First print

New South Wales

Guardianship Amendment Bill 1998

Explanatory note

This explanatory note relates to this Bill as introduced into Parliament.

Overview of Bill

The object of this Bill is to amend the *Guardianship Act 1987* to provide a mechanism that will allow the Guardianship Tribunal to approve certain clinical trials as trials in which persons who lack the capacity to consent to their own medical and dental treatment may participate.

The Bill also makes consequential and other minor amendments to the *Guardianship Act 1987*.

Outline of provisions

Clause 1 sets out the name (also called the short title) of the proposed Act.

Clause 2 provides for the commencement of the proposed Act on a day or days to be appointed by proclamation.

Clause 3 is a formal provision giving effect to the amendments to the *Guardianship Act 1987* set out in Schedule 1.

Schedule 1 Amendments

Schedule 1 [1] replaces a phrase in section 6M of the *Guardianship Act 1987* (the Act) so as to make the terminology of that section consistent with other provisions of the Act.

Schedule 1 [2] amends section 32 (which specifies the objects of Part 5 (Medical and dental treatment) of the Act) so as to bring the participation in clinical trials of patients to whom that Part applies within its ambit.

Schedule 1 [3] inserts a definition of ***clinical trial*** in section 33 (1) of the Act for the purposes of Part 5.

Schedule 1 [5] amends the definition of ***medical or dental treatment*** in section 33 (1) of the Act to make it clear that such treatment in the course of a clinical trial includes the giving of placebos to some of the participants in the trial.

Schedule 1 [4], **[6]** and **[7]** amend the definitions of ***major treatment***, ***minor treatment*** and ***special treatment***, respectively, in section 33 (1) of the Act to make it clear that treatment in the course of a clinical trial does not fall within any of those definitions.

Section 35 of the Act makes it an offence for a person to carry out medical or dental treatment on a patient to whom Part 5 applies unless the treatment is authorised as provided by that section. **Schedule 1 [8]** ensures that the relevant penalty for the offence (imprisonment for 7 years—the same penalty as for carrying out unauthorised ***special treatment*** on such a patient) is provided for the offence of carrying out unauthorised treatment in the course of a clinical trial on such a patient.

Schedule 1 [9] inserts a new Division 4A (proposed sections 45AA and 45AB) in Part 5 of the Act. Proposed section 45AA empowers the Guardianship Tribunal (the Tribunal) to approve certain clinical trials as trials in which patients to whom Part 5 applies may participate. Such an approval

may be given only if the Tribunal is satisfied that (among other things) the drugs or techniques being tested in the trial are intended to cure or alleviate a particular condition from which the patients suffer, that the trial will not involve any known substantial risk to the patients (or, if there are existing treatments for the relevant conditions, will not involve material risk greater than the risks associated with those treatments), that it is in the best interests of patients with that condition that they take part in the trial, and that the trial has been approved by a relevant ethics committee. However, the proposed section also makes it clear that the Tribunal's approval of a trial does not, of itself, authorise the participation in the trial of any particular patient to whom Part 5 applies. Formal consent to carry out medical or dental treatment in the course of the clinical trial must be obtained under Division 3 or 4 of that Part in respect of each individual patient.

Proposed section 45AB provides that, having approved a particular trial, the Tribunal may determine that the function of granting or withholding consent to the carrying out of medical or dental treatment in the course of the trial on patients to whom Part 5 applies is to be exercised by the ***persons responsible*** (within the meaning of Part 5) for those patients, or that the Tribunal is to retain that function itself.

Section 51A of the Act allows the Tribunal to be constituted by fewer than 3 members when exercising certain functions, including the function of giving of consent to the carrying out of ***minor medical or dental treatment*** (but not ***major treatment*** or ***special treatment***). **Schedule 1 [10]** and **[11]** amend that section to make it clear that treatment in the course of a clinical trial is also excluded from its operation.

Schedule 1 [12] amends section 76A (Annual report) of the Act to provide that, if the Tribunal approved a clinical trial during the period covered by the report required by that section, the report must contain details of the trial.

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A Bill for

An Act to amend the *Guardianship Act 1987* in relation to the participation in clinical trials of persons who lack the capacity to consent to their own medical and dental treatment; and for other purposes.

The Legislature of New South Wales enacts:

1 Name of Act

This Act is the *Guardianship Amendment Act 1998*.

2 Commencement

This Act commences on a day or days to be appointed by proclamation.

3 Amendment of Guardianship Act 1987 No 257

The *Guardianship Act 1987* is amended as set out in Schedule 1.

