



**NSW CANCER TRIALS NETWORK
Cancer Trials Nurse
& Data Manager Grants**

GUIDELINES FOR APPLICANTS

CLOSING DATE: 24TH OCTOBER 2008

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1. ACRONYMS AND DEFINITIONS

Acronyms

ARC	Australian Research Council
NHMRC	National Health and Medical Research Council

Definitions

Administering Institution* The Area Health Service or Hospital (legal entity) located in NSW that receives and administers the funds. For the purposes of GST arrangements, this institution is defined as the supplier.

Applications are lodged through the Administering Institution.

Research Institution* The institution at which the research will be undertaken

*The Administering Institution and the Research Institution may be the same institution.

GST Goods and Services Tax imposed in accordance with the A New Tax System (Goods and Services Tax) Act 1999, and related Acts and Regulations.

Intellectual Property Includes all industrial and intellectual property rights including but not limited to copyright, patents, trade/business or company names, registered and unregistered trademarks, registered designs, trade secrets, know how, rights in relation to circuit layout and all other rights of intellectual property as recognised by the law in force in NSW.

Supplier Means the persons or bodies party to the written agreement engaged to perform the services and includes officers, employees, agents and authorised sub-contractors (and their employees and agents) utilised by the Supplier.

2. OVERVIEW OF CANCER INSTITUTE NSW RESEARCH PROGRAMS

INTRODUCTION

The Cancer Institute NSW is Australia's first state-wide, government supported cancer control agency. We are saving lives through promoting the best cancer research, prevention, early-detection, and treatment and education initiatives. The Cancer Institute NSW is driving innovation in cancer care in New South Wales by working in partnership with the leaders in our field to deliver the best cancer results for the people of New South Wales.

STATE CANCER RESEARCH PRIORITIES

Cancer research is providing the evidence that will drive rapid improvement in cancer prevention, treatment and the subsequent improvements in survival and quality of life of cancer patients. The cancer research supported in NSW must be performance driven and deliver meaningful and highly significant outcomes.

The acceleration of better cancer control will be driven by new cancer research discoveries. The NSW Cancer Plan 2007-2010 aims to make these discoveries more quickly available to cancer patients and clinicians through research grants and more support for clinical research staff in hospital. The NSW Cancer Trials Network is being expanded under this Plan to make promising new drugs and techniques available more quickly to patients and to evaluate their benefit.

Investment in cancer research promises great benefit in the longer term. Already new therapies, new approaches and a new culture of innovation and research are emerging in NSW hospitals from this support.

Priorities for the Research Division are:

- Research infrastructure, including:
 - Support for technical staff and governance arrangements for research infrastructure;
 - Development of innovative models to encourage networking and collaboration;
- Development of smarter models to enhance translational research and ensure the rapid transfer of research findings into cancer clinical practice and policy;
- Developing capacity in public health, epidemiological and health services research;
- Establishment of a collaborative structure or network for clinical trials in NSW with agreed targets for clinical trial participation and access;
- Streamlined ethical review processes to support cancer patients having access to scientifically robust and ethically sound clinical trials;
- Sustainable career paths (including attracting gifted researchers from interstate and overseas).

CLINICAL TRIALS PROGRAM

Cancer Trials NSW was a program established by The Cancer Council NSW in 2001 to increase participation rates and access to cancer clinical trials in NSW. This program provided funding for the placement of 0.5 Full Time Equivalent (FTE) clinical trials nurse or data manager positions across NSW.

The Cancer Council NSW and the Cancer Institute NSW entered into an agreement to transfer the clinical trials program from The Cancer Council NSW to the Cancer Institute NSW. In line with this agreement, the administration of the Cancer Trials NSW program was transferred from The Cancer Council NSW to Cancer Institute NSW from 1 July 2006. Following the transfer, all positions funded by the clinical trials programs of both organisations have been consolidated into a single program under the NSW Cancer Trials Network.

