

CIRCULAR

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PATIENT INFORMATION AND CONSENT TO MEDICAL TREATMENT

This circular supercedes Circulars 92/21. Patient matters manual also refers.

The attached document states the Department's policies in relation to consent to medical treatment and the provision of information to patients. The document outlines the circumstances where these matters should be documented in writing.

The main points of this document are as follows:

- < A patient needs to give consent in broad terms before undergoing a procedure or treatment - this is to avoid an action for assault and battery;
- < A patient needs to be informed of the material risks associated with a procedure or treatment - this is good practice, and a practitioner who fails to provide this information before a patient undergoes a procedure risks an action for negligence;
- < Responsibility for the above rests with the attending medical officer.

This document expands upon the basis for these requirements, and specifies the circumstances in which routine policy may be departed from. Although the purpose of this document is to outline the legal requirements to be observed in providing medical treatment in public hospitals, the circular may be of assistance to all health care providers in hospitals who undertake procedures, provide information to patients or perform tasks which require patient consent to be sought.

A new Request/Consent Form is attached which should be adopted by all public hospitals as soon as practicable. Other institutions are also encouraged to use the form.

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Director-General

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Distributed in accordance with circular list(s):

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GUARDIANSHIP ACT 1987 - SUBSTITUTE CONSENT

This attachment sets out the circumstances in which substitute consent can be obtained, from whom and the legal requirements for ensuring that a substitute consent is valid.

1. What is the purpose of the Guardianship Act 1987?

The Guardianship Act 1987 establishes who can give a valid substitute consent in circumstances where a person is unable to consent to medical or dental treatment. The object of the Act is to ensure that:

- < people are not deprived of necessary treatment merely because they lack the capacity to consent to the carrying out of such treatment; and
- < any treatment that is carried out for such people is carried out to promote their health and wellbeing.

The Act therefore identifies a substitute decision maker for patients unable to consent which is consistent with the level of treatment proposed. In some cases (outlined below) treatment may proceed without consent.

2. When do the provisions of the Guardianship Act apply?

The Act applies to a patient who is of or above the age of sixteen years and who is incapable of giving consent to the carrying out of medical or dental treatment. Section 33(2) of the Guardianship Act provides that a person is incapable of giving consent if the person is incapable of understanding the general nature and effect of the proposed treatment, or is incapable of indicating whether or not he or she consents or does not consent to the treatment.

3. What if the treatment is required in an emergency?

The Guardianship Act provides that treatment may be provided to a person who is unable to consent where the medical practitioner or dentist carrying out or supervising the treatment considers treatment is necessary as a matter of urgency to save life, to prevent serious damage to patient's health, or (except in the case of *Aspecial medical treatment*), to alleviate significant pain or distress. A substitute consent is not required in these circumstances.

4. Is medical or dental treatment defined in the Guardianship Act?

Medical or dental treatment is defined to mean:

- < medical treatment (including any medical or surgical procedure, operation or examination and any prophylactic, palliative or rehabilitative care) normally carried out by or under the supervision of a medical practitioner; or
- < dental treatment (including any dental procedure operation or examination) normally carried out by or under the supervision of a dentist.

In the case of a clinical trial, medical treatment is taken to include the giving of placebos to some participants in the trial.

However, the Act specifies that this does not include:

- (i) any non intrusive examination made for diagnostic purposes (including a visual examination of the mouth, throat, nasal cavity, eyes or ears);
- (ii) first aid medical or dental treatment; or
- (iii) the administration of a pharmaceutical drug for the purpose, and in accordance with the dosage level, recommended in the manufacturer's instructions for which a prescription is not normally required and which is normally self administered.

These minor procedures may proceed without consent.

5. What must a medical practitioner do before they carry out treatment when a person is unable to consent?

Practitioners should be aware, it is an offence under section 35 of the Act to provide medical or dental treatment to a person who is 16 years or older who is incapable of giving consent unless:

- < a substitute consent for the treatment has been obtained in accordance with the Guardianship Act 1987 NSW; or
- < the carrying out of the treatment is authorised by the Guardianship Act and no consent is required.

Therefore practitioners need to determine whether treatment can proceed without consent or whether a substitute consent is required, and from whom.

The Act makes different arrangements for obtaining consent depending on the level of intervention proposed. Distinctions are drawn between **minor treatment**, **major treatment** and **special medical treatment**.

It is the legal responsibility of the medical practitioner carrying out the treatment to ensure that consent has been obtained.

6. What is special medical treatment?

Special medical treatment is defined as:

- (a) any treatment that is intended, or is reasonably likely, to have the effect of rendering permanently infertile the person on whom it is carried out;
- (b) any new treatment that has not yet gained the support of a substantial number of medical practitioners or dentists specialising in the area of practice concerned; or
- (c) any treatment declared by the regulations to be special treatment for the purposes of the Guardianship Act

The following treatments have been declared by the Regulations to be special treatment:

- (a) any treatment that involves the administration of a drug of addiction (other than in association with the treatment of cancer or palliative care of a terminally ill patient) over a period or periods totalling more than 10 days in any 30 days;
- (b) any treatment that is carried out for the purpose of terminating pregnancy;
- (c) any treatment in the nature of a vasectomy or tubal occlusion;
- (d) any treatment that involves the use of an aversive stimulus, whether mechanical, chemical physical or otherwise.