Schedule 1 Amendments

(Section 3)

[1] Section 6M Tribunal may declare appointment has effect

Omit "in need of guardianship" from section 6M (2) (a).
Insert instead "in need of a guardian".

[2] Section 32 Objects

Omit "only" from section 32 (b).

[3] Section 33 Definitions

Insert in alphabetical order in section 33 (1):

> ***clinical trial*** means a trial of drugs or techniques that necessarily involves the carrying out of medical or dental treatment on the participants in the trial.

[4] Section 33 (1), definition of "major treatment"

Insert "or treatment in the course of a clinical trial" after "special treatment".

[5] Section 33 (1), definition of "medical or dental treatment"

Omit "but does not include".
Insert instead "(and, in the case of treatment in the course of a clinical trial, is taken to include the giving of placebos to some of the participants in the trial), but does not include".

[6] Section 33 (1), definition of "minor treatment"

Omit "neither special treatment nor major treatment".
Insert instead "not special treatment, major treatment or treatment in the course of a clinical trial".

[7] Section 33 (1), definition of "special treatment"

Omit paragraph (c). Insert instead:

(c) any other kind of treatment declared by the regulations to be special treatment for the purposes of this Part,

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

[8] Section 35 Offences

Insert "or treatment in the course of a clinical trial" after "special treatment" in the penalty provision to section 35 (1).

[9] Part 5, Division 4A

Insert after section 45A:

Division 4A Clinical trials

45AA Tribunal may approve clinical trials

(1) The Tribunal may approve, in accordance with this section, a clinical trial as a trial in which patients to whom this Part applies may participate.

(2) The Tribunal may give an approval under this section only if it is satisfied that:

(a) the drugs or techniques being tested in the clinical trial are intended to cure or alleviate a particular condition from which the patients suffer, and

(b) the trial will not involve any known substantial risk to the patients (or, if there are existing treatments for the condition concerned, will not involve material risks greater than the risks associated with those treatments), and

(c) the development of the drugs or techniques has reached a stage at which safety and ethical considerations make it appropriate that the drugs or techniques be available to patients who suffer from that condition even if those patients are not able to consent to taking part in the trial, and

(d) having regard to the potential benefits (as well as the potential risks) of participation in the trial, it is in the best interests of patients who suffer from that condition that they take part in the trial, and

(e) the trial has been approved by a relevant ethics committee and complies with any relevant guidelines issued by the National Health and Medical Research Council.

(3) The fact that a clinical trial will or may involve the giving of placebos to some of the participants in the trial does not prevent the Tribunal from being satisfied that it is in the best interests of patients that they take part in the trial.

(4) The Tribunal's approval of a clinical trial under this section does not operate as a consent to the participation in the trial of any particular patient to whom this Part applies. The appropriate consent must be obtained under Division 3 or 4 before any medical or dental treatment in the course of the trial is carried out on the patient.

(5) In this section:

ethics committee means:

(a) for so long as there is any relevant Institutional Ethics Committee registered by the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act 1992* of the Commonwealth—an Institutional Ethics Committee so registered, or

(b) in the absence of such a committee, an ethics committee established by:

(i) an area health service or a public hospital, or

(ii) a university, being an ethics committee concerned, wholly or partly, with medical research, or

(iii) the National Health and Medical Research Council.

45AB Consent for participation in clinical trials in individual cases

(1) If the Tribunal is satisfied as to the matters specified in section 45AA (2) in relation to a clinical trial, it may, by order, determine:

(a) that the function of giving or withholding consent for the carrying out of medical or dental treatment on patients in the course of the trial is to be exercised by the persons responsible for the patients (in which case Division 3 applies), or

(b) that the Tribunal is to exercise that function itself (in which case Division 4 applies).

(2) Before making a determination referred to in subsection (1) (a), the Tribunal must be satisfied that the form for granting consent and the information available about the trial provide sufficient information to enable the persons responsible to decide whether or not it is appropriate that the patients should take part in the trial.

[10] Section 51A Fewer than 3 Tribunal members may deal with certain matters

Omit "or special treatment" from section 51A (1) (a).
Insert instead ", special treatment or treatment in the course of a clinical trial".

[11] Section 51A (3)

Omit "and ***special treatment***".
Insert instead ", ***special treatment*** and ***clinical trial***".

[12] Section 76A Annual report

Insert after section 76A (2):

(2A) Despite subsection (2), if the Tribunal, during the period of 12 months covered by the report, approved a clinical trial (within the meaning of Part 5) under section 45AA, the report must include details of the trial (or proposed trial).