Under the NSW Cancer Plan 2007-2010, the Clinical Trials Program aims to develop high quality cancer clinical trials in NSW, introduce and study new cancer treatments, increase participation rates in cancer trials and promote a culture of research and innovation in cancer services.

The NSW Cancer Trials Network has been established to meet these aims through the implementation of various partnerships, grants, collaborations and infrastructure. The program has been set the aim of accruing 10% of new cancer patients on to clinical trials by 2010. The NSW Cancer Trials Network is an amalgamation of individual clinical trial units - aligned with Area Health Services, Directors of Clinical Cancer Research, Clinical Regulatory Affairs Personnel and Cancer Trial Nurses and Data Managers. The NSW Cancer Trials Network currently supports a total of 69 Cancer Trials Nurses and Data Managers, across 46 Clinical Trial Units in NSW. Clinical trial activity in NSW is reported based on the combined data of all units funded by the Network.

3. INTRODUCTION TO THE NSW CANCER TRIALS NETWORK CANCER TRIALS NURSES & DATA MANAGER GRANTS

- 3.1 A major initiative of the Clinical Trials Program is the Cancer Trials Nurse and Data Manager Grants. Through these grants, the Cancer Institute NSW and the Cancer Council NSW seeks to place additional Cancer Trial Nurses and Data Managers in hospital-based cancer clinical trials units to provide the infrastructure necessary to support cancer clinical trial related activity within NSW. It is envisioned that the NSW Cancer Trials Network will support the placement of trials nurses and/or data managers within cancer clinical trials units enabling a dedicated hospital based resource, supporting patients, their families and cancer specialists participating in clinical trials.
- 3.2 The Cancer Institute NSW is now inviting applications for 'top up' funding of Cancer Trials Nurses and/or Data Managers, who are current grant recipients of a 0.5FTE position to increase their work in cancer clinical trial units within NSW. Applications will only be considered from these groups.
- 3.3 Priority will be given to those units which can demonstrate a commitment to increasing clinical trial activity in under representative tumor groups including but not limited to cancers of the gastrointestinal tract, colorectal and lung.
- 3.4 The partnership between the Cancer Institute NSW and the successful applicant(s) is considered part of a collaborative approach in providing the resources and expertise required for clinical trials conducted within the state, and for these trials to be considered competitive at an international level.

4. OBJECTIVES

The primary objectives of the NSW Cancer Trials Network Cancer Trials Nurse and Data Manager positions are to:

- 4.1 Provide additional infrastructure for Clinical Trials Units, leading to:
 - Increased number of participants in cancer clinical trials;
 - Increased cancer clinical trials support for patients, their families and cancer specialists;
- 4.2 Provision of reports and comment for relevant parties on Cancer Trial Nurse and Data Manager issues in cancer clinical trials;
- 4.3 Provision of information to the Cancer Institute NSW regarding clinical trial related activity within the clinical trial unit supporting the Cancer Trials Nurse & Data Manager Grant position.

5. ELIGIBILITY

- 5.1 The Head of the Clinical Trials Unit or Group based in NSW must make the application. Where more than one Clinical Trials Unit or Group exists within an Area Health Service (AHS), each Unit or Group desiring funding can apply separately. Alternatively, a network of clinical trial units within an AHS may make one submission,
- 5.2 The successful Clinical Trials Unit(s) will:
 - 5.2.1 Be physically located in NSW;
 - 5.2.2 Be a current recipient of a 0.5FTE Clinical Trials Nurse & Data Manager grant.
 - 5.2.3 Have in place, policies and procedures for the management of public funds, for the management of Intellectual Property, for the proper conduct of research in relation to ethics and good scientific and clinical conduct, and that provides appropriate infrastructure support.
 - 5.2.4 Describe the governance model to support the position.

