of the child, following the process set out in Right 7(4) of the Code of Rights (refer to further information on providing service under Right 7(4) in Section 16.10).

18. Specific responsibilities

Party	Responsibilities
All Employees	• Providing sufficient information to patients to enable them to make informed choices and provide informed consent prior to service. • Obtaining informed consent prior to providing services, or changes to services. • Ensuring written consent is obtained where required as set out in this Policy to services. • Appropriately documenting the consent process in the patient's file on Manaaki.
Regional Manager/ Team Leader	• Ensure clinical personnel are aware of their obligations in relation to obtaining informed consent as set out in this Policy. • Ensure all clinical personnel receive appropriate training in informed consent. • Monitoring the informed consent process to ensure the prosthetist or other health professionals obtain informed consent to services. • Report to the CEO if any issues arise.
Privacy Officer	• Is familiar with current Privacy legislation and practice • Is able to provide Privacy guidance as required
CEO	• Ensure Peke Waihanga - Artificial Limb Service has an Informed Consent Policy that meets legal requirements and that personnel have received adequate training in informed consent.
Board	Provide responsible governance and monitoring of compliance with legal and professional obligations.

[19] Section 36(3) of the Care of Children Act.

19. Legal compliance

- Care of Children Act 2004
- Health Act 1956
- Health and Disability Commissioner Act 1994
- Code of Health & Disability Services Consumers' Rights (1996)
- Health & Disabilities Commissioner Guidance on Open Disclosure Policies
- Health Information Privacy Code 2020
- New Zealand Bill of Rights Act 1990
- Privacy Act 2020
- Protection of Personal and Property Rights Act 1988

20. Key Related documents

- Acupuncture Patient Information and Consent Form
- Clinician Allocation Policy
- Consent to Receive Services Form
- Research and Trial Consent Form
- Images and Recordings Authorisation Form
- Information Request Policy
- Privacy Policy

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Document development and approval			
Review period	3 years	Next review date	March 2027
Legal review required?	✓	Board approval required?	✓
Interconnected processes and documents affected by this document?	Privacy Policy Consent to Receive Services Form Research and Trial Consent Form Images and Recordings Authorisation Form Acupuncture Patient Information and Consent Form		

Version history		
Version No.	Version Date	Description of Change
1.6	March 2024	Reviewed and updates
1.5	December, 2020	Updated policy
1.4	September, 2017	Addition of reference to privacy officer responsibilities
1.3	October, 2016	Update references to regional manager/ team leader and LIMS
1.2	August, 2016	Recommended wording changes around consent requirements for adjustments and repairs
1.1	December, 2015	Incorporation of feedback from Board, Management and Claro
1.0	December, 2015	New policy

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Implementation history	
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Procurement, IT, or other budgetary considerations	
When updated, these people need to be notified	