

# Outreach Facility for Investigator Initiated Public Good Trials

## Access Policy

### 1. Introduction

#### 1.1 NHMRC policy guidelines regarding access to facilities

- 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 Overview and objectives of the outreach facility

The Outreach Enabling Grant has been used to provide a national resource for facilitating the development and conduct of investigator-initiated clinical trials in priority health areas of 'public good'.

The specific aims/objectives of this funded facility are to:

- Ensure the highest quality of clinical trials research conducted by clinical trials researchers in new/priority health research areas, at all institutions throughout Australia
- Provide resources in clinical trials expertise and web-based clinical trials management systems to enable investigator-initiated clinical trials of public good
- Provide a national resource for new trials in new areas based on investigator-initiated trials including trials in surgery, trials of current clinical practice, new health technologies, clinical management studies and trials in palliative and supportive care and complementary medicine

#### 1.3 Types of resources available or being developed for the facility

The Outreach Enabling Grant is supporting human and technical resources in clinical trials initiation, design and conduct including:

- Specific clinical trials expertise in areas such as clinical trials design, data management, quality assurance and regulatory & ethical requirements
- Expertise and advice in biostatistics including in relation to trial design, sample size calculations, interim analyses and translational clinical research
- Database development in areas of randomisation, drug distribution, electronic CRFs
- Advice and/or help in setting up clinical trial networks.

## **2. Types of Access**

The Trial Support Facility is open to all Australian researchers in terms of initial consultation and advice. Initial requests for advice or help can be made on-line via the web-site or by simple phone or email contact. This initial advice is at no charge.

More in-depth development of clinical trial concepts, protocols and database systems are dependent on funding, with the aim to undertake this work on a cost recovery basis. This additional funding may already be available to the user or be sought from a subsequent research grant application.

Principles for undertaking more in-depth work on any clinical trial concept are as follows:

1. Clinical trial concept is of sufficient scientific merit and potential health benefit that further development is considered worthwhile – this is based on criteria in clinical trial check list
2. Australian researchers are able to provide funds to undertake the work (on a cost recovery basis) or seek to apply for research funds in collaboration with members of the facility.
3. Use of facility beyond initial concept and protocol development will be dependent on successfully obtaining research funds for the project.

### **2.1 Funding and prioritising access**

Access to the resource will be:

1. Unlimited for initial consultation and advice
2. Limited for more in-depth work based on scientific merits and available funds (see above)
3. Where funds are not available, prioritisation of the development new concepts will be based on likelihood of success – which is usually subject to full peer-review of scientific merits and health value of the trial
4. The Management Committee will review and prioritise requests for new work, with independent members providing advice when there are different views on how to prioritise this work.

The overall process and any problem arising is being overseen by the NHMRC Clinical Trials Centre's Scientific Advisory Committee, chaired by Professor Andrew Coats.

## **2.2 Criteria for assessing scientific and public health of new proposals**

The NHMRC Clinical Trials Centre has developed a check list for considering new clinical trial proposals and concepts. Some of these criteria are addressed in the work-up or development of the concept (eg reviewing existing evidence) and so are not all criteria are available at the time of initial assessment. However, since trial concepts will require separate funding for the bulk of their work (eg from NHMRC, industry, other) independent review of the merits of the proposal is a necessary step in any successful trial undertaken. The following criteria are therefore just as much an aid to the investigator in developing the concept as a screening tool.

Trials check list includes the following questions:

1. What are the size of the health problem in the patient population and the potential impact of improving health outcomes?
2. What is the potential effectiveness of the interventions and how plausible is this based on preliminary studies?
3. Is the treatment likely to be cost-effective for these potential benefits?
4. What is the existing evidence of standard and proposed therapies? Does this include a systematic review or meta-analysis of existing evidence?
5. Has a sensitivity analysis (eg decision analysis) been undertaken on important variables
6. Is the trial addressing scientifically valid and important question(s)?
7. Will the trial design be able and likely to answer these questions in terms of adequate power, unbiased design and outcome assessments?
8. Has there been / will there be independent scientific review?
9. Has there been / will there be appropriate ethical approval?
10. Will the study conduct and analysis be independent of commercial sponsors?
11. Is appropriate independent safety monitoring of trial being planned?
12. Will there be high quality control and quality assurance procedures in place?
13. Is there / will there be sufficient funding for the trial conduct?
14. Are there appropriate staff, facilities and expertise?
15. Is there adequate collaborative support of from appropriate clinical investigators?
16. Are there potentially sufficient numbers of eligible patients for the proposed trial?

## **2.3 International access**

The primary purpose of the resource is to facilitate investigator-initiated public good trials in priority areas of health. The facility will also be available for international access provided this does not compromise access of Australian researchers or the quality or availability of the resource.

## **3. Appeals Process**

It is not anticipated that there will be many disputes concerning the facility since:

1. Any initial requests for advice will be provided without cost.
2. Any substantive work of undertaking specific clinical trials will require separate funding and use of the facility in this regard will be on a cost-recovery basis.

Nevertheless, in the event of any dispute concerning access to the resource, an appeals process has been established as follows:

1. The appeal will be able to be lodged via the web-based access, including outlining the proposed clinical trial concept, the proposed work from the facility (trial design, research application, database development, etc), the level of funding available for the work and the reason for appeal.
2. The specific trial concept and potential scientific merits will be independently peer-reviewed (for all projects under appeal and for any others where appropriate).
3. Prioritising clinical trial concept developments will be undertaken by management committee and in particular by the independent members when there are any potential conflict.
4. Any appeal that is lodged will be referred to the Outreach Ombudsman for further advice.
5. Any issues of process will be referred subsequently to the Scientific Advisory Committee for discussion.

