Support for Cancer Clinical Trials Program Grant Guidelines
Grant Program Process Flowchart

APPLICATION
Applicant completes an application.

SUBMIT AN APPLICATION
Applicant submits an application.

ASSESSMENT
The application is accepted. The application is assessed against eligibility and assessment criteria.

ADVICE TO CANCER AUSTRALIA’S FUNDING APPROVER
Advice provided to Cancer Australia’s Funding*Approver on the merits of each application against the Program Guidelines. (*FMA Reg 3 defines Approver as a Minister, a Chief Executive or a person authorised to approve proposals to spend public money)

DECISION/NOTIFICATION
The Approver makes a decision on the application and the Applicant is advised of the decision.

CONTRACT/FUNDING
An agreement is negotiated and signed by the Applicant and the Agency.

DO/COMPLETE/ACQUIT
Applicant undertakes funding activity, completes milestones, provides reports and acquits funds against expenditure. Agency makes payments and monitors progress.

EVALUATION
Agency evaluates the outcomes of the program. Applicant provides information to assist this evaluation.
1. Introduction
Clinical trials benefit the community by improving the survival of people affected by cancer, and contribute to a reduction in premature death and disability. Clinical trials are fundamental to establishing whether new cancer treatments, diagnostic tests or preventive interventions are effective and they help generate evidence for best-practice cancer care.

1.1. Program Background
Under the Support for Cancer Clinical Trials program the Australian Government is supporting Australia’s capacity to conduct cancer clinical trials.

Through this program Cancer Australia supports 13 National Cancer Cooperative Trials Groups to develop industry-independent cancer clinical trials.

The 13 National Cancer Cooperative Trials Groups are:
- Australasian Gastro-Intestinal Trials Group;
- Australasian Leukaemia and Lymphoma Group;
- Australasian Lung Cancer Trials Group;
- Australasian Sarcoma Study Group;
- Australia and New Zealand Melanoma Trials Group;
- Australia New Zealand Gynaecological Oncology Group;
- Australian and New Zealand Children’s Haematology and Oncology Group;
- Australian and New Zealand Urogenital and Prostate Cancer Trials Group;
- Australian New Zealand Breast Cancer Trials Group;
- Cooperative Trials Group for Neuro-Oncology;
- Primary Care Collaborative Cancer Clinical Trials Group
- Psycho-Oncology Co-operative Research Group;
- Trans-Tasman Radiation Oncology Group; and

The Australian Government, through its Agency Cancer Australia, is seeking funding applications from the 13 National Cancer Cooperative Trials Groups currently funded under the Support for Cancer Clinical Trials program. Cancer Australia will provide direct funding to each National Cancer Cooperative Trials Group of up to $460,000 (GST exclusive) per financial year up to a maximum of $1,380,000 million GST exclusive) over a maximum three years. Cancer Australia will also provide access to National Technical Services of up to $75,000 per annum per Group. The funding will be provided to support the development of industry-independent cancer clinical trial protocols over a period of up to three years from 1 July 2013 – 30 June 2016.
Industry-independent cancer clinical trials can play an important role in the cancer research landscape as these trials can address important questions in patient treatment and care which may not be of commercial interest to the pharmaceutical industry.


### 1.2. Program Purpose, Scope, Objectives and Outcomes

The Cancer Australia Act (2006) paragraph (1) (b) specifies that the agency will 'guide scientific improvements to cancer prevention, treatment and care'.

Important advances in cancer prevention, treatment and care can be made through clinical trials and people diagnosed with cancer will benefit from the outcomes of cancer clinical trials through improved evidence-based, best-practice care.

The purpose of the Support for Cancer Clinical Trials program is to support National Cancer Cooperative Trials Groups to develop industry-independent cancer clinical trials and the program objectives are:

- To increase the participation in clinical trials by people affected by cancer.
- To increase the number of cancer clinical trials conducted in Australia.
- To increase the number of clinical sites actively participating in clinical trials.
- To increase the involvement of clinicians and researchers in clinical trials within Australia.

The outcome of this program is to guide scientific improvements in cancer prevention, treatment and care and in doing so build the evidence-base for best practice cancer care to improve health outcomes for Australian’s affected by cancer.

