Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

Clinical Trial Notification scheme

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 <https://www.tga.gov.au/treatment-information-provided-tga>.

Changes to a clinical trial notified under the Clinical Trial Notification (CTN) scheme

To be used for:

- Changes to a clinical trial notified to the TGA under the Clinical Trial Notification (CTN) scheme prior to 1 July 2015, for example the notification of one or more additional sites.

This form cannot be used for:

- Changes to a clinical trial notified on or after 1 July 2015.

  Changes would need to be made online to the previously acknowledged trial.

- Changes which render the therapeutic goods separate and distinct from the previously notified goods, for example a change in dosage form.

- The addition of a new therapeutic good to a previously notified trial.

  A change to a therapeutic good that renders the good as separate and distinct from the previously notified goods and the addition of a new therapeutic good to a previously notified trial will require the sponsor to submit a new CTN. Section 16 of the *Therapeutic Goods Act 1989* (the Act) lists the criteria which make goods *separate and distinct*.

- Notification of a new clinical trial.

  A new CTN should be submitted using the online form available on the TGA website.

For detailed information about the CTN Scheme, please see the document Access to unapproved therapeutic goods - Clinical trials in Australia available on the TGA website.

On completion please email or mail this form to the Therapeutic Goods Administration:

Email: accountsrec@tga.gov.au

Mail:

Courier address

Product Billing and Industry Assistance
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609
Australia

or

Postal address

Product Billing and Industry Assistance
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Please read the following instructions before completing this form

- **Before completing this form, all named parties should read about their respective responsibilities in the clinical trial**. These roles are outlined in the following documents:
  - Access to unapproved therapeutic goods - Clinical trials in Australia, TGA, 2004.
  - The National Statement on Ethical Conduct in Research Involving Humans, NHMRC, 2007.
  - Guidelines for the Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies, NHMRC, 1999.
- Under the Act, the **Therapeutic Goods Administration (TGA) has the authority to enquire into clinical trials where necessary. 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 Act**. The sponsor of the trial is required to acknowledge the potential for release of information about the use of unregistered therapeutic goods to State and Territory regulatory authorities.
- For the purpose of notifying a Clinical Trial of Medicines or Medical Devices, 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. The **"approving authority"** is the body, organisation or institution that approves the conduct of the trial at the site. Thus, the Human Research Ethics Committee (HREC) can also be the Approving Authority for a particular trial site. The same person can be named as the HREC and the Approving Authority but they should indicate their position or capacity in relation to each. Also, the same person may be named on behalf of the sponsor of the trial and the Approving Authority. However, because of the potential for conflict of interest, the same person cannot be named on behalf of the sponsor of the trial and the HREC.
- **Key points for sponsors of the trial** to check before completing and submitting this form for updating a CTN to the Therapeutic Goods Administration (TGA) are:
  - Prior to notification, you will need to obtain the contact details of the relevant Human Research Ethics Committee, Approving Authority and Principal Investigator for **each additional site** at which the trial will be conducted.
  - Sites may be notified in any sequence. That is, all sites can be notified in the first instance; notified in groups; or notified singly. The fee for notification of a multi site trial is the same as that for a single site trial providing the sites involved in the multi site trial are declared simultaneously. However, if sites are notified individually or added for an existing trial, an additional fee equivalent to the fee for a single site applies to each notification.
  - Full details of the fee structure for the CTN scheme can be obtained from the Fees and payments section of the TGA website: <https://www.tga.gov.au/fees-payments>.
  - Each new and/or additional trial site must be notified to the TGA prior to the trial commencing at that site.
  - **When notifying additional sites, quote the protocol number exactly**.
  - The TGA assigns a unique clinical trial number. The clinical trial number will have appeared on an acknowledgement letter from the TGA when the trial was first notified. Subsequent notifications to TGA of additional trial sites and other correspondence relating to the clinical trial post acknowledgement, such as reporting of adverse reactions, must include the protocol number and the clinical trial number as points of reference (see below under section 1).
  - A CTN notification is not effective until the correct fee has been paid.

The sponsor should complete all sections of this document.

Section 1.

This section should be completed by the sponsor of the clinical trial to allow the TGA to confirm details of the previously notified trial.