6. SELECTION CRITERIA

- 6.1 In awarding a Cancer Trials Nurse and Data Manager Grant, the following criteria will be taken into account:
 - 6.1.1 Demonstrated evidence of commitment and expertise in cancer clinical trials with a commitment to increasing clinical trial activity in under represented tumor groups including but not limited to cancers of the gastrointestinal tract, colorectal and lung. Including a demonstrated understanding of clinical trials issues locally, nationally and internationally **(25%)**;
 - 6.1.2 Proven recruitment record in cancer clinical trials over the last 2 years (or 3 if available) **(25%)**;

- 6.1.3 A proposed recruitment projection for the next 12 months (i.e. January to December 2009) and demonstrate anticipated benefits of the position in relation to the objectives stated in Section 4 of these guidelines **(25%)**;
- 6.1.4 Provision of adequate resources to support the roles of Cancer Trials Nurse(s) and/or Data Manager(s) **(25%)**.

7. REVIEW CONSIDERATIONS

- 7.1 Upon receipt, applications will be reviewed for completeness and for eligibility by the Research Secretariat. *Late, incomplete or ineligible applications will not be accepted.*
- 7.2 The independent Cancer Institute NSW Clinical Trials Grants Review Committee will score and rank applications based on:
- An assessment of merit against the stated selection criteria.
 - Consideration of independent assessor or referee reports if required.
- 7.3 Information provided within the Application Form should attempt a complete and accurate description of all clinical trials activity, both Pharmaceutical, Independent (In-House) and Group studies conducted within the trials unit. It is intended that this information will form the basis of ongoing funding applications for future Cancer Trials Nurses and Data Managers.
- 7.4 Applications may be reviewed by appropriate independent assessors.
- 7.5 Recommendations for Cancer Trials Nurse and Data Manager Grants will then be made by the Cancer Institute NSW Clinical Trials Grants Review Committee to the Board of the Cancer Institute NSW;
- 7.6 The lodging of an application does not confer any entitlement upon the applicant.
- 7.7 The making of a recommendation is totally within the discretion of the Cancer Institute NSW.
- 7.8 The Cancer Institute NSW Clinical Trials Grants Review Committee requires its members and independent assessors to declare conflicts of interest and to withdraw from considering applications where such conflict exists.

8. ADMINISTERING INSTITUTION RESPONSIBILITIES

- 8.1 The Administering Institution is responsible for the administration of the Cancer Trials Nurse and Data Manager Grant funds in accordance with the executed agreement and accepts financial responsibility.
- 8.2 Payment of the funds will be made to the Administering Institution in accordance with the payment schedule in the executed agreement. Funds may only be used for the purposes approved under the Cancer Trials Nurse and Data Manager Grants.
- 8.3 The Administering Institution and Head of the Clinical Trials Unit will ensure that the NSW Cancer Trials Network Cancer Trials Nurse(s) and/or Data Manager(s) is provided with sufficient resources to effectively undertake the role.

- 8.4 The position descriptions for NSW Cancer Trials Network Cancer Trials Nurse(s) and/or Data Manager(s) will be developed by the successful Clinical Trials Unit in collaboration with the Cancer Institute NSW.
- 8.4 Recipients will be required to attend annual training provided by the Cancer Institute NSW.
- 8.5 It is the responsibility of the Administering Institution to ensure that appropriate ethical and research governance clearances are obtained before any trial commences.
- 8.6 These Awards may be regarded as a “taxable supply” and therefore a Goods and Services Tax may be payable. The Award will be increased by 10% and the Research Institution will be required to collaborate in the recovery of the GST component. The written agreement with the Cancer Institute NSW will therefore include the following clauses:
- *To the extent that the Supplier is liable to pay GST in connection with services supplied under this Agreement, the fees specified in this Agreement are inclusive of GST.*
 - *The Supplier will forward their Australian Business Number ("ABN") to Cancer Institute NSW at the commencement of the Agreement. Where no ABN is supplied, Cancer Institute NSW will withhold from any payments an amount of 48.5% in accordance with GST legislation unless appropriate documentation is provided.*
- 8.7 For the purposes of payments under this agreement, the Supplier (the research Institution is the Supplier) will provide invoices to the Cancer Institute NSW in the form of a GST Tax Invoice as prescribed in the GST legislation.

