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 <http://www.tga.gov.au/about/tga-information-to.htm>.

Notification of intent to supply unapproved therapeutic goods under the Clinical Trial Notification (CTN) scheme

Therapeutic Goods Act 1989

To be used for:

- initial notifications of clinical trials involving medicines, biologicals and/or medical devices under the Clinical Trial Notification (CTN) Scheme; or
- notification of one or more additional sites for a Clinical Trial previously reported under the Clinical Trial Notification (CTN) Scheme.

This is the form approved by the Secretary of the Department of Health

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

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

Courier address	**or**	**Postal address**
Financial Services Group Therapeutic Goods Administration 136 Narrabundah Lane Symonston ACT 2609 Australia		Financial Services Group Therapeutic Goods Administration PO Box 100 Woden ACT 2606 Australia

Cheques should be made payable to "Therapeutic Goods Administration"

Please read the following instructions before completing this form

- Notification under the CTN scheme (or application under the Clinical Trial Exemption (CTX) 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.

- **Before completing this form, all parties providing certification 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 *Therapeutic Goods Act 1989*, the **Therapeutic Goods Administration (TGA) has the authority to enquire 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***. Completion of this notification form requires the sponsor of the trial, principal investigator, Human Research Ethics Committee and the approving authority to agree, in writing, to make all records available to TGA on request and to cooperate with TGA investigations. The sponsor of the trial is also 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 sign on behalf of the HREC and the Approving Authority but they should indicate their position or capacity in relation to each. Also, the same person may sign 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 sign on behalf of the sponsor of the trial and the HREC.

- **Key points for sponsors of the trial** to check before completing and submitting the CTN form to the Therapeutic Goods Administration (TGA) are:

  – You will need to have a TGA Client ID in order for your notification 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.
  – You will need to obtain signatures from the relevant Human Research Ethics Committee, Approving Authority and Principal Investigator for **each** site at which the trial will be conducted. Only ORIGINAL signatures are acceptable.
  – 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 Business Management Unit of TGA.
  – Each new and/or additional trial site must be notified to the TGA prior to the trial commencing at that site.
  – You must assign a protocol number to each new trial. Take care not to assign to a new trial a protocol number used previously. Also, check that the protocol number notified to the TGA matches the version of the protocol approved by the Human Research Ethics Committee. When notifying additional sites, quote the protocol number exactly.
  – The TGA assigns a unique clinical trial number. The clinical trial number will appear on an acknowledgement letter from the TGA. Subsequent notifications to TGA of additional trial sites and other correspondence relating to the clinical trial post acknowledgement, such as reporting of adverse reactions, should include the protocol number and the clinical trial number as points of reference.
  – A CTN notification is not effective until the correct fee has been paid.

For TGA use only

Total fee paid	$	Receipt number	
Client ID code		TGAIN number	

Section 1. To be completed by the sponsor of the trial

1.1 Notification type

Complete this section for all notifications. Select one box only. If multiple sites are being notified, complete a 'Trial Site Details' page for each site.

☐ Initial notification of a single CTN site (new trial) ☐ Subsequent notification of a single additional CTN site

☐ Initial notification of multiple CTN sites (new trial) ☐ Subsequent notification of multiple additional CTN sites

1.2 Potential use of restricted goods

Complete this section for all notifications of medicines only.

Does this trial involve the use of any medicine as an abortifacient or for “post-coital” or “emergency”contraception in women, or the use of a progesterone antagonist or a vaccine against human chorionic gonadotrophin for any purpose? ☐

1.3 Sponsor of the trial

Complete this section for all notifications. 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 Client Details Form. If in doubt, contact the Experimental Products Section.

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

1.4 Trial details

Protocol Number

(Complete for all notifications; maximum of 20 characters)

If adding a site, Clinical Trial Number

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

Title of study

Complete for all notifications. Maximum of 255 characters. Title should indicate the aim of the 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.