Recent amendments to the Act have clarified that special medical treatment does not include treatment administered in the course of a clinical trial. Special arrangements apply to such treatment - see paragraph 11.

7. Who provides substitute consent to special medical treatment?

Consent to the initial administration of special medical treatment may only be granted by the Guardianship Tribunal. The process for making an application to the Tribunal is detailed later in the document.

Once the initial consent of the Guardianship Tribunal has been obtained, the guardian of a person may consent to the carrying out of continuing or further special treatment if the Tribunal has authorised the guardian to give consent to the continuation of treatment or to further treatment of a similar nature.

Practitioners should note that the Guardianship Regulations identify two specific types of special medical treatment for which different criteria apply for obtaining consent from the Tribunal. These include: (i) any special treatment that involves the administration to a patient of one or more restricted substances for the purpose of affecting the central nervous system of the patient, but only of the dosage levels, combination of the numbers of restricted substances used or the duration of the treatment are outside the accepted mode of treatment; and (ii) any special treatment that involves the use of androgen reducing medication for the purpose of behavioural control. If these treatments are to be administered, the matters should be discussed with the Tribunal.

8. What is major medical treatment?

The definition of major medical treatment is broad. It includes:

- (i) any treatment that involves the administration of a long acting injectable hormonal substance for the purpose of contraception or menstrual regulation;
- (ii) any treatment that involves administration of a drug of addiction (except where classified as special medical treatment as outlined above);
- (iii) Any treatment that involves the administration of a general anaesthetic or other sedation, but not involving treatment involving:

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- (a) sedation used to facilitate the management of fractured or dislocated limbs; or
 - (b) sedation used to facilitate the insertion of an endoscope into a patient's body for diagnostic purposes unless the endoscope is inserted through a breach or incision in the skin or a mucous membrane.
- (iv) Any treatment used for the purpose of eliminating menstruation;
- (v) Any treatment that involves the administration of a restricted substance for the purpose of affecting the central nervous system, but not a treatment;
- (a) substance that is intended to be used for analgesic, antipyretic, anti-Parkinsonian, anticonvulsant, antiemetic, anti-nauseant or antihistaminic purposes; or
 - (b) that is to be given only once; or
 - (c) that is a PRN treatment (that is, given when required, according to the patient's needs that may be given not more than 3 times a month); or
 - (d) given for sedation in minor medical procedures.
- (vi) Any treatment that involves a substantial risk to the patient (that is risk that amounts to more than a mere possibility) of: (a) death; or (b) brain damage; or (c) paralysis; or (d) permanent loss of function of any organ or limb; or (e) permanent and disfiguring scarring; or (f) exacerbation of the conditions being treated; or (g) an unusually prolonged period of recovery; or (h) a detrimental change of personality; or (i) a high level of pain and stress.
- (vii) Any treatment involving testing for the HIV virus.

Major dental treatment is defined to include treatments involving the administration of a general anaesthetic or simple sedation, a procedure intended or likely to result in removal of all teeth, a treatment likely to result in the patient's ability to chew food being significantly impaired for an indefinite or prolonged period.

Major treatment does not include treatment administered in the course of a clinical trial.

9. What is minor treatment?

Minor treatment is any medical or dental treatment which does not fall within the meaning of special medical treatment or major treatment. As noted at point 4, this does not include a number of specific minor procedures for which no consent is required.

Minor treatment does not include treatment administered in the course of a clinical trial.

10. How is consent obtained for major and minor medical treatment?

Consent to carry out major and minor medical treatment can be obtained from the *person responsible* for the patient within the meaning of the Act.

A consent given by a person responsible has effect as if the treatment had been consented to by the patient. However, the consent of a person responsible is not valid if the practitioner carrying out or supervising the treatment is aware or ought to be aware the patient objects to the procedure or treatment or if the proposed treatment is to be carried out for any purpose other than that of promoting or maintaining the health and well-being of the patient. However, an objection by the patient may be disregarded if the patient has minimal or no understanding

of what the treatment entails and the treatment will cause the patient no distress or, if it will cause the patient some distress, the distress is likely to be reasonably tolerable and only transitory.

Alternatively, where such an objection is expressed by a patient, the request for consent must be referred to the Tribunal except where a legal guardian of the patient has been specifically authorised by the Tribunal to override the patient's objection.

In the case of major medical treatment the Guardianship Tribunal may also consent to treatment. However, in all instances, practitioners should first ascertain if there is a person responsible for a patient unable to consent before seeking the consent of the Guardianship Tribunal.