### 1.3. Roles and responsibilities

The Grant Program Process Flowchart on the first page outlines the roles and responsibilities of each party.

Cancer Australia’s Funding Approver for the Support for Cancer Clinical Trials program is Professor Helen Zorbas, Chief Executive Officer, Cancer Australia.
1.4. Anticipated key dates

The following table outlines the anticipated timeline for the program.

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Anticipated Dates</th>
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<tbody>
<tr>
<td>Invitation to Apply posted on Cancer Australia website</td>
<td>12 April 2013</td>
</tr>
<tr>
<td>Applications Close</td>
<td>6 May 2013</td>
</tr>
<tr>
<td>Assessment and Decision</td>
<td>7-24 May 2013</td>
</tr>
<tr>
<td>Letter of Offer and Funding Agreements sent to successful Applicants</td>
<td>By 31 May 2013</td>
</tr>
<tr>
<td>Funding Agreements Executed</td>
<td>By 21 June 2013</td>
</tr>
<tr>
<td>Project Period Begins</td>
<td>1 July 2013</td>
</tr>
<tr>
<td>Project Period Ends</td>
<td>30 June 2016</td>
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2. Eligibility

2.1. Who is eligible to apply for funding?

The following National Cancer Cooperative Trials Groups are eligible to apply for funding:

- Australasian Gastro-Intestinal Trials Group;
- Australasian Leukaemia and Lymphoma Group;
- Australasian Lung Cancer Trials Group;
- Australasian Sarcoma Study Group;
- Australia and New Zealand Melanoma Trials Group;
- Australia New Zealand Gynaecological Oncology Group;
- Australian and New Zealand Children’s Haematology and Oncology Group;
- Australian and New Zealand Urogenital and Prostate Cancer Trials Group;
- Australian New Zealand Breast Cancer Trials Group;
- Cooperative Trials Group for Neuro-Oncology;
- Psycho-Oncology Co-operative Research Group;
- Trans-Tasman Radiation Oncology Group; and
- Primary Care Collaborative Cancer Clinical Trials Group

2.2. What is eligible for funding?

The Agency expects that the funding will be awarded for staffing, administrative, and minor assets costs (up to $5,000 (GST exclusive)) that support existing National Cancer Cooperative Trials Groups to develop industry-independent cancer clinical trials protocols to the stage of applying for grant funding. Funding will be considered for activities such as those listed in the Table below:
| Salaries for Scientific, Clinical and/or Administrative personnel to support trials design and protocol development to the stage of submission of a grant application | Activities include:  
- Literature reviews  
- Peer review and approval of concept  
- Protocol development including:  
  - Identification of sponsor  
  - Identification of potential sites for patient recruitment  
  - Statistical evaluation of concept including:  
    - Sample size and other relevant statistical calculation  
    - Design of data fields  
    - Design of CRF  
    - Data management evaluation process  
  - Financial Evaluation and budget preparation  
- writing protocols,  
- writing grant applications |
|---|---|
| Education and training in clinical trials design | Funding support for:  
- training within Australia, of National Cancer Cooperative Trials Groups members in clinical trials design and management  
Such funding support would include attendance at workshops offered by groups like ACCORD and can include associated travel costs to attend training within Australia |
| Office costs | Funding support for:  
- office costs i.e. premises rental, stationery |
| IT support and communications | Funding support for:  
- hardware (i.e. computers, telephones) and software  
- telephone line rental and teleconference costs for COGs business and meetings  
- website hosting and maintenance/upgrade |
| Travel | Funding support for:  
- Face-to-face COGs group meetings for trials development |
Group committee meetings - Includes venue, catering, and accommodation costs
- International travel for trials protocol development
  International travel must be approved prior to the meeting by the Cancer Australia CEO, economy class airfares (max of 3 international fares per annum)

- Individual funding proposals from eligible National Cancer Cooperative Trials Groups will be considered for up to $460,000 GST exclusive ($506,000 GST inclusive) per financial year, up to a maximum of $1,380,000 million GST exclusive ($1,518,000 GST inclusive) over a maximum three years.
- The contract period will commence from execution of the Funding Agreement by the Commonwealth and will conclude on 31 August 2016.
- The project period for funded activities will be from 1 July 2013 to the 30 June 2016 (for three-year Funding Agreements).
- All funding must be expended by 30 June 2016 (for three-year Funding Agreements).