#### **4. Publication policy and acknowledgements**

Any published work which involves the Outreach Resource should acknowledge the resource or may involve co-authorship when members of the resource have contributed significantly to the clinical trial project:

1. The nature of the acknowledgement will depend on the contribution.
2. If the acknowledgement relates to intellectual contribution from members of the resource, they must have the opportunity to review the publication to ensure the publication and acknowledgement are appropriate.
3. Where members of the resource will be making significant contribution to the study, agreement in principle on possible co-authorship should be agreed in advance.

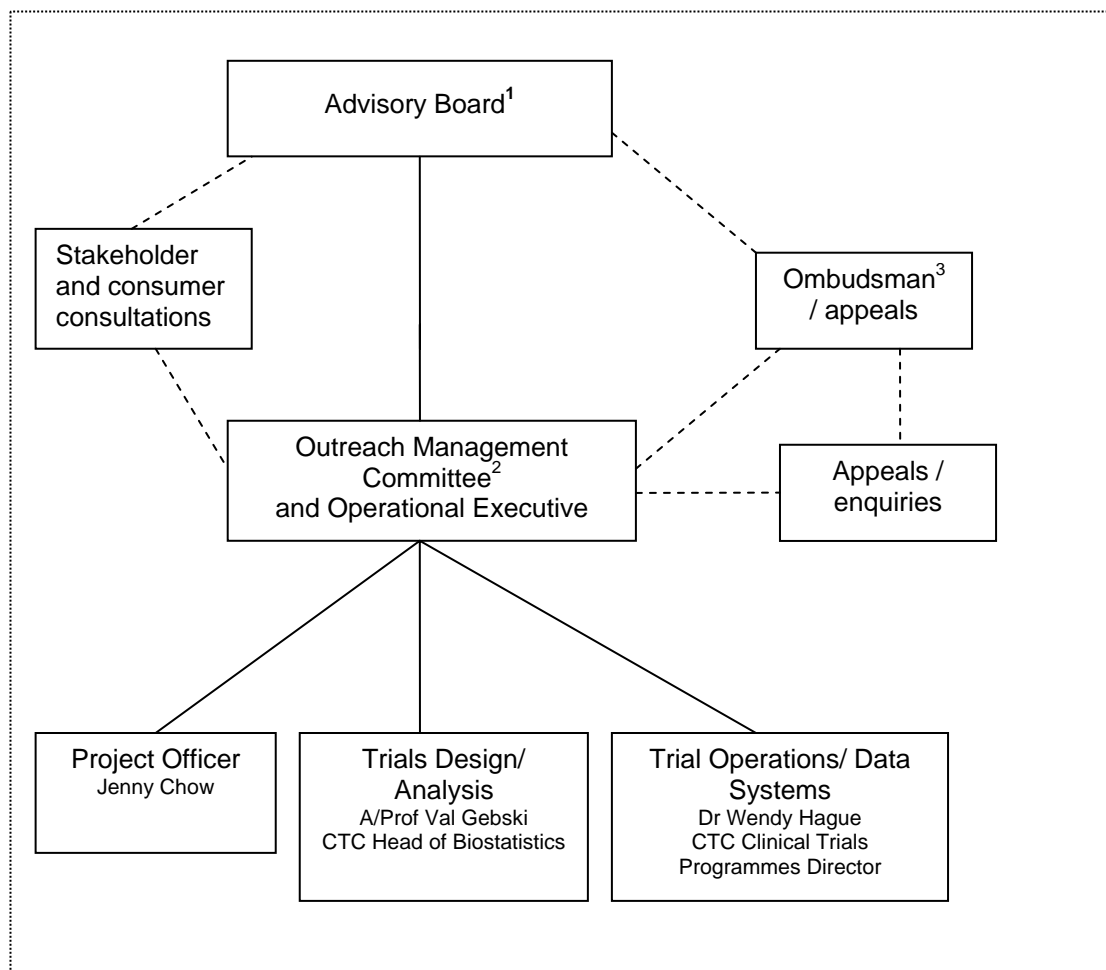
#### **5. Ethical approval of the research**

Ethics approval is a requirement of all clinical trials undertaken and obtaining such ethics approval prior to commencement of any trial is a requirement of use of the resource.

#### **6. Management of access to facility**

Management of requests to use the facility are overseen by the Management Committee consisting of some Chief Investigators of the enabling grant and some members independent of the facility. The list of projects being supported will be reviewed on a quarterly basis by this management committee. The day to day operations will be managed by the operational executive of this committee. In the event of potential conflicts, the process will involve adjudication by the Ombudsman and referral to the CTC's Independent Scientific Advisory Committee as appropriate.

**Figure 1. Outreach Program Governance Structure Flowchart**



**¹ CTC’s Scientific Advisory Committee and Outreach Advisory Board**

Professor Andrew Coats, University of Sydney  
 Professor James Best (NHMRC Representative)  
 Professor Les Irwig, University of Sydney  
 Professor Judith Lumley, Centre for the Study of Mother’s and Children’s Health, Melbourne  
 Mr John Stubbs, Consumer Representative, CEO, Cancer Voices Australia

**² Outreach management committee**

- \* Professor John Simes (CIA)
  - \* A / Professor Val Gebski (CIB)
  - \* Dr Wendy Hague (CIC)
  - \* Ms Jenny Chow
- Professor Jonathan Craig, independent member, Westmead Childrens Hospital  
 + 1 other independent member tbc

\* Members of operational executive

**³ Ombudsman – Professor Caroline Crowther, Adelaide University**