PURPOSE

- This policy on informed consent provides a framework to clarify the recommended best practice in all situations that may require informed consent.
- It ensures compliance with all legislated requirements

1. SCOPE

a. Applies to all staff and clients / service uses of Total Care Health Services

2. DEFINITIONS

a. **Client**

The term 'consumer' is used in the Code of Health and Disability Services Consumers' Rights when referring to individuals who receive health services. To obtain consistency, in this document, the term 'client' has been used.

b. **Representative**

The term 'personal representative' is defined in two acts -

The Health Act

The Mental Health Compulsory Assessment and Treatment Act

to mean:

- Where the individual is under 16 and cannot be confirmed to fully understand the health care to be provided and any associated side effects of the care; the parent or guardian.
- Where the individual is alive, over 16 and is unable to give consent, the person "appearing to be lawfully acting on the individual's behalf".

As to the last, this could be someone nominated by the client, or a family member or even a friend.

3. RESPONSIBILITIES

a. Business managers

i. Ensuring all staff have the opportunity to be informed and educated regarding their responsibilities regarding provision of information and gaining of informed consent

ii. Ensuring consent forms to be signed by the clients capture all information as required under legislation

b. **Line Managers & CNLs**

i. Ensuring education relating to informed consent is provided to staff

ii. Ensuring all staff understand their responsibilities related to obtaining consent

iii. Ensuring that information pertaining to consent that is captured by staff is correctly entered into the client's file

iv. Ensuring that where a client remains a service user for longer than six months or where there are significant changes in the clients condition or service provision further signed consent is obtained

c. **Community Nurses**

I. To ensure they have full knowledge and understanding around their responsibilities related to Informed Consent
II. That they ensure the Client Service Agreement is completed and signed at the first visit and again when so directed
III. They ensure that when attempting to gain consent they give consideration to the clients age, understanding, cultural background, their proficiency in English and any temporary or permanent disabilities that may impact on their ability to understand the information to be given
IV. They report any concerns relating to their clients ability to provide an Informed Consent to their CNL or Business Manager.
V. That where verbal consent is gained [when appropriate] that this is clearly documented in the client's clinical notes

4. PROCEDURE

What is Informed Consent?
Informed consent may be defined as the process whereby someone who has the capacity/competence to consent, having been given sufficient information, arrives at a reasoned decision as to whether or not to agree to a proposed therapy or procedure

Consent may be given in writing or orally depending upon a number of issues – the Client Service Agreement outlines those issues where TCHS requires consent to be in writing. Where consent is sought verbally; in instances where a treatment plan is to be changed, a GP is to be updated due to a change in condition or care, or where the client is to be referred to another provider this must be clearly documented in the client's notes by the staff member obtaining the consent.

Informed Consent is not the act of filling out forms, but rather a process of exchange of information so that an informed decision can be made by that person.

Why is Informed Consent necessary?
The client has the right to be accurately and adequately informed about a proposed procedure or treatment and to agree or refuse to have that procedure or treatment.
All health professionals have a responsibility to inform clients about proposed procedures and to gain consent to procedures.
Where difficult situations arise, advice should be sought by the health professional from their Clinical Director and/or Medical Advisor.

When is Informed Consent required?
Generally informed consent must be obtained for each treatment or procedure proposed There are a few situations in which individuals may be treated without consent. Acts of Parliament such as the Mental Health Compulsory Assessment and Treatment Act, control the conditions under which this may happen. With TCHS clients this most commonly occurs when emergency treatment or referral is required

Written consent has two main purposes:

- The protection of the patient and their rights by ensuring that health professionals do take steps to secure informed consent and to alert the patient to the fact that some procedures are more significant than others. The issue of significance must include an assessment from the patient's perspective.

- The protection of the health professional and the institution as evidence that the legal and ethical requirements for gaining informed consent have been carried out.

If there is any doubt as to whether consent should be in writing written consent must be obtained.

Regardless of whether written consent is obtained, the contents of what is discussed and the process which is completed should be documented in the patient's notes.

It is advisable to make a special record in the patient's notes of important or contentious issues. Relevant information should also be recorded should a patient decline to undergo any procedure.

What about Emergencies?
Obviously in an emergency, the primary need is to treat the client.
The key features of an emergency are:

- extreme urgency, or
- serious consequences of failure or delay in acting

Gaining informed consent is preferable but the circumstances may make this impossible.

In general, treatment provided in an emergency when the capacity to consent is impaired or absent should only be that which is necessary to treat the immediate problems.
After the emergency, the client must be given information regarding the procedures carried out.