Trial type

Complete for initial notification only of trials involving the use of medicines; tick relevant box(es) or otherwise describe.

Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☐ Bioavailability/bioequivalence ☐

Describe if necessary	

This trial

Complete for initial notification only; tick only those boxes which are applicable. 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.

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 ☐

Expected trial start date (Complete for initial notification)		Expected trial completion date (Complete for all notifications)	

Medicine/biological details

Complete for all notifications of clinical trials involving 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 trialed 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 (eg. tablet, injection) and include a secondary descriptor (eg. 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 all notifications of clinical trials involving 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.

1.5 Trial site details

Complete for all notifications. Submit a Trial Site Details page for each site at which the trial will be conducted. Enter the name and location of the site (eg. 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 Drugs Section if they have any questions regarding the use of composite sites.**

Site expected start			
Site			
Site address			
		Post code:	

1.6 Sponsor certification

Complete this section last for all notifications. 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. (Do not enter a company or organisation name here - the entity name appears in Section 1.3) In the Position field, state the person's position within, or relationship to, the entity sponsoring the trial.

I, the undersigned, certify:

- all details contained in this form are true and accurate, and all required information and signatures have been included;
- the sponsor of the trial named in section 1.3 of this form is taking overall responsibility for the conduct of the trial;
- the sponsor of the trial has met or agrees to meet all Human Research Ethics Committee conditions of approval;
- the investigator(s) has/have training and experience relevant to the conduct of this trial;
- the participating institution has resources adequate for the proper conduct of the trial;
- the sponsor of the trial has received an undertaking from the investigator(s) to conduct the trial in accordance with the Guidelines for Good Clinical Practice, as described in regulation 12AB(2)(a) of the Therapeutic Goods Regulations, and the National Statement on Ethical Conduct in Research Involving Humans, as described in regulation 12AD(c) of the Therapeutic Goods Regulations or in regulation 7.3(2a) of the Therapeutic Goods (Medical Devices) Regulations 2002;
- the sponsor of the trial agrees to report all serious and unexpected adverse reactions to the Therapeutic Goods Administration;
- the sponsor of the trial agrees to conduct the trial in accordance with the Guidelines for Good Clinical Practice as described in regulation 12AB(2)(a) of the Therapeutic Goods Regulations and the National Statement on Ethical Conduct in Research Involving Humans as described in regulation 12AD(c) of the Therapeutic Goods Regulations or in regulation 7.3(2a) of the Therapeutic Goods (Medical Devices) Regulations 2002;
- the sponsor of the trial agrees to comply with requests by an authorised officer, whether made before or after the start of a clinical trial, to give information about the conduct of the clinical trial and allow an authorised officer (regulation 2A of the Therapeutic Goods Regulations or regulation 10.1 of the Therapeutic Goods (Medical Devices) Regulations 2002) to do the things mentioned in regulation 12AC and regulation 12AB of the Therapeutic Goods Regulations or in regulation 7.4 of the Therapeutic Goods (Medical Devices) Regulations 2002; and
- the sponsor of the trial accepts that information concerning the use of unregistered therapeutic goods may be released to State and Territory regulatory authorities.

Name (Print)	Alexandra Robertson	Position	Director
Signature		Phone	9345 6924
Date		Fax	

Section 2. To be completed by the 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.

Principal investigator certification

I, the undersigned:

