ANZCTR
Australian New Zealand Clinical Trials Registry

ACCESS POLICY
Version 3
April 2008

1. Introduction

1.1 Purpose of the Access Policy

This policy has been formulated to comply with the NHMRC "Enabling Grants Access to Facilities Policy". The NHMRC policy states that in formulating an access policy the following general principles should be taken into consideration:

- There should be a clear and transparent access policy which enables equitable access for all Australian researchers; acknowledging that different internal and external rates may apply.
- Access may, to some extent, be determined by limitations around the resource (eg a tissue bank may have limited amounts or numbers of a given tissue).
- The process should be overseen by an independent body of eminent persons.
- An appeals process for dispute resolution should be established. Broader issues of governance should also be addressed as they may influence the mechanism by which disputes are managed.
- It is not the NHMRC's intention to influence the issue of international or commercial access. Such decisions are the prerogative of the facility so long as international or commercial access does not in any way compromise the access of Australian researchers or the quality or availability of the resource.
- Acknowledgement. It is obviously mandatory that investigators acknowledge the facility in any published work that results from accessing the resource. It is suggested that each facility specify this requirement including the wording of the acknowledgement.

1.2 What is the Australian New Zealand Clinical Trial Registry?

The Australian New Zealand Clinical Trials Registry (ANZCTR) is a comprehensive on-line register of clinical trials being undertaken in Australia and New Zealand. It was established in 2005 at the NHMRC Clinical Trials Centre, University of Sydney, with $1.5 million in funding from the Australian Government, through a National Health and Medical Research Council (NHMRC) Enabling Grant.

The registry is managed by an Operational Executive and an external Advisory Committee with wide representation from a variety of stakeholders including government, clinicians, the research community, journal editors, the pharmaceutical industry and regulator, and consumers.

1.3 Objectives of the ANZCTR

The ANZCTR aims to improve clinical practice and hence improve health outcomes by:

- developing and maintaining a comprehensive, prospective, register of clinical trials. The register can include trials assessing all types of health care interventions (including lifestyle, drugs, surgery and devices).
- making information on ongoing trials readily accessible to investigators, patients and funding groups. This is primarily achieved through a web-based data system.
- increasing participation in ongoing clinical trials by better informing health care practitioners, patients and their families and apparently healthy subjects.
- providing a reliable and unbiased source of information for systematic reviews, meta-analyses and evidence-based guidelines.

1.4 ANZCTR core date items

The core data items housed on the ANZCTR database conform with the requirements of the International Medical Journal Editors (www.icmje.org/clin_trialup.htm) and the World Health Organisation International Clinical Trials Registry Platform (www.who.int/ictrp/data_set/en/index1.html) for acceptable trial registries.

The core ANZCTR data items are:

- study title
- condition
- intervention
- primary and secondary outcomes
- key inclusion and exclusion criteria
- study design
- sample size
- recruitment status
- funder and sponsor details
- ethics committee approval status
- date of registration
- date of first enrolment
- study contact details
- unique trial number

1.5 How are data on the ANZCTR maintained?

Information about a registered study is supplied by the study's Sponsor or an appropriate representative. A Sponsor is an individual, company or institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial (as defined by the NHMRC and TGA). An appropriate representative of a Sponsor is any individual with delegated authority to agree to the conditions of registration on behalf of the Sponsor. The Sponsor is responsible for the accuracy of the supplied data.

Once submitted data are checked for completeness, the study's dataset is registered. These data then become a permanent record of the study's status at the time of registration. Registrants are able to update their study's information on an ongoing basis. This updated information will supplement, rather than replace, the data supplied at the time of registration.

2. Levels of access

The ANZCTR can be accessed in different ways: either as a 'registrant' wishing to submit a study for registration or as a 'user' searching for information about registered studies.

2.1 Access as a 'registrant' wishing to submit trial data for registration

- Application to submit data to the Australian New Zealand Clinical Trials Registry (ANZCTR) is made directly by registrants via the website: www.anzctr.org.au . Registrants must first register as an ANZCTR user. Their email address is verified upon user application. Authorised registrants then submit data electronically which is assessed for accuracy and completeness by the ANZCTR staff. Once data submission is complete, the trial is registered and assigned a unique number (ACTRN).
- Access to the ANZCTR is available 24 hours per day, 7 days a week. There is no cost to users, including those wishing to submit data and those wanting to view data regarding registered trials via the website.
- A trial must be registered by the person deemed to be the trial's Sponsor. A Sponsor is defined as an individual, company or institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial.
- Any legitimate Sponsor wishing to register a trial on the ANZCTR is able to do so. Registrants may also be directed to other international registers (such as clinicaltrials.gov) if it is more appropriate to register their trial elsewhere.