Trial details

Protocol Number

(maximum of 20 characters)

Clinical Trial Number

(assigned by TGA; see acknowledgment letter for previously notified sites; leave blank if unsure)

Title of study

The title should indicate the aim of the existing trial and give a broad description of the trial. Include, for example: phase, indication(s) being treated, main medicines and comparators, use of placebo-control, focus of the study, patient population and any other significant or novel aspects. “A Trial of X” is not adequate. Similar detail is required for device trials. *(Maximum of 255 characters)*

This trial

Note: For the purpose of this document, gene therapy includes related therapies that overlap with the traditional concept of gene therapy by virtue of the fact that they introduce DNA into somatic cells. For example, modifications to immunisation strategies in which DNA, rather than protein, is used to generate an immune response for the purposes of prevention or treatment of chronic viral infection or as part of cancer treatment, would be considered a related therapy. *Tick only those boxes which are applicable:*

- ☐ involves the use of a medicine
- ☐ involves the use of a device
- ☐ is placebo controlled
- ☐ is comparator controlled
- ☐ is also being conducted in other countries
- ☐ involves gene therapy

Medicine/biological details

Complete for clinical trials that involve medicines or biologicals. Do not use for clinical trials involving the use of devices only. List the therapeutically active components in formulations being used in the trial. All medicines/biologicals being trialled should be listed, including comparators. The form has space for four products. For more than four, attach details of additional medicines/biologicals 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 website. 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 (e.g. 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 trial.

1. Active name			
Trade name		Code name	

Dosage form		Strength		Biological origin	

2. Active name					
Trade name		Code name			
Dosage form		Strength		Biological origin	

3. Active name					
Trade name		Code name			
Dosage form		Strength		Biological origin	

4. Active name					
Trade name		Code name			
Dosage form		Strength		Biological origin	

Device details

Complete for clinical trials that involve devices. Do not use for clinical trials involving the use of medicines/biologicals 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.

Section 2

This section should be completed by the sponsor of the trial to indicate the nature of the change requested for a trial previously notified to the TGA.

If additional sites are being notified or there is a change of site address complete a 'Trial Site Details' page for each site.

- ☐ Change to Principal Investigator
- ☐ Change to Human Research Ethics Committee
- ☐ Change in site name
- ☐ Other *(please provide comments below)*
- ☐ Subsequent notification of additional CTN sites
- ☐ Change to Approving Authority
- ☐ Change in site address

Comments:

Section 3.

The sponsor should only complete the relevant sections below as they relate to the change(s) being requested in section 2 above.

Sponsor of the trial

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 TGA via the Organisation details Form. If in doubt, contact the Experimental Products Section.

In the Name field, print the **name of the person** signing the form on behalf of the company, organisation, institution, body or individual sponsoring the trial. In the Position field, state the person's position within, or relationship to, the entity sponsoring the trial.

Sponsor name (Enterprise Business Name)	
Client ID Code (If known)	
Sponsor address	

Contact name (Print)		Position	
		Phone	
		Email	

Trial site details

Submit a Trial Site Details page for each **additional site** at which the trial will be conducted. Enter the name and location of the site (e.g. name and address of hospital, institution, clinic or practice). For large institutions, the address need not include specific department details unless essential to identify the location or unless the unit /body/practice operates as a separate entity within the campus. In some rare circumstances, it will be appropriate to notify a trial as a composite site trial. For example, a GP-based trial conducted by a general practice network may need to be notified as a composite site trial. The site details should indicate clearly that there are multiple sites involved and include the name, address and contact numbers for the principal investigator. **A list of all practices (sites) involved should be submitted as an attachment. The ethics committee and approving authority for such a trial must have appropriate authority for all sites. A sponsor intending to notify a composite site for the first time should contact the Experimental Products Section of the TGA if they have any questions regarding the use of composite sites.**

Site expected start		
Site		
Site address		
	Post code	

Principal Investigator

The principal investigator is the person responsible for the conduct of the clinical trial at a trial site. In the case of a trial being conducted by a team of individuals at the site, the principal investigator is the responsible leader of the team.