- am the principal investigator at the site shown in section 1.5 of this form;
- agree to personally supervise the clinical trial at this site in accordance with the relevant current protocol(s) and will only make changes in a protocol after approval by the sponsor;
- have received and read the trial protocol and other relevant information;
- have met or agree to meet all Human Research Ethics Committee conditions of approval for this trial:
- acknowledge my obligations with respect to monitoring patient safety, record management and reporting requirements for adverse events;
- agree to ensure that all associates, colleagues and employees assisting in the conduct of the trial are informed of their obligations in meeting the above requirements;
- agree to promptly report to the Human Research Ethics Committee all unanticipated problems and will not make any changes to the trial without Human Research Ethics Committee and sponsor approval, except where necessary to eliminate apparent immediate hazards to subject safety;
- agree to conduct the clinical trial(s) in accordance with the Guidelines for Good Clinical Practice as described in regulation 12AB(2)(a) of the Therapeutic Goods Regulations and the National Statement on Ethical Conduct in Research Involving Humans as described in regulation 12AD(c) of the Therapeutic Goods Regulations or in regulation 7.3(2a) of the Therapeutic Goods (Medical Devices) Regulations 2002;
- agree to comply with requests by an authorised officer, whether made before or after the start of a clinical trial, to give information about the conduct of the clinical trial and allow an authorised officer (regulation 2A of the Therapeutic Goods Regulations or regulation 10.1 of the Therapeutic Goods (Medical Devices) Regulations 2002) to do the things mentioned in regulation 12AC and regulation 12AB of the Therapeutic Goods Regulations or in regulation 7.4 of the Therapeutic Goods (Medical Devices) Regulations 2002; and
- accept that information concerning the use of unregistered therapeutic goods may be released to State and Territory regulatory authorities.

Name (Print)		Phone	
Signature		Fax	
Date			

Section 3. To be completed by the human research ethics committee responsible for monitoring the trial

This section must be completed by a Human Research Ethics Committee (HREC) that satisfies the following definition of an ethics committee, as set out in the *Therapeutic Goods Act 1989*, 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:	The Royal Children's Hospital Human Resaerch Ethics Committee		
HREC address:	50 Flemington Road, Parkville VIC		
		Post code:	3052
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 ☑

Human Research Ethics Committee Certification

I, the undersigned, certify:

· I am a member of the above-named Human Research Ethics Committee;

· the above-named Human Research Ethics Committee is a properly constituted ethics committee and operates in accordance with the guidelines issued by the National Health and Medical Research Council and has notified its existence to the Australian Health Ethics Committee;

· the above-named Human Research Ethics Committee, having regard to the guidance provided by the *National Statement on Ethical Conduct in Human Research* and, where applicable, the *Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies*, has approved the clinical trial protocol identified above and has assumed responsibility for monitoring the conduct of the trial; and

· the above-named Human Research Ethics Committee agrees to comply with requests by an authorised officer, whether made before or after the start of a clinical trial, to give information about the conduct of the clinical trial and allow an authorised officer (regulation 2A of the Therapeutic Goods Regulations or regulation 10.1 of the Therapeutic Goods (Medical Devices) Regulations 2002) to do the things mentioned in regulation 12AC and regulation 12AB of the Therapeutic Goods Regulations or in regulation 7.4 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Name (Print)	Prof Agnes Bankier	Position	HREC Chair
Signature		Phone	9345 5044
Date		Fax	

Section 4. To be completed by the authority approving the conduct of the trial

Complete for all notifications. 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** 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	The Royal Children's Hospital		
Address	50 Flemington Road, Parkville VIC		
		Post code:	3052

Approving authority certification

I, the undersigned

- am authorised to represent the body, organisation or institution at which the above mentioned clinical trial will be conducted and, having regard to the advice and approval of the trial protocol by the Human Research Ethics Committee responsible for monitoring the trial at this site, give approval for this trial to proceed;
- undertake that the use of the drug will comply with all relevant Commonwealth and State or Territory legislation; and
- undertake to comply with requests by an authorised officer, whether made before or after the start of a clinical trial, to give information about the conduct of the clinical trial and allow an authorised officer (regulation 2A of the Therapeutic Goods Regulations or regulation 10.1 of the Therapeutic Goods (Medical Devices) Regulations 2002) to do the things mentioned in regulation 12AC and regulation 12AB of the Therapeutic Goods Regulations or in regulation 7.4 of the Therapeutic Goods (Medical Devices) Regulations 2002.

Name (Print)	Alexandra Robertson	Position	Director
Signature		Phone	9345 6924
Date		Fax	