2.2 Access as a 'user' wishing to view registered trial data

- Once a trial is registered, all submitted data are available to the public via the website - there are no limitations to access. Users are able to search the entire database of registered trials.
- Access is available on-line 24 hours per day, 7 days per week. There is no cost to users to search and view registered trials on the ANZCTR website.
- Users can view registered trial data by using the basic and/or advanced search function on the ANZCTR. The basic search function allows users to search for text words in all fields of the trial record and an advanced search allows the user to search for specific data in specific fields.
- The ANZCTR will consider, on an *ad hoc* basis, specific requests for the publicly available data to be supplied in specific formats (e.g. all studies with commercial Sponsors, ordered by recruitment status category, supplied as an Excel file).
- Such requests must be submitted by email or in writing and the request will be considered by the ANZCTR management prior to approval, with consideration given to available resources and timelines.
- Should a request be denied, the ANZCTR will provide reasons for refusal, in writing, to the requestor within 7 days. The requestor has the right to appeal the request refusal by writing to the independent ANZCTR Ombudsman (currently Prof Caroline Crowther, Adelaide) within one month of notice of the request refusal. The ANZCTR Ombudsman will consider the appeal within one month of receipt and his/her decision will be final.

3. Management of access

The management of access to the ANZCTR is overseen by two principal bodies: the ANZCTR Operational Executive and the ANZCTR Policy Advisory Committee.