2.3 What is not eligible for funding?
Retrospective items/activities (i.e. those undertaken prior to 1 July 2013) will not be funded through the new Funding Agreements.

The Agency also will not provide funds for the following:
- Activities associated with the conduct of specific cancer clinical trials. It is expected that competitive grant funding will be applied for to support conduct and management of specific cancer clinical trials and associated activities such as site activation, ethics applications, and quality assurance activities.
- Overseas sites, international members or the conduct of specific cancer clinical trials outside Australia.
- The support of health professionals from other countries.
- Clinical service delivery or infrastructure for clinical services.
- The management of this grant/ Funding Agreement, in particular:
  - bank fees;
  - legal costs;
  - University overheads;
  - time taken to manage the Funding Agreement/ prepare progress/ final reports for Cancer Australia in relation to the grant/ Funding Agreement; and
  - indemnity and insurance costs
- The development or printing of corporate sponsorship material.
• Fundraising activities or staff salaries to support fundraising activities.
• Assets over $5,000 (GST exclusive).

3. **Probity**
The Australian Government is committed to ensuring that the process for providing funding under the Support for Cancer Clinical Trials program is transparent and in accordance with published Guidelines.

*Note: Guidelines may be varied from time-to-time by the Australian Government as the needs of the program dictate. Amended Guidelines will be published on the Agency’s website.*

3.1. **Conflict of interest**
A conflict of interest may exist, for example, if the Applicant or any of its personnel:

- Has a relationship (whether professional, commercial or personal) with a party who is able to influence the application assessment process, such as an Agency staff member;
- Has a relationship with, or interest in, an organisation, which is likely to interfere with or restrict the Applicant in carrying out the proposed activities fairly and independently; or
- Has a relationship with, or interest in, an organisation from which they will receive personal gain as a result of the granting of funding under the Support for Cancer Clinical Trials program.

Each Applicant will be required to declare as part of their application, existing conflicts of interest or that to the best of their knowledge there is no conflict of interest, including in relation to the examples above, that would impact on or prevent the Applicant from proceeding with the project or any Funding Agreement it may enter into with the Australian Government.

Where an Applicant subsequently identifies that an actual, apparent, or potential conflict of interest exists or might arise in relation to this application for funding, the Applicant must inform the Agency in writing immediately.

3.2. **Confidentiality and Protection of Personal Information**
Each Applicant will be required to declare as part of their application, their ability to comply with the following Legislation/Clauses in the Funding Agreement it may enter into with the Australian Government.
The Protection of Personal Information Clause requires the Participant to:

- comply with the Privacy Act (1988) (‘the Privacy Act’), including the 11 Information Privacy Principles (IPPs), as if it were an agency under the Privacy Act, and the National Privacy Principles (NPPs);
- refrain from engaging in direct marketing (s 16F of the Privacy Act), to the extent that the NPP and/or s 16F apply to the Participant; and
- impose the same privacy obligations on any subcontractors it engages to assist with the Project.

The Confidentiality Clause imposes obligations on the Participant with respect to special categories of information collected, created or held under the Agreement. The Participant is required to seek the Commonwealth’s consent in writing before disclosing Confidential Information.

4. How to Apply

4.1. Obtaining an application
The Invitation to Apply (ITA) documentation package for the Support for Cancer Clinical Trials Program is provided as a separate document to these guidelines. The ITA documentation package including the application form (Part D of ITA) is available for download from Cancer Australia’s website on the Support for cancer clinical trials call for applications page http://canceraustralia.gov.au/research-data/support-clinical-trials/call-for-applications

4.2. Application requirements
Applications must be submitted to the Agency by email by 5.00pm Australian Eastern Standard Time on Monday 6 May 2013.

Answers to questions must be no more than one page in length, unless otherwise indicated on the application form.

Please refrain from using acronyms.