Name (Print)		Phone	
		Email	

The Human Research Ethics Committee responsible for monitoring the trial

The Human Research Ethics Committee (HREC) must satisfy the following definition of an ethics committee, as set out in the Act, otherwise the notification is invalid:

- A committee constituted and operating in accordance with guidelines issued by the National Health and Medical Research Council as in force from time to time and which has notified its existence to the Australian Health Ethics Committee.

HREC certification should not be given until all conditions of approval of the protocol by that HREC have been met. Wherever possible, the certification should be completed by the Chair or Deputy Chair of the Human Research Ethics Committee. Guidelines for the approval of clinical trials by HRECs are located at National Statement on Ethical Conduct in Human Research, NHMRC, 2007 and in the TGA publication 'HRECs and the Therapeutic Goods Legislation'.

For trials of gene therapy and related therapies, the proposal must be approved by all relevant bodies as per the NHMRC Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies.

HREC name		
HREC address		
	Post code	
Protocol Number approved by HREC		

Does the trial for which approval is being given involve the use of gene therapy or a related therapy? (See NHMRC Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies) Yes ☐ No ☐

If the trial involves gene therapy or a related therapy, has the Gene and Related Therapies Research Advisory Panel (GTRAP) agreed that the trial can be conducted under the CTN Scheme? Yes ☐ No ☐

Authority approving the conduct of the trial

In cases where the Human Research Ethics Committee or Approving Authority for more than one site is the same, it is still necessary to submit a Trial Site Details Page for each additional site. The bodies approving the conduct of the trial at each site need to be declared individually. This requirement also still applies in cases where, for example, an Area Health Service or Hospitals Group may encompass several different institutions.

The Approving Authority must appoint a person to be responsible for giving approval on its behalf. The terms of approval for the conduct of the trial must be consistent with the Human Research Ethics Committee's (HREC) recommendations and these terms must be no less restrictive than the HREC advice.

Approving Authority name		
Address		
	Post code	

Section 4. Sponsor declaration

By submitting this notification to the TGA:

I **declare** that I am authorised by the sponsor to notify the TGA on its behalf in relation to this clinical trial.

I **acknowledge** that:

- the sponsor is taking overall responsibility for the trial
- the relevant goods only remain exempt by reason of their use in the clinical trial only for so long as:
  - the approval of the goods for the trial has been given by the sponsor (if the sponsor is conducting the trial), or by the body or organisation conducting the trial for the sponsor, having regard to the advice of the ethics committee responsible for monitoring the conduct of the trial, on terms no less restrictive than terms advised by that committee
  - the sponsor has not received advice from the ethics committee that is inconsistent with the continuation of the trial
  - the requirements in regulation 12AD of the Therapeutic Goods Regulations 1990 (in the case of therapeutic goods other than medical devices) and regulation 7.5 of the Therapeutic Goods (Medical Devices) Regulations 2002 (in the case of medical devices) are complied with, including that the use of therapeutic goods in the trial must be in accordance with the Guidelines for Good Clinical Practice and the National Statement on the Ethical Conduct in Research Involving Humans published by the National Health and Medical Research Council, as defined in the Therapeutic Goods Regulations
  - the Secretary has not under Item 3 of Schedule 5A of the Therapeutic Goods Regulations (in the case of therapeutic goods other than medical devices) or Item 2.3 in Part 2 of Schedule 4 of the Therapeutic Goods (Medical Device) Regulations 2002 directed that the trial not be conducted on the basis that the Secretary has become aware that to conduct the trial would be contrary to the public interest
- the Secretary can under the Act, require the sponsor to provide specified information or documents relating to any exempt goods
- the Secretary can provide information obtained in response to an authority or the Commonwealth, or a State or Territory that has functions in relation to therapeutic goods or the registration or medical practitioners or pharmacists in the relevant State or Territory
- it is an offence under the Act to fail to provide that information or documents required by the Secretary, or to provide information or documents that are false or misleading in a material particular, to the Secretary
- it is a requirement of the Guidelines on Good Clinical Practice that the sponsor report all serious and unexpected adverse reactions arising from the use of the relevant goods in the trial to the TGA
- it is a serious offence under Commonwealth law to provide information for the purposes of this notification that is false or misleading in a material particular.

I **declare** that all information provided for the purposes of the notification is true and accurate and that all required information has been included.

Sponsor name		
Signature		
	Date	