NCAT
NSW Civil and Administrative Tribunal

July 2025

Application for

Approval of a clinical trial

GUARDIANSHIP DIVISION

Before completing this application form, please refer to the 'Clinical trials' fact sheet. For more information contact NCAT's Guardianship Division on (02) 9556 7600 or 1300 006 228.

1. The applicant

title	☐ Dr ☐ Mr ☐ Mrs ☐ Ms ☐ Other, specify
given name	
family name	
organisation and position	
postal address	
suburb/town, state, postcode	
daytime phone	after hours phone
mobile phone	
fax	pager
email	

2. The trial

full trial name	
short trial title	
has the trial, or a previous phase of the trial, been heard by the Tribunal before?	☐ No ☐ Yes If yes, please specify reference number:
has the trial been approved or commenced in other Australian states? Please provide details	
does the trial include delayed consent provisions?	☐ No ☐ Yes Delayed consent is not permissible under NSW Legislation.
estimated year of completion	
trial coordinator name (chief investigator)	
phone	
email	
company or organisation sponsoring the trial	
company representative name	
phone	
email	

3. Site details

Indicate only NSW sites in this application form. If there are more than five sites, please include the information in an attachment. Please use Site 1 for the details of the lead site.

Site 1 Name

principal investigator

position

other investigator

position

postal address

phone

mobile

fax

email

other investigator/s

Site 2 Name

principal investigator

position

other investigator

position

postal address

phone

mobile

fax

email

other investigator/s

Site 3 Name

principal investigator

position

other investigator

position

postal address

phone

mobile

fax

email

other investigator/s

Site 4 Name

principal investigator

position

other investigator

position

postal address

phone

mobile

fax

email

other investigator/s

Site 5 Name

principal investigator

position

other investigator

position

postal address

phone

mobile

fax

email

other investigator/s

4. Other research contacts

Provide details of any other key contacts that will participate in the hearing or can provide information to the Tribunal about the clinical trial.

title

name

position

postal address

phone mobile

fax

email

title

name

position

postal address

phone mobile

fax

email

title	
name	
position	
postal address	
phone	mobile
fax	
email	

5. Hearing details

Please indicate which persons may be available to attend the hearing and any special requirements. The applicant must attend the hearing in person. A principal investigator must be available, in person or by phone, to answer questions about the clinical trial.

- ☐ Applicant
- ☐ Principal Investigator name:
- ☐ In person ☐ by phone
- ☐ Other/s (please specify)

Special requirements

6. Required submissions

You are required to provide documents as listed below to support your application. The Tribunal will not proceed in hearing an application until four (4) copies of all relevant documents have been received.

- ☐ Letter addressing the legislative criteria in section 45AA of the *Guardianship Act 1987*. See information sheet, *Information for Applicants,* for the required headings.
- ☐ The Current Clinical Trial Protocol
- ☐ Final Ethics Committee Approval (for each site)
- ☐ Ethics Committee Application (for each site)
- ☐ Person Responsible Information Sheet (for each site)
- ☐ Person Responsible Consent Form (for each site)
- ☐ A paper copy of the PowerPoint presentation of the clinical trial to be presented at hearing

6A Optional submissions

You may provide documents as listed below to support your application. You are required to provide four (4) copies of all relevant documents.

- ☐ Investigator's brochure (if available)
- ☐ Medicine Information Sheet (optional)
- ☐ Current version of the Patient Information Sheet (for each site)
- ☐ Current version of the Patient Consent Form (for each site)
- ☐ Other (please specify)

7. Declaration

Having read through the completed application:

- ☐ I consider that, to the best of my knowledge, all of the information is true and accurate.
- ☐ I have not intentionally left out important information or the names of parties who have a legitimate interest in this application
- ☐ I understand that it is an offence to make a false or misleading statement in an application.

Signature of applicant _____

Date _____

To lodge your application

To lodge your application, return all pages of the form to NCAT's Guardianship Division. Check that you have completed all relevant items and signed the application form. For urgent applications, email your application and supporting documents to gd@ncat.nsw.gov.au and call the Registry on 1300 006 228.

NCAT Guardianship Division

Email:	gd@ncat.nsw.gov.au
Postal address:	PO Box K1026, Haymarket NSW 1240
Street address:	Level 6 John Maddison Tower, 86-90 Goulburn Street, Sydney
Telephone:	(02) 9556 7600 or 1300 006 228 Interpreter Service (TIS) 13 14 50 National Relay Service for TTY Users 13 36 77
Website:	www.ncat.nsw.gov.au