Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

Supply of unapproved therapeutic goods under the Clinical Trial Approval (CTA) Scheme *Therapeutic Goods Act 1989*

Part 1: the CTA application

To be used for CTA Scheme trials of medicines biologicals and medical devices

For detailed information about the CTA Scheme, please see the document *Access to Unapproved Therapeutic Goods - Clinical Trials in Australia* available from the "Unapproved Therapeutic Goods" web page on the TGA Internet site <https://www.tga.gov.au/>.

On completion please send this form to the Therapeutic Goods Administration:

Courier address	**or**	**Postal address**
The Business Manager		The Business Manager
Business Management Unit		Business Management Unit
Therapeutic Goods Administration		Therapeutic Goods Administration
136 Narrabundah Lane		PO Box 100
Symonston ACT 2609		Woden ACT 2606
Australia		Australia

Cheques should be made payable to "Therapeutic Goods Administration"

TGA use only - BMU

Total Fee Paid	$	Receipt Number	
Client ID Code		TGAIN Number	

CTA30 ☐ CTA50 ☐

TGA use only - EDS/ODBT

Date application received	/ /	CTA Number	/ /

Please read the following notes before completing this form

- Application under the Clinical Trial Approval (CTA) scheme (or notification under the CTN scheme) is required for clinical investigational use of:
  - any medicine, biological or device not entered in the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or
  - a marketed medicine, biological or device beyond the conditions of its marketing approval, including new indications extending the use of the product to a new patient group and the extension of doses or duration of treatments outside the approved range.
- A sponsor cannot commence a CTA trial until:
  - written approval has been received from the TGA regarding the application; and
  - approval for the conduct of the trial has been obtained from an ethics committee and the institution at which the trial will be conducted.

There are two forms, each reflecting these separate processes (Parts), that must be submitted by the sponsor. Part 1 (this form) constitutes the formal CTA application. It must be completed by the sponsor and submitted to TGA with data for evaluation. Part 2 is used to notify the commencement of each new trial conducted under the CTA scheme as well as new sites in ongoing CTA trials. The notification, containing certifications of the sponsor, principal investigator, HREC and Approving Authority, is required to inform the TGA of the conduct of each specific trial and to demonstrate that all of the parties involved in the conduct of individual trials have complied with legislative and regulatory requirements and agree to release information to the TGA about the conduct of the trial in the event of an inquiry or audit of the trial by the TGA. There is no fee for notification of trials under the CTA scheme. Part 2 must be completed and submitted to TGA within 28 days of either the commencement of each new trial or the addition of a new site in an ongoing CTA trial.

- Sponsors of clinical trials are advised to read following guiding documents:
  - Access to Unapproved Therapeutic Goods - Clinical Trials in Australia, TGA, 2004;
  - The National Statement on Ethical Conduct in Research Involving Humans, NHMRC, 2007; and
  - Guidelines for the Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies, NHMRC, 1999.
- Under the *Therapeutic Goods Act 1989*, the Therapeutic Goods Administration (TGA) has the authority to inquire into and/or audit clinical trials, where necessary, on safety grounds and to investigate non-compliance with either Good Clinical Practice guidelines or legislative requirements. In addition, information concerning the supply and use of unregistered therapeutic goods may be released to State and Territory regulatory authorities under section 61 of the *Therapeutic Goods Act 1989*.
- The **"sponsor of the trial"** is the company, organisation, institution, body or individual (enterprise) that initiates, organises and supports a clinical study of an investigational product on human subjects. As a result, the sponsor of the trial takes responsibility for the overall conduct of the trial.
- You will need to have a TGA Client ID in order for your application fee to be accepted and receipted by the TGA Business Management Unit. If you have not conducted business with the TGA before, you will need to obtain a Client ID. Client Details Forms are available from the Experimental Products Section or the TGA Business Management Unit and can be submitted simultaneously with this notification.

Section 1. General details

1.1 Sponsor of the trial

Complete this section for all applications. If an individual, provide full name; if a corporation, the registered company name under the Companies Code; or a business name under which you propose to trade for the purposes of the Therapeutic Goods Act 1989. In cases where a trial is sponsored by an individual, that person's name may also be the Enterprise Business Name. Business details can be provided to the TGA via the Client Details Form. If in doubt, contact the Experimental Products Section, DSEB. Maximum of 100 characters.

Sponsor name (Enterprise Business Name)	
Client ID Code (if known)	

1.2 Data details

For trials of medicines, data should be submitted as four (4) copies of one (1) volume consisting of up to six (6) Parts as outlined in 'Access to Unapproved Therapeutic Goods - Clinical Trials in Australia, October 2004'.

For trials of medical devices, data should be submitted as two (2) copies of one volume consisting of up to seven (7) Parts as outlined in 'Access to Unapproved Therapeutic Goods - Clinical Trials in Australia, October 2004'.

	Part 1	Part 2	Part 3	Part 4	Part 5	Part 6	Part 7 (devices)
No. of pages							

Relevant TGA file number(s) from previous correspondence				

1.3 Sponsor declaration

I apply to conduct clinical trials using the goods described in this form and declare that the information given is, to the best of my knowledge, current and correct.

I certify that, to the best of my knowledge, this application is accompanied by such information relating to the goods as is required by the Secretary or delegate (ie complies with the requirements set out in Access to Unapproved Therapeutic Goods - Clinical Trials in Australia, TGA 2004).

Name			
Signature		Date	
Position			

If you are not the sponsor, have you attached a copy of the current 'Instrument of appointment' authorising you to act as a duly appointed agent of the sponsor? Yes ☐ No ☐

Section 2. Medicine (active ingredient)/biological details

Complete for all applications for clinical trials involving medicines or biologicals. Do not use for clinical trials involving the use of devices only. Provide details for test (investigational) medicines/biologicals only. Do not include reference (comparator) medicines - these should be included in the CTA Part 2 form. List the therapeutically active components in formulations to be used. The form has space for three medicines/biologicals. For more than three, attach details of additional products in the same format. For the **Active name**, enter the active ingredient name using where possible, the Australian Approved Name (AAN). A list of such names (the Approved Terminology for Medicines) is available on the TGA Internet site <https://www.tga.gov.au/>. If no AAN, BAN or USAN has been assigned, a code name (see below) or chemical name must be given. For the **Code name**, enter code name/s used currently or previously to identify the drug. For the **Dosage form**, enter a primary descriptor for dosage form (eg. tablet, injection) and include a secondary descriptor (e.g. sustained release, microsphere emulsion) where necessary, particularly if a new dosage form is the focus of the CTA.

1 Active name

Trade name | Code name

Dosage form | Strength | Biological origin ☐

Route of administration | Country of manufacture of the active

Identify species if material of animal or bacterial origin was used at any stage in the manufacture/ formulation

2 Active name

Trade name | Code name

Dosage form | Strength | Biological origin ☐

Route of administration | Country of manufacture of the active

Identify species if material of animal or bacterial origin was used at any stage in the manufacture/ formulation

3 Active name

Trade name | Code name

Dosage form | Strength | Biological origin ☐

Route of administration | Country of manufacture of the active

Identify species if material of animal or bacterial origin was used at any stage in the manufacture/formulation

Section 3. Medical device details

Complete for all applications for clinical trials involving devices. Do not use for clinical trials involving the use of medicines only. Provide: name (trade name(s), if applicable); description of the device; details of design, composition, specification, mode of action and application; and method of use.