How long is the Consent valid?
The length of time that consent having been given may still be considered valid is dependent on:

- the nature of the procedure
- progression of condition
- likelihood of change in health status between consent and procedure
- change in competence

The currency of the consent must be reviewed if any of the documented factors change for any TCHS client. Where a client is a service user for **longer than six months** continuously a further consent form indicating informed consent should be obtained

What and how much Information should be given?
The amount of information given should be that which a reasonable client, and in particular the individual client with whom the clinician is speaking, would expect to discuss in order for a reasoned decision to be made.
The higher the probability of risk or the greater the magnitude of harm, the more care and detail in giving information is required. It is accepted that clients may refuse information.
Every client has the right to receive:

- an explanation of their condition; and
- an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
- advice as to the estimated time within which the services will be provided; and
- any other information required by legal, professional, ethical and other relevant standards; and
- the results of tests; and
- the results of procedures

Every client has the right to receive honest and accurate answers to questions relating to services, including:

- the identity and the qualifications of the provider; and
- the recommendation of the provider; and
- how to obtain an opinion from another provider; and
- the results of research
- Every client has the right to receive on request a written summary of information provided.

Right to Refuse
It must always be remembered that under section 11 of the New Zealand Bill of Rights Act 1990, everyone has the right to refuse or withdraw consent to services. This is, of course subject to any statutory negation of that right by the provisions of Acts such as those mentioned in “Laws Concerning Procedures Without Consent”. (See page 14).
It should be made clear to the client that he or she has the right to refuse or withdraw from treatment without fear of recrimination or penalty.

How should Information be given?
Care must be taken to reduce in all possible ways the client’s feelings of excessive dependency and vulnerability and any discomfort they may feel about asking questions or suggesting alternative points of view.
Privacy should be ensured for discussions of diagnosis and treatment options. Information should be given in a language, style and form that the client can easily understand. Where necessary it should be translated into the client’s own language.
Sufficient time should be allowed for the client to read written information, and discuss this and any verbal information with whom-ever he/she wishes.
Clients should be advised that they have a right to have another person or persons present during the discussion related to the proposed treatment or procedure. A Client Advocate may attend at the request of the client.

Visual material should be included where it could be helpful in providing the information needed.

Who should give the Information?
The primary responsibility for ensuring information is imparted lies with the person who is responsible for the procedure.
In some situations it is impracticable for all information to come from the health professional conducting the procedure. In such cases an appropriate health professional familiar with the treatment or procedure and with adequate knowledge of the risks and benefits of the treatment or procedure may impart the information.
In situations where a team is involved in management or treatment the process of imparting information may be shared between various members of the team.
Anyone involved in the care or treatment of a client who believes the client is not being kept adequately informed should convey this to their line manager

Responsibility for Obtaining Consent
The principles for responsibility for obtaining consent are the same as those for imparting information.
The responsibility lies with the person who is responsible for the procedure.
Where the situation arises where obtaining consent is delegated, the client should be told the reason why the person carrying out the treatment or procedure could not personally obtain consent.
No consent should be requested until the health professional is satisfied that the client has demonstrated adequate understanding of what is proposed.
In situations in which a client cannot give consent for himself/herself, it should be recorded who gave consent and the relationship to the client. These situations include children who are unable to exercise their rights i.e. because they are too young or too ill, and those whose mental state leaves them (temporarily or permanently) without the capacity to consent.

Advance Directive
Every client may use an advance directive to consent to or refuse a health care procedure. An advance directive is the client's instructions to consent to or to refuse treatment given at a time when the client was competent, for use when they are subsequently of diminished competency. An advance directive can be verbal or written.
Issues to consider are:

- An undocumented verbal advance directive may be difficult to substantiate. Written advance directives are preferable.
- Whether the client's consent/refusal was likely to be on an informed basis.
- Whether the advance directive is likely to have become out of date.
- Whether the client is likely to have changed their mind.

Teaching, Observers and Research
Clients have a right to consent to or decline involvement in teaching (including the presence of observers during treatment or examination) or to take part in research. "Observers"

(including students) are defined as those additional to the normal nursing team immediately involved in the procedure and staff directly concerned with the on-going care.

Clients must not be included in research without their written informed consent.

Composite Procedures

Patients should give informed consent for each treatment or procedure before it begins. However, there are times when a group of procedures or treatments are closely linked, and should be discussed as a composite procedure for the purpose of gaining consent

Interdependent Treatments
Interdependent treatments are those where the treatments are routine and necessarily interdependent, for example, insertion of intra-vascular lines accompanied by administration of Intravenous antibiotics and IV fluids.
In such cases, all the component procedures should be clearly described to the client as an integral part of the treatment for which she/he is consenting

Children

Introduction

This document provides a framework under which decisions on the process for obtaining informed consent for children can be made.

Code of Rights

Subject to the following, the Code of Rights applies to children as it does to adults.

Age of Consent

The age of consent is not defined under the code. The code simply requires a person to consent provided they are competent to do so. As a general rule it is assumed that the nearer to 16 a child is, the more likely they can consent to a procedure. However this will depend on the nature of the procedure, the risks involved and the maturity of the child.