Letters of support or additional documentation must also be submitted by the time and dates specified above.

Before submitting their proposal, Applicants should ensure all necessary information has been provided by completing the Application Checklist which is included in the ITA documentation.
Further assistance in the application process can be obtained by contacting the contact officer Gayle Jones by email at gayle.jones@canceraustralia.gov.au

4.3. How to submit an application
Applications must be submitted in the following manner:

- The application must be submitted on the official application form which can be downloaded as part of the Invitation to Apply document (Part D): http://canceraustralia.gov.au/research-data/support-clinical-trials/call-for-applications

- Applications must be submitted by email to: gayle.jones@canceraustralia.gov.au by 5:00pm Australian Eastern Standard Time on Monday 6 May 2013 and must:
  - Quote Support for Cancer Clinical Trials in the email subject heading
  - Include one complete signed electronic copy of your application in pdf format (Filename: Support for Cancer Clinical Trials _Applicants Name)
  - One complete electronic copy of your application in Microsoft Office Word format that does not exceed 5 MB in size (Filename: Support for Cancer Clinical Trials _Applicants Name).

- Applicants may confirm safe receipt of the submitted proposal by telephoning the Contact Officer Gayle Jones on 03 8866 0448.
- Applications must be emailed to allow sufficient time for them to be received before the closing time. Applicants should be aware that there can be delays and uncertainties in the delivery of email, and it is the responsibility of the person or organisation making the submission to make sufficient time allowance for their submission to be received before the closing time.
- Cancer Australia is under no obligation to provide suppliers with confirmation of delivery of applications.

To assist with the assessment of an application, clarifying information may be requested by the Agency. Applicants will be notified by email or post where this is required.

5. Assessment

5.1. Assessment process
Those applications which do not satisfy the eligibility criteria may not be assessed.

Based on the information provided, the Agency will undertake an evaluation of eligible applications against the assessment criteria outlined below.
An independent, assessment committee will be established by Cancer Australia to assess applications against the assessment criteria. The committee will consist of officers from Cancer Australia, representatives with expertise in funding cancer clinical trials and community representatives. The assessment committee will make recommendations to Cancer Australia’s Funding Approver regarding the applications to be supported and the recommended levels of funding.

5.2. Assessment criteria
Applications will be assessed against the following criteria:

- **Threshold Criteria** are the criteria that an application must satisfy in order to be considered for funding. These are also variously expressed as ‘eligibility criteria’, ‘mandatory criteria’, ‘compliance criteria’, or ‘gateway criteria’. Threshold Criteria often involve the use of expressions such as ‘must’, ‘must not’, ‘will’ or ‘will not’ (e.g. Unincorporated Associations).

- **Assessment Criteria** are the criteria against which all eligible, compliant applications will be assessed in order to determine their merits against the program objectives and, for competitive programs, other competing applications.

- **Assessment criterion 1 – Compliance with principles**
  - Principle 1 – National multi-disciplinary membership
  - Principle 2 & 3 – Governance structure and succession planning
  - Principle 4 – Strategic and business planning
  - Principle 5 – Data and quality
  - Principle 6 – capacity building
  - Principle 7 – increasing participation in clinical trials
  - Principle 8 – collaboration and mentoring
  - Principle 9 – translation into policy and practice

- **Assessment criterion 2 – how the funding will be utilized**

- **Assessment criterion 3 – budget and value for money**

Please note that all assessment criteria are equally weighted

6. Decisions

6.1. Approval of funding
Following an assessment of the applications by the assessment committee, advice will be provided by the assessment committee to Cancer Australia’s Funding Approver on the merits of the application/s.

Cancer Australia’s Funding Approver will consider whether the proposal will make an efficient, effective, economical and ethical use of Commonwealth resources, as required by Commonwealth legislation, and whether any specific requirements will need to be imposed as a condition of funding.
Funding approval is at the discretion of Cancer Australia’s Funding Approver. Cancer Australia reserves the right to negotiate the level of funding and timeframe of funding with each Applicant.

6.2. Advice to Applicants

Applicants will be advised by letter of the outcome of their application. Letters to successful Applicants will contain details of any specific conditions attached to the funding.

