NCAT
NSW Civil & Administrative Tribunal

Clinical trials

This fact sheet explains how NCAT's Guardianship Division determines applications for the approval of clinical trials which seek to involve a person with a decision making disability.

Role of NCAT's Guardianship Division

Under *Part 5 of the Guardianship Act 1987*, clinical trials which seek to involve a person aged 16 years or older with decision making disability must be approved by the Guardianship Division of the NSW Civil and Administrative Tribunal (NCAT).

NCAT must also decide whether consent to the treatment proposed during the trial is to be given by a *person responsible* or by NCAT itself.

The purpose of the provisions is to ensure that people with disabilities:

- Can access treatment which is only available through a clinical trial, and
- Are only provided with treatment that promotes their health and well-being.

NCAT can only approve a clinical trial if it is satisfied that:

- Only people who have the condition to be treated will participate in the trial
- Risks posed to the patient are no greater than those posed by existing treatments
- Development of the treatment has reached a stage at which safety and ethical considerations make it appropriate for the treatment to be available to people who cannot consent
- Approval by the relevant ethics committee has been obtained
- Relevant National Health and Medical Research Council guidelines have been complied with, and
- Potential benefits are balanced against potential risks, it is in the interests of people who have the condition to participate in the trial.

In many clinical trials, some of the participants receive only a placebo. NCAT can only approve a clinical trial that use a placebo if there is no treatment for the condition being investigated other than medical observation, treatment of symptoms and nursing care.

Application process

Completing the form

An application form for the approval of a clinical trial needs to be completed and submitted with all relevant documents to NCAT's Guardianship Division.

- **Part 1** identifies the details of the applicant.
- **Part 2** identifies the details of the clinical trial and the company or organisation sponsoring the trial.
- **Part 3** identifies the trial sites. NCAT can only approve clinical trial sites in NSW. If the trial is proposed to be carried out at more than one site in NSW, the details of each site must be completed. If there are more than five sites, please include this information in an attachment.
- **Part 4** provides space for additional research contacts. This would include the full details of any person involved in the trial who may want to attend or participate in the hearing, but is not the trial co-ordinator or a principal investigator at a site.
- **Part 5** identifies the persons who will be available to attend or participate in the hearing and any special requirements.
- **Part 6** identifies the types of documents that are required to be submitted (in quadruplicate) to NCAT before a hearing date can be scheduled.

The applicant should be an appropriately qualified representative of the company proposing the trial. All documentation must be provided in quadruplicate. There is no fee for lodging an application.

If the trial is proposed to be carried out at more than one site in NSW, the name of each site should be provided. The application form may be used to add new sites to an existing clinical trial which has been approved by NCAT.

The application form for approval of a clinical trial is available on the NCAT website **www.ncat.nsw.gov.au**.

Required submissions

NCAT must receive the following documents:

- A letter addressing the legislative criteria to be considered by the Tribunal
- The Current Trial Protocol
- Final Ethics Committee Approval (for each site)
- The Ethics Committee Application (for each site)
- Person Responsible Information Sheet and Consent Form (for each site)
- A paper copy of the PowerPoint presentation to be given during the hearing.

Optional submissions may include the investigator's brochure and/or the medicine information sheet.

Legislative criteria

The letter must address each of the following legislative criteria as a separate heading.

Under s45AA(2) of the *Guardianship Act 1987*, NCAT may approve a clinical trial 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.

The use of placebos does not prevent NCAT from being satisfied that it is in the best interests of the patients that they take part in the trial.

Ethics committee approval

Given the requirements outlined in section 45AA(2)(e) of the *Guardianship Act 1987*, NCAT will not hear an application for approval of a clinical trial until the ethics committee application and approval have been submitted to NCAT for all nominated sites.

If the application is to add new sites to an existing clinical trial, the ethics committee approval for each of the additional sites must be submitted.

Consent for trial participants

NCAT's approval of a clinical trial does not operate as consent to the participation of a particular individual in the trial.

