



# **Informed Consent Policy**

Function: Clinical Business Activity: Privacy and 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 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:
  - (a) **Right 5:** The right to effective communication.
  - (b) **Right 6:** The right to be provided with all necessary information, including information about options, risks, and benefits.
  - (c) **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 service. This extends to when a patient is participating in, or it is proposed that the patient participate in, teaching or research.

### 2. Purpose

2.1 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; and written consent is obtained where required. For the purposes of this Policy 'services' includes procedures, service, prescriptions, fitting of prosthesis, and all health and disability services carried out by Peke Waihanga - Artificial Limb Service including the volunteer Peer Support Service.

# 3. Scope

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

# 4. Policy

4.1 Informed consent is a fundamental part of good practice. Informed consent **must** be obtained before any services are provided to a patient, including where the prosthetist or other health professional proposes changes to the prescription, limb, or other service being provided. The only exceptions to this that apply to services provided by Peke Waihanga - Artificial Limb Service are set out in this Policy. These exceptions relate primarily to emergency situations and incompetent patients. There are also other statutory exceptions to the requirement to gain informed consent which in general will not apply to Peke Waihanga - Artificial Limb Service in the normal course of providing services and are not covered in this Policy.

### 5. Definitions

Advance directive – Is 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 – These 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 – A child is defined in the Care of Children Act as a person under 18 years of age.

**Enduring Power of Attorney ('EPOA')** – Means 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 in relation to consenting to medical service for the child until the child reaches 18, or earlier

Health professional/clinician – A healthcare professional qualified in a particular area of medicine or health who is registered health practitioner in the <u>Health Practitioners Competence Assurance (HPCA) Act 2003</u> as well as prosthetists and orthotists (who are not registered under the act). Whether registered or not, all health professionals/clinicians are required to meet standards of practice usually set by their relevant professional bodies

Informed consent – Is the process whereby the patient (or a person legally entitled to consent on behalf of the patient) who has the capacity to consent to a given service, having been given sufficient information, voluntarily arrives at a decision to agree to the proposed service.

**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.

# 6. Key elements of informed consent

- 6.1 There are three key elements required for informed consent. These elements are:
  - Capacity/competence: The person must have the necessary capacity to consent to the service, or to refuse the service in question; and
  - Sufficient information: The person must be appropriately informed in order for them to make an informed choice about the proposed service; and
  - Voluntariness: The person's consent must be given voluntarily and without pressure from any other person.

6.2 All three elements must be present for consent to be legally valid and are discussed further below.

### 7. Determining 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 particular 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 are able to:
  - (a) Understand the nature, purpose, and effects of the proposed service, or of refusing the service; and
  - (b) Weigh up the service options, balancing the risks and benefits; and
  - (c) Foresee the consequences of consenting or refusing to consent; and
  - (d) 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.<sup>2</sup> 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 medical file and the reasons clearly stated. Where it is unclear whether a patient has the level of competence required for the particular decision, the prosthetist 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.
- 7.5 For further information on treating adult patients who are incompetent to consent refer to section 13 of this Policy.

<sup>&</sup>lt;sup>1</sup> Right 7(2) of the Code of Rights.

<sup>&</sup>lt;sup>2</sup> Right 7(3) of the Code of Rights.

#### Sufficient information

- 7.6 A competent patient, or a person legally entitled to consent on behalf of an incompetent patient, must be given sufficient information to enable him or her to make an informed choice and consent or to refuse consent to the proposed service.
- 7.7 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 (refer to paragraph 8.1 of this policy). This duty to provide sufficient information does not depend on the patient asking questions.<sup>3</sup> If a patient does ask questions, they must be given honest and accurate answers.
- 7.8 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.
- 7.9 Information needs to be provided to the patient in a form, language and manner that enables the patient to understand the information provided to them. Where necessary and reasonably practicable, this may involve arranging for an interpreter, or for another suitable person to be present.

#### **Environment and support persons**

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

### When a patient doesn't want to be informed

- 7.11 If a competent patient wants a service but does not want to be told all the details involved care is required. 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 information about the proposed service explained to them.
- 7.12 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 medical file on Manaaki. If the prosthetist or other health professional has any doubt whether the service should proceed in this circumstance, legal advice should be sought.

<sup>&</sup>lt;sup>3</sup> Right 5 of the Code of Rights.

<sup>&</sup>lt;sup>4</sup> Right 1(2) of the Code of Rights.

#### Voluntariness of

- 7.13 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, as long as the other person does not overbear the patient's decision.
- 7.14 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 making a decision.