Whilst the Guardianship Tribunal can also provide consent to minor treatment, such treatment may be carried out on a patient without consent if there is no person responsible for the patient or the person responsible is unavailable or unwilling to make a decision concerning the patient. In such cases, the practitioner carrying out the minor treatment is required to certify in writing in the patient's clinical record that the treatment is necessary and is the form of treatment that will most successfully promote the patient's health and well being; and the patient does not object to the carrying out of the treatment.

If consent is refused by a person responsible and the practitioner remains of the view that the treatment is in the best interests of the patient, the matter should be referred to the Guardianship Tribunal.

11. Treatment administered in the course of a clinical trial

A clinical trial is defined as a trial of drugs or techniques that necessarily involves the carrying out of medical or dental treatment on the participants in a trial. This includes the administration of placebos to patients.

A person unable to consent may not participate in a clinical trial unless the trial has been approved by the Guardianship Tribunal under the Act. In approving such a trial, the Guardianship Tribunal will decide whether consent can be granted by person responsible or should be granted by the Tribunal.

12. Who is the person responsible for a patient?

The Act establishes a hierarchy for determining who is the person responsible for a person unable to consent to treatment.

- < If the person is under guardianship, the guardian is the person responsible.
- < If there is no guardian, an enduring guardian appointed by the patient with authority to make decisions regarding medical care.
- < If there is no enduring guardian, a spouse (including a de facto spouse) with whom the person has a close continuing relationship is the person responsible.
- < If there is no guardian or spouse, a person who has the care of the patient unable to consent is the person responsible. Such a person is regarded to have the care of the patient if they have provided, or have arranged to be provided, domestic services and support otherwise than for remuneration. Where the patient has been cared for by a

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person in a nursing home, hostel, boarding house or other group accommodation, that person does not have care of the person. In such cases the patient remains in the care of the person he or she was immediately with before residing in the institution.

- < If there is no guardian, spouse, or carer, a close relative or friend may act as the person responsible provided they are not receiving remuneration for any services provided.

If the person is in the care of the Director-General under s 13 of the Guardianship Act, the Director-General is the person responsible.

13. Who is an enduring guardian?

Until 1997, guardians were appointed by either the Tribunal of the Supreme Court. However, amendments to the Act provided that an individual may appoint an enduring guardian to carry out certain roles and functions where the individual lacks sufficient capacity to make appropriate decisions.

A person 18 years of age or above may appoint an enduring guardian. Such an appointment must be made on the prescribed form, copies of which are available from the Guardianship Tribunal, and be witnessed by a legal practitioner or a clerk of the local court.

An appointment only has effect during a period in which the person is in need of a guardian. Further, the decisions which an enduring guardian may make on behalf of the person in need of a guardian are determined by the prescribed form appointing the person. As the person appointing the enduring guardian may limit the decisions which may be made by the appointee, practitioners should ask to review the appointment form to ensure that the enduring guardian has power to make decisions in relation to medical or dental treatment.

14. What is required to obtain consent from a person responsible?

A request to a person responsible for consent may be made by any person. Such a request shall specify the following information:

- (a) the grounds on which it is alleged that the patient is a patient to whom this part applies;
- (b) the particular condition of the patient that requires treatment;
- (c) the alternative courses of treatment that are available in relation to that condition;
- (d) the general nature and effect of each of the courses of treatment;
- (e) the nature and degree of the significant risks (if any) associated with each of these courses of treatment; and
- (f) the reasons for which it is proposed that any particular course of treatment should be carried out.

A request to a person responsible is to be made in writing. However:

- (i) if the request is for major medical treatment, it may be made orally if it is not practicable to make the request in writing because of the need to provide the treatment quickly.

- (ii) if the request is for minor medical or dental treatment, the request may be made orally, if it is not practicable to make the consent in writing or the person whose consent is sought does not require the consent to be made in writing.

Written confirmation of an oral request for consent must be provided for major treatment or for minor treatment where the person whose consent was sought requires confirmation.

15. What must the person responsible do to grant a valid consent?

In all cases, the person responsible must consider the views (if any) of the patient, the information provided by the person requesting consent and the objectives of the Act.

Consent to the carrying out of major medical treatment is to be given in writing, however, the consent may be given orally if it is not practicable to do so in writing because of the need to provide treatment quickly. Written confirmation of the consent must be provided where oral consent is provided.

Consent to the carrying out of minor medical treatment is also to be given in writing, although it may be given orally if: (i) it is not practical to give written consent; and (ii) the person by whom the treatment is to be carried out does not require it to be given in writing. However, written confirmation of the consent may be requested.

16. Do records need to be kept?

A person who carries out treatment pursuant to a substitute consent is to keep a written record of the name of the person by whom consent was given, the date, conditions on the consent and the treatment. If written consent was obtained, the form should be kept. Such records must be retained for seven years.

17. What if an application needs to be made to the Guardianship Tribunal?

Requests to the Guardianship Tribunal for consent generally require the same information that needs to be provided to a person responsible. A standard request form is available from the Guardianship Tribunal ph (02) 9555-8500; Toll Free 1800 463 928 or fax (02) 9555-9049. The Tribunal has an after-hours service which may be contacted on the toll free number.