

Informed Consent Policy

Table of Contents

| | | |
|----|---|----|
| 1 | Background | 2 |
| 2 | Purpose | 2 |
| 3 | Scope | 2 |
| 4 | Policy | 3 |
| 5 | Definitions | 3 |
| 6 | Key elements of informed consent..... | 4 |
| 7 | Who should seek consent | 7 |
| 8 | Process for obtaining informed consent | 7 |
| 9 | When is written consent required..... | 9 |
| 10 | Right to refuse service and withdraw consent | 10 |
| 11 | Emergencies..... | 10 |
| 12 | When a patient is not competent to give informed consent..... | 10 |
| 13 | Research, implementation trials and teaching | 13 |
| 14 | Audio or visual recordings..... | 14 |
| 15 | Providing service to children..... | 15 |
| 16 | Specific responsibilities | 16 |
| 17 | Legal compliance | 17 |
| 18 | Related Policies, Procedures and Forms | 17 |
| 19 | Revision History | 18 |

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 services¹ provided are lawful; the consent process is properly documented; and written consent is obtained where required.

3 Scope

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

¹ For the purposes of this Policy 'services' includes procedures, service, prescriptions, fitting of prosthesis, and all health and disability services carried out by NZALS.

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 NZALS 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 NZALS in the normal course of providing services and are not covered in this Policy.

5 Definitions

- 5.1 **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.
- 5.2 **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.
- 5.3 **Child** – A child is defined in the Care of Children Act as a person under 18 years of age.
- 5.4 **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.
- 5.5 **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.²
- 5.6 **Health professional** – Includes health practitioners registered under the Health Practitioners Competence Assurance Act, prosthetists, and orthotists.
- 5.7 **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.
- 5.8 **Provider** – Includes health professionals and other staff providing services to a patient and/or the health or disability organisation as the context requires.

² A guardian of a child has rights in relation to consenting to medical service for the child until the child reaches 18, or earlier if the child marries, enters a civil union; or if a child 16 or older lives with another person as a defacto partner.

- 5.9 **Service(s)** – For the purposes of this Policy ‘service(s)’ includes procedures, service, prescriptions, fitting of prosthesis, and all health and disability services carried out by NZALS.
- 5.10 **Welfare Guardian** – Means 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:
- (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 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.
- 6.2 All three elements must be present for consent to be legally valid and are discussed further below.

Determining capacity/competence

Presumption of competence

- 6.3 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.³ 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

- 6.4 Assessing competence is a matter of clinical judgement. Generally, a patient will have capacity to make a particular decision if they can:
- (a) Understand the nature, purpose, and effects of the proposed service, or of refusing the service;
 - (b) Weigh up the service options, balancing the risks and benefits;
 - (c) Foresee the consequences of consenting or refusing to consent; and
 - (d) Can communicate the decision.

³ Right 7(2) of the Code of Rights.

Patients with diminished capacity

- 6.5 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.⁴ 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.
- 6.6 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.
- 6.7 For further information on treating adult patients who are incompetent to consent refer to section 13 of this Policy.

Sufficient information

- 6.8 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.
- 6.9 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.⁵ If a patient does ask questions, they must be given honest and accurate answers.
- 6.10 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. Where this occurs this should be done in consultation with the Regional Manager/Team Leader.
- 6.11 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.

⁴ Right 7(3) of the Code of Rights.

⁵ Right 5 of the Code of Rights.

Environment and support persons

- 6.12 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,⁶ 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

- 6.13 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.
- 6.14 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.

Is the consent given voluntarily

- 6.15 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 and to make their decisions as a result, as long as the other person does not overbear the patient's decision.
- 6.16 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.

⁶ Right 1(2) of the Code of Rights.

7 Who should seek consent

- 7.1 The prosthetist or other health professional that 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.
- 7.2 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.
- 7.3 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 will be a different health professional that will be providing the service.

8 Process for obtaining informed consent

Initial consultation

- 8.1 When a patient attends for their first appointment the prosthetist or other member of the multidisciplinary team should ensure the patient is provided with all the information the patient would expect to receive in order to provide valid consent to the proposed service (provision of their primary limb etc.). Under Right 6 of the Code of Rights this **must** include:
 - (a) An explanation of the patient's condition as it relates to the service that NZALS 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, expected risks and benefits of the different options and prosthesis and components, and costs if any, associated with each option. This would include for example options around; the type of limbs available, prescription, 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.

8.2 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 NZALS. This is particularly important given the long term nature of the relationship patients have with NZALS.

8.3 The patient should also be given general information about services provided by NZALS and NZALS facilities and support services at their first appointment. This general information is set out in the Patient Information Checklist. This can be given to the patient by a member of the multidisciplinary team or an administration staff member. A copy of the Patient Information Checklist should be kept in the patient's medical file in Manaaki.

Documenting the consent process

8.4 When the patient has been provided with sufficient information (refer to paragraph 8.1), has had time to ask questions, and is ready to consent to the agreed service, the patient should be asked to fill in and sign the **Agreement to Receive Services Consent Form**. The prosthetist or health professional who has provided the information and obtained the patient's consent should also sign this form, and document in the patient's medical file what information was provided to the patient, relevant aspects of the discussion including any issues that have arisen, 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 the outcome of the discussion(s).