### 8. Who should seek consent?

- 8.1 The prosthetist or other health professional 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 the service **before** it is commenced. The proposed change must be explained to the patient and the patient must consent to it before proceeding.
- 8.2 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 through the information about the service provided on the Peer Support Website. Referrers are reminded to obtain informed consent during electronic enrolment to the service through the website.
- 8.3 There may be situations where it is impractical for consent to be obtained by the prosthetist or other health professional undertaking the service. In this situation, obtaining consent may be delegated to another member of the multidisciplinary team as long as 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, in order to be able to provide the patient with the information required to obtain legally valid consent.
- Where delegation occurs, the prosthetist or other health professional 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 that it Process for obtaining informed consent will be a different health professional that will be providing the service.

### 9. When is informed consent obtained?

- 9.1 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.
- 9.2 It is important that patients receive sufficient information at each point of their journey to enable them to consent to the service (and any changes or new developments) they are about to receive. This means informed consent is required from the time of their first interaction with a Peke Waihanga staff member if any part of the service is being provided. Consequently, staff may need to begin the informed consent process at the hospital, during phone or video conversations, at regional clinics and continue it during a patient's first consultation at a limb centre.

- 9.3 The level of information given should match the situation so, 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 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 supporting patient resources. Later, when they attend their first consultation with the prosthetist or other member of the multi-disciplinary team more detail can be provided in order for the patient to provide valid consent to the service proposed for them, e.g. provision of their primary limb.
- 9.4 Throughout the informed consent process, it is important that staff emphasise the importance of the patient's own role in decision-making.

# 10. What information should be provided?

- 10.1 Under Right 6 of the Code of Rights the information to be provided at the initial consultation must include:
  - (a) An explanation of the patient's condition as it relates to the service that Peke Waihanga Artificial Limb Service provides (i.e. if the patient's physical condition, age or any other infirmity or condition is likely to impact on the options available).
  - (b) The available options and their expected risks and benefits, including 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.
  - (c) 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.
  - (d) An explanation of the members of the multidisciplinary team and the role each member plays in the patient's assessment, service, and rehabilitation.
  - (e) Advice of any proposed participation in any teaching, research, or trials.
  - (f) Any other information relevant to the patient's service and rehabilitation pathway (including support services available).
  - (g) The results of any relevant tests or procedures.
  - (h) Any additional specific service information relevant to the patient, including where it is proposed to refer the patient to another health professional or provider.
- 10.2 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 Artificial Limb Service. This is particularly important given the long-term nature of the relationship patients have with Peke Waihanga.

#### Documenting the consent process

10.3 The consent process is documented in the patient's clinical record where the prosthetist or other health professional obtaining the patient's consent records the information 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 limb or componentry is most applicable for the patient in his/her circumstances and any decisions made.
- 10.4 Under the Code of Rights the patient's consent must be in writing if the patient in the situations set out in paragraph 11.1 below.

#### Subsequent service decisions, changes to service

10.5 At subsequent appointment(s)/consultations the patient should be encouraged to ask any questions and further consent (following the process set out above) should be obtained for any new service (for instance any proposed change in componentry, or a replacement limb).

#### Requirements for written consent 11.

- 11.1 Under the Code of Rights written consent is required if <sup>5</sup>
  - (a) The patient is to participate in any research; or
  - (b) The service is experimental; or
  - (c) The patient will be under general anaesthetic; or
  - (d) There is significant risk of adverse effects to the patient.
- 11.2 For Peke Waihanga purposes the patient's **consent must be in writing** when:
  - (a) a patient is to participate in research;
  - (b) the service to be provided to the patient is experimental, or
  - (c) 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.6
- 11.3 When written consent is obtained, it should be recorded on the Consent to Receive Services Form, or where the patient has agreed to participate in research or an implementation trial the patient's consent should be recorded on the Consent for Research/Trial Form. The consent form(s) must be placed in the patient's medical file on Manaaki. Regardless of the legal requirements, obtaining consent in writing and/or recording the options and risks discussed with the patient in their medical 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 actually obtained.

<sup>&</sup>lt;sup>5</sup> Right 7(6) of the Code of Rights.

<sup>&</sup>lt;sup>6</sup> 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.

# 12. Right to refuse service and withdraw consent

An adult patient may refuse to receive any service even if this results in that patient's death or serious consequences to their health. 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. If a patient refuses service that the prosthetist or other health professional 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 medical file in Manaaki. If the prosthetist or other health professional has reasonable grounds for doubting the person's competence, or whether the refusal of consent is voluntary, further advice should be sought.

### 13. Emergencies

13.1 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 patient's. 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.<sup>9</sup>

### 14. When a patient is not competent to give informed consent

- 14.1 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:
  - (a) In reliance on the patient's advance directive; 10 or
  - (b) If consent is given by a person legally entitled to consent on behalf of the incompetent patient (refer to paragraph 13.3); or
  - (c) After following the steps in Right 7(4) of the Code of Rights if there is no other person legally entitled to consent on behalf of the patient (refer paragraph 13.9); or
  - (d) Under authorisation from the Courts.

