

[Act 1998 No 7]



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 *minormedical 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.