9. PERMITTED USE OF CANCER TRIALS NURSE AND DATA MANAGER GRANTS FUNDS

- 9.1 The NSW Cancer Trials Network Cancer Trials Nurse and Data Manager Grants will provide funds for the salary of each NSW Cancer Trials Network Cancer Trials Nurse and/or Data Manager, of \$32,000 (per 0.5FTE) per annum.
- 9.2 These Grants will be awarded for 2 years, commencing January 2009 and terminating in December 2010. It is possible that some of these grants will be renewable at the end of that period based on performance.
- 9.3 Funds awarded shall not be used for any purpose associated with overhead infrastructure costs (i.e. institutional overheads or administrative levies).
- 9.4 Funds must be used for Cancer Clinical Trials. Non malignant clinical trial activity is not covered by this award.

10. REPORTING REQUIREMENTS

- 10.1 Recipients will be required to submit a **Progress Report** at 6 monthly intervals during the funding period; these reports include information on the progress and outcomes of the Cancer Trials Nurse and Data Manager Grants.

- 10.2 The **Progress Reports** must be submitted to the Research Secretariat by the 1st August and 1st February each year of the funding period. Report proforma's are available at www.cancerinstitute.org.au.
- 10.3 Recipients will be required to submit a **Financial Report** for each financial year that includes information on the expenditure of funds in relation to the Cancer Trials Nurse and Data Manager Grants.
- 10.4 **Financial Reports** must be submitted to the Research Secretariat, within 45 days of the end of each financial year. Report proforma's are available at www.cancerinstitute.org.au.
- 10.5 Where a Cancer Trials Nurse and Data Manager Grant recipient fails to submit satisfactory reports, as required, the Cancer Institute NSW may determine that funds have not been used in accordance with conditions applicable to the Grant, and that all or part of the Grant must be repaid. In this case, the Cancer Institute NSW may initiate recovery of the Cancer Trials Nurse and Data Manager Grant money.
- 10.6 Recipients may be required to participate in and present at forum(s) at the request of the Cancer Institute NSW.

11. ACKNOWLEDGEMENT OF SUPPORT

- 11.1 All publications or discussion of results from research carried out with the assistance of a NSW Cancer Trials Network *Cancer Trials Nurse and/or the Cancer Trials Data Manager* must acknowledge the support of the Cancer Institute NSW.
- 11.2 Awardees must indicate their status as recipients of this support in scientific publications and programs of scientific meetings and in any other public connection. This includes acknowledgement in his/her title as a '*NSW Cancer Trials Network Cancer Trials Nurse or NSW Cancer Trials Network Cancer Trials Data Manager*'.

12. PRIVACY AND CONFIDENTIALITY

- 12.1 Documents containing personal information will be handled and protected in accordance with the provisions of the Privacy and Personal Information Protection Act 1998. Personal information would be disclosed only with permission of the individual to whom it relates or where the Act allows.
- 12.2 Applicants consent to the information supplied as part of their application being disclosed for the purposes of the assessment of their application and for purposes connected with the making and administration of the Grant. Such disclosure includes, but is not limited to, disclosure to members of Cancer Institute NSW Clinical Trials Grants Review Committee, independent readers/assessors requested by the Committee to provide advice, and relevant employees of the Cancer Institute NSW and Government involved in the Grant process.

- 12.3 Applicants acknowledge that announcement of the Cancer Trials Nurse and Data Manager Grants will involve the dissemination of information to the public about the general nature of the grant funded including the lay description provided in the application, the professionals and organisations involved in the grant.
- 12.4 Information contained in applications will be regarded as confidential.