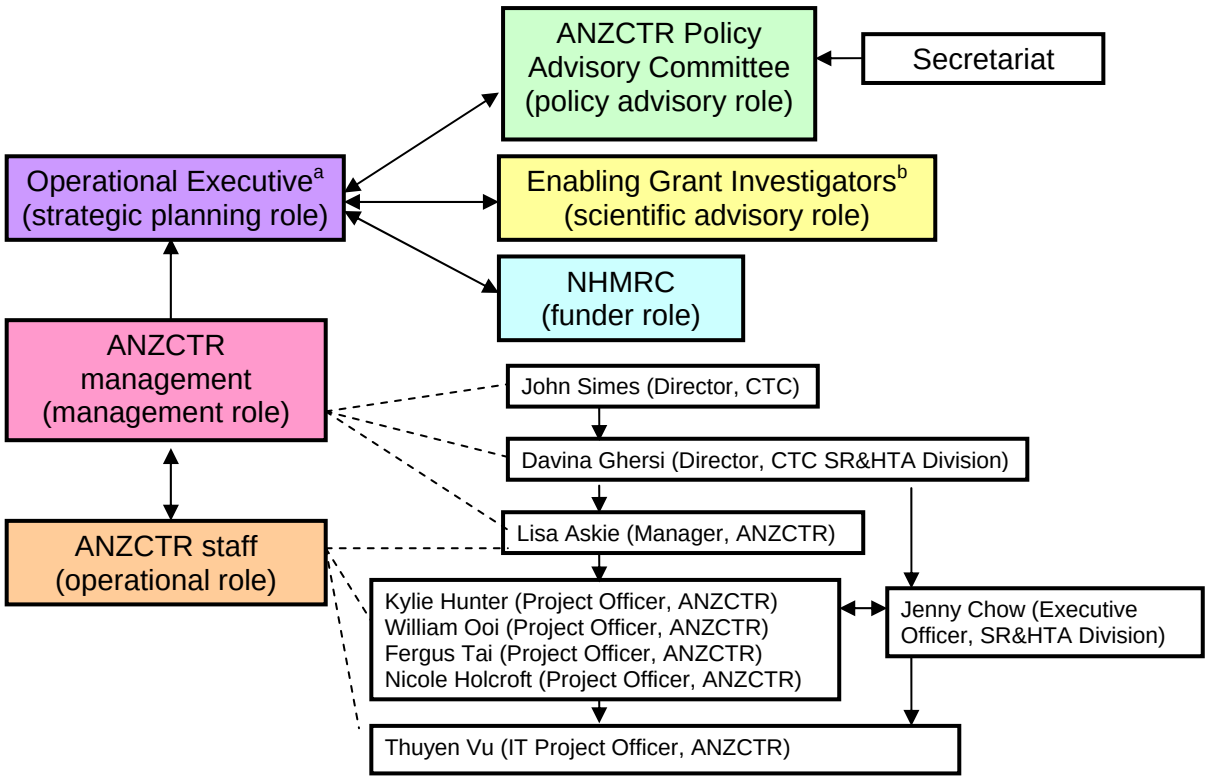
3.1 ANZCTR Operational Executive

- The terms of reference / functions of the ANZCTR Operational Executive are to
  - oversee the operationalisation of the ANZCTR Strategic Plan
  - authorise ANZCTR policy and procedure (including the Access Policy)
  - be the link between the various bodies contributing to the governance of the ANZCTR (see Figure 1)
- The membership of the ANZCTR Operational Executive includes representatives of the ANZCTR's Advisory Committee, management, funder and the Enabling Grant Investigators (12 monthly rotating position).
- Meetings are held approximately six times per year, usually via teleconference.

3.2 ANZCTR Policy Advisory Committee

- The role of the ANZCTR Policy Advisory Committee is to provide the NHMRC and the TGA with advice in relation to the implementation, operation and development of the ANZCTR.
- Membership of the Policy Advisory Committee is by invitation only and comprises representatives of the key stakeholders relevant to the operation and function of the ANZCTR including government, funders, industry, regulators, journal editors, clinicians, consumers, and the research community.
- The frequency of Policy Advisory Committee meetings is annually at minimum.
- The Policy Advisory Committee is currently convened under the auspices of the NHMRC Research Committee.

Figure 1: ANZCTR governance structure flowchart



[a]Operational Executive Members

- Prof John Simes (chair)
- Dr Lisa Askie
- Dr Davina Ghersi
- A/Professor Sally Green

[b]Enabling Grant Chief Investigators

- Professor John Simes (CIA)
- Dr Davina Ghersi (CIB)
- A/Professor Martin Stockler (CIC)
- Professor Tony Keech (CID)
- A/Professor Sally Green (CIE)
- Professor Henderson-Smart (CIF)
- Professor Henry Krum (CIG)
- Professor Garry Jennings (CIH)

3.3 Conflicts of interest

Members of the ANZCTR governance structure (see Figure 1) are asked to declare any potential or actual conflict of interests. The Advisory Committee operates under the auspices of the NHMRC Research Committee and conflicts of interests of Board members are managed in accordance with the requirements of the *National Health and Medical Research Council Act 1992*.

In order for a variety of views and perspectives to be brought to the Operational Executive, the Enabling Grant Investigator representative position is rotated on a 12 monthly basis. Similarly, the presence of members not involved in the day-to-day running of the facility on the Operational Executive also assists the management of any potential conflicts of interest.

3.4 Dispute resolution

Currently, there are no restrictions to accessing ANZCTR data. All information regarding registered trials is made publicly available. Procedures for dealing with requests for data to be made available in specific formats or for specific sub-sets of the total dataset are outlined in Section 2.2.

4. Acknowledgement of access

4.1 Agreement to acknowledge the ANZCTR in published work

It is mandatory that any published work that results from the use of ANZCTR data appropriately acknowledges the ANZCTR as a data source (see Section 2.2.2).

4.2 Suggested acknowledgement wording

The suggested wording that should be used when citing a trial that is registered on the ANZCTR is: “This trial is registered on the Australian New Zealand Clinical Trials Registry (www.anzctr.org.au), an ICMJE acknowledged register: ACTRN012606000338561.”

4.3 Authorship policy for Enabling Grant Chief Investigators

The Enabling Grant Chief Investigators are required to fulfil the ICMJE requirements for authorship, namely that “an ‘author’ is generally considered to be someone who has made substantive intellectual contributions to a published study” and “authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.”

The Enabling Grant Investigators are up-dated of the ANZCTR’s progress and planning at regular intervals, via email and teleconference. They are invited to participate in various ANZCTR activities and projects, such as data audits, methodological research or stakeholder consultations, as appropriate and as such projects arise.

4.4 Recognition of funding on promotional material and website

Recognition of funding support via an NHMRC Enabling Grant is located prominently on the ANZCTR home page (see below), and is noted on all ANZCTR promotional material.

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Welcome to the Australian New Zealand Clinical Trials Registry (ANZCTR)
The Australian New Zealand Clinical Trials Registry has been established at the NHMRC Clinical Trials Centre, University of Sydney, with funding from the Australian National Health and Medical Research Council (NHMRC) and New Zealand Health Research Council.