<sup>&</sup>lt;sup>7</sup> 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.

<sup>&</sup>lt;sup>8</sup> Right 7(5) of the Code of Rights.

<sup>&</sup>lt;sup>9</sup> 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.

<sup>&</sup>lt;sup>10</sup> 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.

14.2 These circumstances are discussed further below.

### Who can legally consent for an incompetent adult?

- 14.3 The only persons able to consent on behalf of an incompetent adult are:
  - (a) A welfare guardian; or
  - (b) 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).
- 14.4 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

14.5 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.

### The role of EPOAs for personal care and welfare or welfare guardian

- 14.6 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 service and make personal care and welfare decisions for the patient. In such circumstances:
  - (a) 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);
  - (b) The welfare guardian or EPOA for personal care and welfare should be provided with all the information necessary to give informed consent;
  - (c) 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 medical file in LIM.
- 14.7 There are limits placed on EPOAs for personal care and welfare and welfare guardians' powers. In particular an EPOA for personal care and welfare and a welfare guardian:
  - (a) 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;<sup>11</sup>

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<sup>&</sup>lt;sup>11</sup> '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'.

- (b) Can consent for a service that does not meet the 'significant' threshold in the PPPR Act, as long as the EPOA believes on reasonable grounds that the patient is mentally incapable;
- (c) 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.<sup>12</sup>
- 14.8 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.
- 14.9 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.<sup>13</sup>
- 14.10 The steps that must be followed in order to provide service under Right 7(4) are:
  - (a) The patient must **be incompetent** to make an informed choice and give informed consent to the proposed service; **and**
  - (b) There is no person entitled to consent on behalf of the patient available; and
  - (c) The service is in the best interests of the patient; and
  - (d) Reasonable steps have been taken to ascertain the views of the patient; and
  - (e) 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. 14
- 14.11 Right 7(4) does not apply if the patient:
  - (a) Is competent to consent to the service; or
  - (b) Has a valid advance directive relevant to the situation; or
  - (c) Has a welfare guardian or EPOA for personal care and welfare in place, and that person is available.

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<sup>&</sup>lt;sup>12</sup> 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.

<sup>&</sup>lt;sup>13</sup> 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.

<sup>&</sup>lt;sup>14</sup> 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

### 15. Research, implementation trials and teaching

#### Research and implementation trials

- 15.1 Under the Code of Rights if a patient is to be involved in research or an implementation trial, the patient must:<sup>15</sup>
  - (a) Be informed of the proposed participation in research or the trial, including whether the research requires and has received ethical approval;
  - (b) Be given a full explanation of the all the implications of the research or trial including any experimental aspects to the service;
  - (c) Consent in writing to participating in the research or trial;<sup>16</sup>
  - (d) Be told that if they do not wish to participate in the research or trial this will not compromise their care in anyway; and
- 15.2 Research may need to be approved by an accredited ethics committee. This will depend on the nature of the research and it is the researchers' responsibility to apply for ethics approval where appropriate.
- 15.3 If the research or trial is changed or amended once consent has been obtained the relevant prosthetist or other health professional must renew the patient's consent.
- 15.4 If the service is part of research, the researcher must ensure the patient understands the full implications of the service, especially the uncertainties. Consent must be recorded on the Consent to Research Form, and a copy must be kept in the patient's medical file in Manaaki.
- 15.5 Sometimes Peke Waihanga Artificial Limb Service carries out an implementation trial of a new component to see whether it will be added to the approved list of components. The health professional involved in trialling 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 Consent to Participate in Implementation Trial Form, which must be recorded in the patient's medical file in Manaaki.

### Teaching and involvement of students

- 15.6 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 actually participating in providing care to patients.
- 15.7 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 clear to the patient. Consent can be verbal, but it is good practice to document the discussion and patient's agreement in the patient's medical

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<sup>&</sup>lt;sup>15</sup> Refer in particular to Rights 6(1)(d), 6(3)(d), 7(6), and 9 of the Code of Rights.

 $<sup>^{16}</sup>$  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.

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.

# 16. Audio or visual recordings

- 16.1 Consent should be obtained for any visual or audio recording, including photographs or other visual images. For the consent to be valid, the purpose and intended future use of the recording must be explained to the patient before their consent is obtained.
- 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 consent to this prior to the recording being taken, or if that is not practicable before the recording is used.
- 16.3 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 Clinical Images and Recordings Authorisation Form must be signed by the patient and a copy retained in the patient's medical file on Manaaki.