13. INTELLECTUAL PROPERTY

Applicants must adhere to an Intellectual Property Policy approved by the governing body of the host research organisation that is congruent with the document "National Principles of Intellectual Property Management for Publicly Funded Research" released in September 2001: http://www.arc.gov.au/pdf/01_01.pdf

14. CONFLICT OF INTEREST

All parties involved in or associated with Cancer Institute NSW funded research proposals/projects are required to disclose to the Cancer Institute NSW, any conflict of interest which has the potential to influence, or appear to influence, the research and activities, publications and media reports, or requests for funding related to the proposal/project. Such conflicts must be disclosed to the Cancer Institute NSW at the time of the submission of a proposal, and in reporting on Cancer Institute NSW-funded research projects as soon as practicable after the conflict of interest is identified.

15. FUNDING AGREEMENT

- 15.1 All parties involved in a Proposal should familiarise themselves with the standard Funding Agreement (available at www.cancerinstitute.org.au), but only the Administering Institution and the Cancer Institute NSW will be parties to the Funding Agreement. Parties involved in a funded positions must accept the terms of the Funding Agreement and the Administering Institution must sign the Funding Agreement before payments commence.
- 15.2 Positions must commence as required by the Funding Agreement. Failure to do so may result in termination of the Funding Agreement.
- 15.3 Administering Institutions should note that the Funding Agreement covers post-award management, including reporting requirements and financial management. The standard Funding Agreement can be viewed on the Cancer Institute NSW's Web Site.

16. VARIATIONS TO THE FUNDING AGREEMENT

Requests to vary the Funding Agreement must be forwarded in writing by the Administering Organisation to the Cancer Institute NSW. Forms are available on the Cancer Institute NSW's Web Site. Amendment of any clauses of the Funding Agreement will be at the Cancer Institute NSW's absolute discretion.

17. TIMEFRAME

<i>Action</i>	<i>Date</i>
Call for applications	15 th September 2008
Applications close	24 th October 2008
Review	November 2008
Advice to Applicants	November 2008
Funding commencement	January 2009

18. SUBMISSION PROCEDURES

18.1 How to Apply

Applicants must use the Cancer Institute NSW Cancer Trials Nurse and Data Manager Grants Application Form. This is available from the Cancer Institute NSW web at: www.cancerinstitute.org.au or from the Research Secretariat on 02 8374 3561, email research.secretariat@cancerinstitute.org.au

18.2 Format

Paper: Double sided, A4
Margin: 2cm on each side
Font: At least 12 point
(preferred fonts are Times New Roman, Arial and Helvetica).

18.3 Submission Date

Applicants must submit **BOTH** electronic and hard copies of the application to the Cancer Institute NSW by close of business on 24th October 2008.

18.4 Electronic Copy

Must be submitted in PDF format, to research.secretariat@cancerinstitute.org.au

18.4.1 You must not convert scanned documents into PDF. All attachments are to be converted from the original electronic document (e.g. Word) – signatures are not required on the electronic version of the application.

18.4.2 You must name the PDF file in the following way: NDM _and 1st CI's surname
(e.g **NDM_Smith**).

18.5 Hard Copy

8 hard copies (1 original plus 7 copies) double sided, stapled on top left hand corner of the application should be lodged with the Research Secretariat.

Original documents should be sent to:

Courier address

Research Secretariat
Cancer Institute NSW
Level 1, Biomedical Building
Australian Technology Park
1 Central Avenue
Eveleigh 2015

OR

Mail Address

Research Secretariat
Cancer Institute NSW
PO Box 41
ALEXANDRIA NSW 1435

19. ENQUIRIES

Enquiries about the NSW Cancer Trials Network Cancer Trials Nurse and Data Manager Grants can be directed to the Research Secretariat at research.secretariat@cancerinstitute.org.au; telephone: 02 8374 3530.