The consent requirements that apply for treatment of an adult with a decision making disability apply in relation to the individual treatments provided during the trial (see Part 5 of the *Guardianship Act 1987*).

Before delegating the authority to consent to persons responsible, NCAT must be satisfied that the form for granting consent and the information sheet made available to the person responsible are sufficient to enable them to make an informed decision.

Person responsible

A person responsible is not necessarily the patient's next of kin or carer. A *person responsible* is one of the following people in order of priority.

1. **Guardian** – An appointed guardian (or enduring guardian) who has been given the right to consent to medical and dental treatments, **or**
2. **Spouse or partner** – If there is no guardian, a spouse, de-facto spouse or partner where there is a close continuing relationship, **or**
3. **Carer** – If there is no spouse or partner, an unpaid carer who provides or arranges for domestic support on a regular basis, **or**
4. **Relative or friend** – If there is no carer, a friend or relative who has a close personal relationship with the person.

The person next in the hierarchy may become the *person responsible* if:

- A person responsible declines in writing to exercise the function, or
- A medical practitioner or other qualified person certifies in writing that the person responsible is not capable of carrying out their functions.

Requirements for Information Sheet

The Person Responsible Information Sheet must identify the name and details of the patient. It must also conform to the terminology requirements for person responsible. See also section 45AB(2) of the *Guardianship Act 1987*.

A person responsible is not necessarily the patient's next of kin or carer. This terminology should be avoided in the Information Sheet and Consent Form.

The Information Sheet must also clearly identify the risks associated with the clinical trial. This includes full and detailed disclosure of the each of the risks identified in the protocol. The language used in the Information Sheet must not be diluted to the extent that the risks are understated.

Delayed consent

Delayed consent is not permissible under NSW Legislation. Any protocol that contains provisions regarding the use of delayed consent must identify that it will not be used at NSW sites.

Hearing process

Pre-hearing

Upon receipt of the application, the matter will be allocated to a Team Leader in NCAT's Guardianship Division. The Team Leader will be the point of contact for the trial and will ensure that all documents have been submitted.

Clinical trial hearings are held approximately once every 6 weeks. Upon reviewing the application for completeness, NCAT will allocate a hearing date and notify the applicant of the details.

The Team Leader will contact the applicant before the hearing to confirm the details of those who will be attending or participating by phone.

NCAT prefers that a presentation be made by a principal investigator with PowerPoint slides. This PowerPoint presentation should be submitted by email to the Team Leader at least 5 working days before the hearing.

The hearing

The applicant must attend the hearing in person. The trial co-ordinator or a principal investigator should also be available, in person or by phone, to answer questions about the trial.

If there are multiple sites, the applicant should advise the principal investigators about the application and the details of the hearing should they wish to give evidence.

Clinical trial hearings will generally be heard by three Tribunal Members - a Senior Member (Legal), Senior Member (Professional) and a General Member (Community).

NCAT can make the following orders:

- Approval – the *person responsible* to consent on behalf of participants.
- Approval – NCAT to consent on behalf of participants.
- Non-Approval
- Adjournment.

Participants in the hearing will be advised of NCAT's decision at the end of the hearing, either verbally or in writing at a later date if the matter is reserved. The order and the reasons for decision will be sent to the applicant.

Consent from NCAT

The only opportunity for a patient without a *person responsible* to be included in the trial is by the consent of NCAT. A health professional can make an application to NCAT for consent to special medical treatment.

The application should identify: the grounds on which the patient requires consent from NCAT; the particular condition of the patient that requires treatment; alternative courses of treatment that are available; the general nature and effect of these courses of treatment; the nature and degree of the risks associated with the treatment; and the reasons for which it is proposed that the treatment be carried out.

Please see the fact sheets *Special medical treatment guidelines* and *Consent to medical or dental treatment*.

Contact NCAT

1300 006 228 | www.ncat.nsw.gov.au

Interpreter Service (TIS) 13 14 50
National Relay Service for TTY users 13 36 77

For more information and assistance visit the NCAT website or contact NCAT's Guardianship Division on (02) 9556 7600 or 1300 006 228.