Treatment or investigation involving children under 16 years should not take place unless;

- the child has capacity to consent and does so

or

- the informed consent of the child's parent or guardian has been obtained, with two exceptions set out below

Guardian

Under the Guardianship Act 1968 a guardian is a person who has custody of a child and custody is defined as "the right to possession and care of a child". Normally this will be the parents, or a parent of the child but this may not always be the case. If a guardian is not available the code requires the clinician to consult other suitable persons interested in the welfare of the child eg a school teacher

Information Giving

There is the same requirement for information to be given to parents and for consent to be obtained from parents as in all other cases.

In addition to the need for parents to consent, information should, where practicable, be given to the child in a way that the child can understand and, where possible, the child's agreement should also be sought. Of course this will vary with the age of the child, but the general principle should be to involve the child as much as possible.

Declining Consent

If, despite information on the consequences of non-treatment, the parent or guardian continues to decline treatment, then the child may not be treated at that time.

Where a child with understanding of proposed treatment disagrees with parent, the role of the clinician is to identify a mediator who is acceptable to the child and parents, to facilitate a resolution. Mediators may include other family members, chaplains, kai awhina, GP, etc. The same process should occur where parents disagree between themselves. In such cases the Community Nurse should not commence treatment and refer bck to their CNL or Business Manager

Diminished Capacity and Competence to Consent

Introduction

For consent to be valid it must be voluntary, knowing or informed, and competently given. Medication, intellectual disability, mental illness, inebriation, or physical injuries all may affect the informed consent process.

As stated in Right 7(3) of the Code of Rights a client with diminished competence retains the right to give informed consent appropriate to that client's level of competence.

Capacity to Consent

Individuals with the above conditions may lack the capacity to fully give or withhold consent. In the case of intellectual disability this is a permanent state. In the other cases it is an acquired state which may be brief or prolonged.
A person may be competent in some respects (e.g. to manage their financial affairs) and incompetent in others (e.g. to understand the effect of illness upon them, to assess the value of treatment). Medication can alter mental state, and may either improve or impair competence.

Determining Competency

Clinicians are often concerned to determine competence, i.e. to form an opinion as to whether a client has the capacity to give informed consent.

Where the Community Nurses has any concerns as to the competency of a client and therefore their ability to provide informed consent and there is no legal representative available to do so then they should not commence treatment and should advise their CNL or Business manager of the situation.

In this situation senior staff should defer to the notified legal representative or the GP. Reasonable steps must be taken to ascertain what the client's informed choice might be in the given circumstances. This may necessitate seeking opinion from others having an interest in the welfare of the client. In this regard Right 7(4) of the Code of Health and Disability Services Consumers' Rights applies.

Photography, Video, Audio and Related Recordings

Introduction

Recordings of clients or staff occur in three situations.

1. Clinical Recordings.
   - As part of client diagnosis and management.
   - For education and/or research.

2. Recordings by external agencies.

3. Private Recordings (made by clients or their relatives)

Principles

The two fundamental principles are:

1. Making a recording of any client without informed consent is not permitted.

2. The requirements of the Privacy Act 1993 and the Health Information Privacy Code 1994 must be observed.

Any recordings must be made with consent, the major requirement being to protect the interests of the client.

Clinical Case Note Recordings

For Diagnosis and Management

Where recordings are made as an integral and necessary part of client treatment or management, written consent is required.

The recordings must be used purely for client management and must be part of the client's records or stored in a locked indexed filing system.

In no circumstances may these recordings be used for education or research purposes unless appropriate consent is given.

For Education and Research

Recordings made for purposes of clinical teaching or research require informed consent and compliance with storage requirements.

Consent

The prior written consent of the client or clients who are to figure in the recording must be obtained.

Retrospective consent must be sought in cases where prior consent was impossible to obtain. If retrospective consent is denied, the recording must be destroyed.

In the case of any client who is incapable of consenting personally, consent must be obtained from that client's representative.

No client who has declined consent may be included in a recording.

Where staff or relatives are to be included in the recordings their verbal consent must be obtained for recordings.

Private Recordings

Introduction

Private recordings include any photographs, video and audio recordings made in any WCDHB and CDHB premises by patients or their families/whanau or support persons.

Patients, their families or support persons are entitled to make a recording except in the following circumstances:

- when making the recording might jeopardise patient safety
- when the staff involved in caring for the patient have not given consent to be recorded, and need to continue the caregiving

Patients, visitors and staff member's rights to privacy of identification are to be respected. The person wishing to make the recording must seek the verbal consent of all those likely to be included.

5. REFERENCES

a. Code of Health and Disability Services Consumers' Rights 1996
b. Health Information Privacy Code 1994
c. The Health Act 1956
d. The Protection of Personal and Property Rights Act 1988
e. The Children's, Young Persons and Their Families Act 1989

6. ASSOCIATED FORMS

a. Client Service Agreement