# 17. Providing service to children

- 17.1 A child is a person under 18 years of age. <sup>17</sup> A child's guardians have rights and responsibilities until the child turns 18. <sup>18</sup> The elements required to obtain legally effective consent from a child are the same as for an adult. In particular:
  - (a) The presumption of competence applies regardless of a person's age. Whether or not a child can give or refuse consent to 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;
  - (b) If the child is competent to make the particular decision, he/she must make the decision voluntarily, having received sufficient information to make an informed decision. 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;
  - (c) 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;
  - (d) Under the Code consent must be in writing in the same situations as for an adult.

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<sup>&</sup>lt;sup>17</sup> Section 8 Care of Children Act.

 $<sup>^{18}</sup>$  In most circumstances, a child's parent will be his or her guardian. Guardians can also be appointed by the court.

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

- 17.3 Once a young person is 18 years of age and over, their guardian (including a parent) cannot consent on their behalf. A child who is 16 or 17 years old and who has the capacity to give informed consent has the right **to consent or refuse consent** to medical treatment (including services provided by Peke Waihanga Artificial Limb Service), 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.
- 17.4 Where a child is under 16 years of age, if they are competent to make the particular decision, they can make that decision themselves. The child's guardian can also consent on the child's behalf.
- 17.5 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.
- 17.6 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?

- 17.7 If a child under 18 years of age is not competent to make a particular decision, and does not have a guardian in NZ, 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.<sup>19</sup>
- 17.8 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 this Policy).

# 18. Specific responsibilities

Party	Responsibilities
All Employees	<ul> <li>Providing sufficient information to patients to enable them to make informed choices and provide informed consent prior to service.</li> <li>Obtaining informed consent prior to providing services, or changes to services.</li> <li>Ensuring written consent is obtained where required as set out in this Policy to services.</li> <li>Appropriately documenting the consent process in the patient's file on Manaaki.</li> </ul>

<sup>&</sup>lt;sup>19</sup> Section 36(3) of the Care of Children Act.

Regional Manager/ Team Leader	<ul> <li>Ensure clinical personnel are aware of their obligations in relation to obtaining informed consent as set out in this Policy.</li> <li>Ensure all clinical personnel receive appropriate training in informed consent.</li> <li>Monitoring the informed consent process to ensure the prosthetist or other health professionals obtain informed consent to services.</li> <li>Report to the CEO if any issues arise.</li> </ul>
Privacy Officer	<ul><li>Is familiar with current Privacy legislation and practice</li><li>Is able to provide Privacy guidance as required</li></ul>
CEO	<ul> <li>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.</li> </ul>
Board	Provide responsible governance and monitoring of compliance with legal and professional obligations.

# 19. Implementation and Compliance

- 19.1 Procedures will be implemented immediately following training or as part of new joiner induction.
- 19.2 Compliance will be monitored as per party specific responsibilities outlined in Section 18 of this document.

# 20. Legal compliance

- Care of Children Act 2004
- Crimes Act 1961
- Health Act 1956
- Health and Disability Commissioner Act 1994
- Health & Disability Commissioner (HDC) Code of Rights
- Health Information Privacy Code 2020
- New Zealand Bill of Rights Act 1990
- Privacy Act 2020
- Protection of Personal and Property Rights Act 1988

# 21. Key Related documents

- Code of Conduct Policy
- Privacy Policy
- Privacy Statement
- Privacy Statement- Te Reo
- Privacy and Informed Consent Conversation Procedures

- Privacy Poster
- Privacy Poster- Te Reo
- Internet and Email Use Policy
- Mobile Device Usage Policy
- <u>Clinical Governance Policy</u>
- Medical Device Prescription Policy

#### Forms:

- Consent to Receive Services Form
- Consent Form Research and Trial
- <u>Clinical Images and Recordings Authorisation Form</u>

# For Use by National Office Only

Document development and approval			
Review period	3 years	Next review date	December 2023
Legal review required?	✓	Board approval required?	✓
Interconnected processes and documents affected by this document?	Privacy Policy Privacy and Informed Consent Procedures		

Version history			
Version No.	Version Date	Description of Change	
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	

Authors and reviewers		
Content owner name and role	Service Development Manager	
Content author(s)	Privacy Officer	
Was there a review committee?		
Internal peer reviewer names and roles		
External reviewer names, organisations, and roles	Claro Law	
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Implementation history		
✓ Internal communication	Roles affected:	
☐ Manager in-team training	Everyone (staff, volunteers and board members)	
✓ National roll-out via group workshops		

Implementation history		
☐ Self-learning:		
☐ Other (describe)		
Procurement, IT, or other budgetary considerations		
When updated, these people need to be notified		