- 8.5 Under the Code of Rights the patient's **consent must be in writing** if the patient in the situations set out in paragraph 9.1 below. For NZALS purposes this includes when a patient is to participate in research, the service to be provided to the patient is experimental, or where there is significant risk of adverse effects to the patient.⁷ The consent should be recorded on the **Agreement 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 Form**, or **Consent For Implementation Trial Form**. The consent form(s) must be placed in the patient's medical file on Manaaki.
- 8.6 NZALS requires written consent to be obtained, and kept on the patient's file, for all **significant service decisions**, as well as where the patient is to participate in research or an implantation trial.⁸

Subsequent service decisions, changes to service

- 8.7 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).

9 When is written consent required

- 9.1 Under the Code of Rights written consent is required if:⁹
- (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.
- 9.2 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.

⁷ 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.

⁸ This will include the initial assessment and fitting of a limb, any significant change to componentry from what has previously been consented and any service that could have a significant impact on the patient's health or wellbeing, mobility or rehabilitation, as well as where there is a significant risk of adverse effects to the patient.

⁹ Right 7(6) of the Code of Rights.

10 Right to refuse service and withdraw consent

10.1 An adult patient may refuse to receive any service even if this results in that patient's death or serious consequences to their health.¹⁰ 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.¹¹ 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.

11 Emergencies

11.1 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.¹²

12 When a patient is not competent to give informed consent

12.1 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;¹³ 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.

12.2 These circumstances are discussed further below.

¹⁰ 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.

¹¹ Right 7(5) of the Code of Rights.

¹² 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.

¹³ 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.

Who can legally consent for an incompetent adult?

- 12.3 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).
- 12.4 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

- 12.5 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

- 12.6 **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.**

12.7 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;¹⁴
- (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.¹⁵

12.8 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.

Providing service under Right 7(4) of the Code of Rights

12.9 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.¹⁶

12.10 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**

¹⁴ '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 NZALS 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'.

¹⁵ 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 NZALS.

¹⁶ 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.

- (e) Either:
 - i. 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**
 - ii. 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.¹⁷

12.11 **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.

13 Research, implementation trials and teaching

Research and implementation trials

13.1 Under the Code of Rights if a patient is to be involved in research or an implementation trial, the patient must:¹⁸

- (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;¹⁹
- (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

13.2 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.

13.3 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.

¹⁷ 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.

¹⁸ Refer in particular to Rights 6(1)(d), 6(3)(d), 7(6), and 9 of the Code of Rights.

¹⁹ 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.

- 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. Consent must be recorded on the Consent to Research Form, and a copy must be kept in the patient's medical file in Manaaki.
- 13.5 Sometimes NZALS 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

- 13.6 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.
- 13.7 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 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.

14 Audio or visual recordings

- 14.1 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.
- 14.2 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.
- 14.3 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.

15 Providing service to children

- 15.1 A child is a person under 18 years of age.²⁰ A child's guardians have rights and responsibilities until the child turns 18.²¹ 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.
- 15.2 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

- 15.3 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 NZALS), 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.
- 15.4 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.
- 15.5 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.

²⁰ Section 8 Care of Children Act.

²¹ In most circumstances, a child's parent will be his or her guardian. Guardians can also be appointed by the court.

15.6 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

15.7 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.²²

15.8 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).

16 Specific responsibilities

| Party | Responsibilities |
|---|---|
| Clinical/ Multidisciplinary teams | <ul style="list-style-type: none"> • 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. • Appropriately documenting the consent process in the patient's medical file on Manaaki. |
| Regional Managers/Team Leader | <ul style="list-style-type: none"> • 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 professional obtains informed consent to services. • Reporting to the CEO if any issues arise. |
| CEO | <ul style="list-style-type: none"> • Ensure NZALS has an Informed Consent Policy that meets legal requirements in place and personnel have received adequate training in informed consent. |
| Privacy Officer | <ul style="list-style-type: none"> • Is familiar with current Privacy legislation and practice • Is available to provide Privacy guidance as required |
| Board | <ul style="list-style-type: none"> • Provide responsible governance and monitoring of compliance with legal and professional obligations |

²² Section 36(3) of the Care of Children Act.

17 Legal compliance

- [Health and Disability Commissioner Act 1994](#)
- [Code of Health and Disability Services Consumers' Rights](#)
- [Protection of Personal and Property Rights Act 1988](#)
- [Care of Children Act 2004](#)
- [New Zealand Bill of Rights Act 1990](#)
- [Crimes Act 1961](#)
- [Privacy Act 1993](#)
- [Health Information Privacy Code 1994](#)
- [Health Act 1956](#)

18 Related Policies, Procedures and Forms

- [Code of Conduct Policy](#)
- [Privacy Policy](#)
- [Privacy Statement and Privacy Consent](#)
- [Mobile Device Usage Policy](#)
- [Clinical Governance Policy](#)
- [Prescription Policy](#)

Forms:

- [Agreement to receive services consent form](#)
- [Consent Form - Research](#)
- [Consent Form – Implementation Trial](#)
- [Clinical Images and Recordings Authorisation Form](#)

19 Revision History

| Author | Version number | Version date | Description of changes |
|--------------------|----------------|----------------|---|
| Compliance Advisor | 1.4 | September 2017 | Addition of reference to privacy officer responsibilities |
| Compliance Advisor | 1.3 | October 2016 | Update references to regional manager/ team leader and LIMS |
| Compliance Advisor | 1.2 | August 2016 | Recommended wording changes around consent requirements for adjustments and repairs |
| CEO | 1.1 | December 2015 | Incorporation of feedback from Board, Management and Claro |
| Claro Law | 1.0 | December 2015 | New Policy |