Guide to the legislation relating to the provision of consent for a person with impaired capacity to provide informed consent to participate in the conduct of human research

New South Wales

This guide provides an outline of the relevant legal requirements in the State of New South Wales regarding the provision of consent for a person 16 years of age or older who lacks the capacity to provide informed consent to participate in the conduct of human research. It has been prepared to assist researchers, HRECs and other stakeholders to understand the relevant legal requirements.

Relevant legislation

The following legislation may be relevant to considerations of whether a person who is 16 years of age or older with impaired capacity to provide informed consent can participate or be enrolled in a '*clinical trial*':

- *Guardianship Act 1987* (NSW) (**GA**)
- *Guardianship Regulation 2010* (NSW) (**GR**)

Where are the relevant requirements found?

The relevant requirements are set out in Division 4A of Part 5 of the GA.

What types of research does the GA apply to?

The requirements of the GA apply to a *clinical trial* which might involve a participant who is 16 years of age or older and who is *incapable of giving consent*. A person is incapable of giving consent if they are incapable of understanding the general nature and effect of the proposed treatment, or are incapable of indicating whether or they consents or do not consent to the treatment being carried out (section 33(2) GA).

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 the trial. A detailed discussion of the definition of *clinical trial*, including the decision of the Appeal Panel of the Civil and Administrative Tribunal in *Shehabi v Attorney General (NSW)* [2016] NSWCATAP 137, is included in the Consent and Guardianship Report.

Medical or dental treatment is 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, dental treatment (including any dental procedure, operation or examination) normally carried out by or under the supervision of a dentist and any other act declared by the GR to be treatment (none have been declared by the GR to date).

In the case of treatment in the course of a *clinical trial*, *medical or dental treatment* is taken to include the giving of placebos to some of the participants in the trial. However, *medical or dental treatment* does not include:

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

What are the specific legal requirements under the GA for the conduct of a *clinical trial*?

A *clinical trial* which is to be conducted in New South Wales and which may include a person who is 16 years of age or older who is unable to provide informed consent to treatment must be submitted to the NSW Civil and Administrative Tribunal (**NSW Tribunal**) for approval.

The approval process consists of two elements:

- The first involves the NSW Tribunal deciding whether to approve the *clinical trial* to proceed.
- The second involves the NSW Tribunal determining whether consent for a person aged 16 years or older who has impaired capacity to provide informed consent to participate in the *clinical trial* may be given by the NSW Tribunal or by that person's *person responsible*.

Step 1 – Approval of clinical trial by NSW Tribunal

The NSW Tribunal **may** approve a *clinical trial* as a trial in which patients who lack capacity to provide consent may participate.

The NSW Tribunal may give approval to a *clinical trial* only if it is satisfied of all of the following:

- The drugs or techniques being tested in the clinical trial are intended to cure or alleviate a particular condition from which the patients suffer.
- 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.
- 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.
- 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.
- The trial has been approved by a relevant 'ethics committee' and complies with any relevant guidelines issued by the NHMRC.

The GA defines an *ethics committee* as one of the following:

- As 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* (Cth) - an Institutional Ethics Committee so registered.
- In the absence of such a committee, an ethics committee established by:
    - a local health district or a public hospital
    - a university, if that ethics committee is concerned, with medical research, or
    - the NHMRC.

Step 2 – Determination of who may give consent for an individual to participate in an approved clinical trial

For a *clinical trial* that it approves under the GA, the NSW Tribunal will determine that consent for the carrying out of *medical or dental treatment* on patients in the course of the trial may be given by either the NSW Tribunal or by the patient's *person responsible*.

A. Consent given by the NSW Tribunal itself

Any person may apply to the NSW Tribunal for consent to the carrying out of *medical or dental treatment* on a patient in the course of a *clinical trial*.

The application must specify the matters which are detailed in section 42(2) of the GA. These include the grounds on which it is believed that the patient is a patient to whom the relevant GA provisions apply and the reasons for which the particular course of treatment should be carried out on that patient.

The NSW Tribunal will conduct a hearing into an application for consent to the *carrying out of medical or dental treatment* on a patient in the course of a *clinical trial*. If the NSW Tribunal is satisfied that it is appropriate for the treatment to be carried out, it may consent to the carrying out of the treatment for that patient.

B. Consent given by *person responsible*

A *person responsible* may be requested to provide consent to the carrying out of *medical or dental treatment* on the patient in the course of a *clinical trial*.

A *person responsible* is, in descending order of hierarchy, one of the following:

- The person's guardian, if any, but only if the order or instrument appointing the guardian provides for the guardian to exercise the function of giving consent to the carrying out of *medical or dental treatment* on the person
- The spouse of the person, if any, if:
    - the relationship between the person and the spouse is close and continuing, and
    - the spouse is not a person under guardianship.
- A person who has the care of the person
- A close friend or relative of the person

The request for a *person responsible* to provide consent must be made in writing (Regulation 13, GR) and the consent given by *person responsible* must also be given in writing (Regulation 14, GR).

Can a medical research procedure be carried out on an impaired capacity patient without consent in emergency circumstances?

There is no legislative basis for 'delayed' or 'waived consent' for clinical trials on patients incapable of consenting. Section 37 of the GA provides that *medical or dental treatment* may be carried out on an impaired capacity patient without consent if the medical practitioner or dentist carrying out or supervising the treatment considers the treatment is necessary, as a matter of urgency to:

- save the patient's life
- prevent serious damage to the patient's health, or
- prevent the patient from suffering or continuing to suffer significant pain or distress.

To the extent that a *clinical trial* involves the provision of medical or dental treatment in the circumstances described above, section 37 might apply to it. However, the relevant *clinical trial* would still need to be submitted to the NSW Tribunal for approval.

What other roles does the NSW Tribunal have in relation to the conduct of a clinical trial?

Apart for the functions of the NSW Tribunal described above, the NSW Tribunal exercises other powers which may be relevant to the conduct of a clinical trial. For example, the NSW Tribunal determines issues relating to guardians and hears disputes relating to matters arising under the GA. The NSW Tribunal can also confer on guardians the authority to override a patient's objections in limited circumstances (section 46A).

Current Review of the GA

The GA is currently being reviewed by the NSW Law Reform Commission. Relevantly, the NSW Attorney-General has asked the Law Reform Commission to consider the 'provisions of Division 4A of Part 5 of the Guardianship Act 1987 relating to clinical trials'. As of 7 February 2017 the Law Reform Commission's review is continuing.

Checklist of matters for HRECs to consider

- Does the research involve participants aged 16 years or older who lack the capacity to provide informed consent?
- Does the research constitute a *clinical trial* as defined in the GA?
- If the research constitutes a *clinical trial*, does the proposal satisfy the requirements for submission to the NSW Tribunal for approval?
- In the event the NSW Tribunal determines that consent is to be given by the *person responsible* for that *clinical trial*, does the proposal include appropriate documentation to ensure that the request to the *person responsible* to provide consent and any consent given by the *person responsible* will be in writing?
- If the research is not a *clinical trial*, does the proposal include appropriate documentation to enable the *person responsible* to consider a request to provide consent and to give that consent?
- Is the HREC's approval conditional on the research being conducted in accordance with all relevant legal requirements regarding the approval of the research proposal by the NSW Tribunal and the obtaining of consent for participants who lack the capacity to provide informed consent?
- Having considered the above, does the HREC need to seek further advice from the researcher?