The Agency will notify all unsuccessful Applicants, in writing, after execution of the agreements with the successful Applicants.

6.3. Complaint handling

Cancer Australia’s Procurement and Funding Complaints Handling Policy applies to complaints that arise in relation to a procurement or funding process. It covers events that occur between the time the request documentation is released publicly and the date of contract execution, regardless of when the actual complaint is made. Cancer Australia requires that all complaints relating to a procurement or funding process, must be lodged in writing. Further details of the policy are available in the ‘Publications & Resources’ page on the Agency’s internet site http://canceraustralia.gov.au/publications-resources/cancer-australia-publications/procurement-and-grants-complaint-handling-policy

Any enquiries relating to funding decisions for this Program, should be directed to Gayle Jones at gayle.jones@canceraustralia.gov.au

7. Conditions of Funding

7.1. Contracting arrangements

Successful Applicants will be required to enter into a Funding Agreement with the Commonwealth (represented by the Agency).

For legal and accountability reasons, only incorporated bodies can enter into a Funding Agreement with the Australian Government. It is not necessary for the National Cancer Cooperative Trials Group to become a company limited by guarantee nor a separately incorporated body. The incorporated body can receive funding payments from Cancer Australia and make these available to the National Cancer Cooperative Trials Group.

A template of the standard Funding Agreement is available on the Agency’s website at http://canceraustralia.gov.au/research-data/support-clinical-trials/call-for-applications
An individualised Reference Schedule will be attached to each Funding Agreement and will provide a detailed description of the approved activities, budget and outcomes.

The Agency will work with successful Applicants with the aim of having Funding Agreements sent by 31 May 2013 and signed by 21 June 2013.

7.2. Specific conditions
Successful National Cancer Cooperative Trials Groups must, as part of their Funding Agreement with Cancer Australia, use the national technical services identified by Cancer Australia for the period of the Funding Agreement.

Successful National Cancer Cooperative Trials Groups must, as part of their Funding Agreement with Cancer Australia, comply with the Supporting Cancer Clinical Trials in Australia Principles Document, Supporting Cancer Clinical Trials in Australia Evaluation framework and the Support for Cancer Clinical Trials - Guide to travel/meeting policy for National Cancer Cooperative Trials Groups. All documents can be downloaded from http://canceraustralia.gov.au/research-data/support-clinical-trials/call-for-applications

There may be additional specific conditions attached to the funding approval required as a result of the appraisal process or imposed by Cancer Australia’s Funding Approver. These will be identified in the offer of funding or during Funding Agreement negotiations.

7.3. Payment arrangements
Payments will be available on signing of the Funding Agreement and/or on achievement of milestones.

Before any payment can be made, funding recipients will be required to provide:
- a tax invoice for the amount of the payment.
- evidence of meeting the obligations of the Funding Agreement

Where payments are linked to the achievement of specific milestones, payments will only be made after the Agency is satisfied that those milestones and associated obligations of the Funding Agreement have been met.

7.4. Reporting requirements
Funding recipients will be required to provide progress reports on the agreed milestones. These progress reports may include funding acquittal requirements.
The timing of progress reports will be specified as part of the Funding Agreement.

7.5. **Monitoring**
The funding recipient will be required to actively manage the delivery of the project. The Agency will monitor progress against the Funding Agreement through assessment of progress reports and by conducting site visits as necessary.

7.6. **Evaluation**
An evaluation by the Agency will determine how the funding contributed to the objectives of the program. Funding recipients will be required to provide information to assist in this evaluation for a period of time, as stipulated in the Funding Agreement, after funding has been provided.

7.7. **Branding**
The Funding Recipient must acknowledge the financial and other support it has received from Cancer Australia in:

   a) all publications, developed resources, promotional and advertising materials, public announcements and activities by it or on its behalf in relation to the Project or any products, processes or inventions developed as a result of the Project; and
   b) the form set out in the Reference Schedule of the Funding Agreement, and if not set out in there, then in a form approved by Cancer Australia prior to its use.

The Funding Recipient must not use the Cancer Australia logo without prior written approval from Cancer Australia.